



Paul R. LePage
Governor

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Anne L. Head, Esq.
Commissioner

Geraldine L. Betts
Administrator

January 7, 2014

Notice on Effective Date of these Rules

The effective dated posted by the Secretary of State at the bottom of the Rule-making Cover Sheet is in error and should read:

December 11, 2013 and not 2014

If you have any questions feel free to contact our office at
pharmacy.board@maine.gov

Sincerely,
Geraldine Betts
Administrator

Licensing (207)624-8620
Main Receptionist (207)624-8603
Hearing Impaired/TTY MAINE RELAY 711



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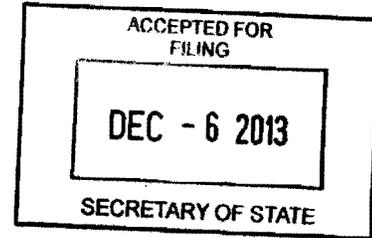
OFFICE LOCATION: GARDINER ANNEX
76 NORTHERN AVENUE, GARDINER, MAINE

Rule-Making Cover Sheet

2013-298

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Definitions
4. Chapter number assigned to the rule: 1
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13 (date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

Part 1-General Information

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1: DEFINITIONS

Summary: As used in the board's rules, unless the context otherwise indicates, the following words have the following meanings:

[NOTE: Additional definitions are found in 32 M.R.S.A. §13702-A.]

1-A(1). Affiliated. "Affiliated," for purposes of Chapter 35 of the board's rules, means a relationship in which one entity owns 100% of the ownership of both a hospital and a nursing facility or skilled nursing facility.

1-A. APPE. "APPE" is the advanced pharmacy practice experience.

1. Authorized person. An "authorized person" is a person other than a pharmacy technician (e.g., computer technician, bookkeeper) who the pharmacist in charge has designated to be present in the prescription filling area in the absence of a pharmacist pursuant to Chapter 13, Section ~~6(7)~~6(8).

2. ~~Authorized pharmacy technician.~~ ~~An "authorized pharmacy technician" is a pharmacy technician authorized by the pharmacist in charge to be present in the prescription filling area during the absence of a pharmacist pursuant to Chapter 13, Section 6(7).~~ ~~[deleted]~~

3. ~~Biological safety cabinet.~~ ~~"Biological safety cabinet" is a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to NSF International Standard 49, "Class II (Laminar Flow) Biohazard Cabinetry" (February 14, 2003), which the board hereby incorporates into its rules by reference. A copy of Standard 49 is available from-~~

~~_____ NSF International
 _____ P.O. Box 130140
 _____ 789 N. Dixboro Road
 _____ Ann Arbor, MI 48113-0140 [deleted]~~

4. Blood. "Blood" is whole blood collected from a single donor and processed either for transfusion or further manufacturing.

5. **Blood component.** "Blood component" is that part of blood separated by physical or mechanical means.
6. **Central fill drug-outletpharmacy.** "Central fill drug-outletpharmacy" is a drug outletpharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to it by a retail drug-outletpharmacy, rural health center or free clinic; or by a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and returns the labeled and filled prescriptions to the retail drug-outletpharmacy or other source of origin for delivery to the patient or the authorized agent of the patient.
7. **Centralized prescription processing.** "Centralized prescription processing" refers to the functions and activities of a central fill drug-outletpharmacy and a central processing center. A central fill drug-outletpharmacy and central processing center may, but need not, operate in the same facility.
8. **Central processing center.** "Central processing center" is a drug-outletpharmacy that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail drug-outletpharmacy, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board.
- 8-A. **Certified midwife.** "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.
9. **Class 100 environment.** "Class 100 environment" is an atmospheric environment which contains fewer than 100 particles of 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones" (September 11, 1992), which the board hereby incorporates into its rules by reference. A copy of Federal Standard 209E is available from-
- _____ Institute of Environmental Sciences
 _____ 940 E. Northwest Highway
 _____ Mount Prospect, IL 60056[deleted]
10. **Class 1000 environment.** "Class 1000 environment" is an atmospheric environment which contains less than 1000 particles of 0.5 microns in diameter per cubic foot of air according to Federal Standard 209E.[deleted]
- 10-A. **Closed-shop pharmacy.** "Closed-shop pharmacy" is a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population such as residents of a long term care facility, assisted living program, residential care facility, intermediate care facility for persons with mental retardation, or residential mental health facility.

11. **Contact hour.** A "contact hour" is 60 minutes of participation in a continuing professional education activity described in 32 M.R.S.A. §13735 or Chapter 5 of the board's rules.
12. **Cytotoxic.** ~~"Cytotoxic" is a pharmaceutical that is capable of killing living human or animal cells.[deleted]~~
13. **DEA.** "DEA" is the United States Department of Justice, Drug Enforcement Administration.
14. **Direct supervision.** "Direct supervision" is the ability of a pharmacist to:
- (A)1. ~~Oversee the actions-activities of a pharmacy intern or pharmacy technician by being physically present within the same work area as the technician being supervised;~~
 - (B)2. Direct the activities of a pharmacy intern or pharmacy technician who has no fixed workstation (e.g., visits individual patient rooms); or
 - (C)3. ~~Oversee the actions-activities of a pharmacy intern or pharmacy technician (advanced) at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician-(advanced).~~
- "Direct supervision" includes activities performed by a pharmacy intern or pharmacy technician during the supervising pharmacist's short-term absence from the workplace for meals or breaks.
- 14-A. ~~**Drug administration clinic.** "Drug administration clinic" is the administration of influenza or other vaccines identified in 32 MRSA §13831 on a mass basis at a scheduled event, with or without sign up times, within or outside a retail pharmacy, rural health center or free clinic licensed under 32 MRSA §13751. "Drug administration clinic" does not include the administration of influenza or other vaccines to an individual on a walk-in or appointment basis at a retail pharmacy, rural health center or free clinic at any other time.[deleted]~~
- 14-B. **DHHS.** "DHHS" means the Maine Department of Health and Human Services.
15. **Drug sample.** "Drug sample" is a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
16. **Electronic device.** An "electronic device" includes, but is not limited to, a facsimile machine, computer system, portable device, or any other system or equipment approved by the Board.
17. **Electronic signature.** "Electronic signature" is an electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.
- 17-A. **Electronic prescription.** "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.
18. **Enteral.** ~~"Enteral" means within or by way of the intestine.[deleted]~~

- 18-A. Extended hospital pharmacy.** “Extended hospital pharmacy” means a pharmacy owned by and located in a hospital licensed by the Maine Department of Health and Human Services that is further licensed by the board to dispense drugs as set forth in Chapter 35 of the board’s rules.
- 19. FDA.** “FDA” is the United States Department of Health and Human Services, Food and Drug Administration.
- 20. Hard copy.** “Hard copy” is a prescription drug order which has been transferred to paper, whether by hand or by equipment, and is readable without the aid of any special devices.
- 20-A. IPPE.** “IPPE” is the introductory pharmacy practice experience.
- 20-B. Medical oxygen.** “Medical oxygen” means oxygen in liquid or gaseous form intended for therapeutic use.
- 21. MPJE(r).** “MPJE” is the Multistate Pharmacy Jurisprudence Examination.
- 22. NABP(r).** “NABP” is the National Association of Boards of Pharmacy.
- 23. NAPLEX(r).** “NAPLEX” is the North American Pharmacist Licensure Examination.
- 23-A. Non-sterile compounding pharmacy.** “Non-sterile compounding pharmacy” means a pharmacy that engages in the compounding of drug products in a non-sterile environment.
- [NOTE: “Compounding” is defined in 32 MRSA §13702-A(4).
- 24. ~~Nuclear drug outlet~~pharmacy.** “~~Nuclear drug outlet~~pharmacy” is a ~~drug outlet~~pharmacy that compounds, stores, dispenses, labels or delivers any radioactive drug.
- 25. ~~Parenteral.~~** “~~Parenteral~~” is a sterile preparation of drugs for injection through one or more layers of the skin. “Parenteral” means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous, or intramuscular routes.
- 26. Pharmacist on duty.** “Pharmacist on duty” is a pharmacist who performs the duties of a pharmacist at any given time.
- 27. Pharmacy intern.** “Pharmacy intern” is a pharmacy student, ~~or~~ recent graduate or foreign graduate engaged in the practice of pharmacy under the direct supervision of a pharmacist while enrolled in the internship program described in Chapter 6-A of the board’s rules.
- 27-A. Point of care location.** “Point of care location” means the premises where prescriptions filled by an automated pharmacy system that is not wholly located in a retail pharmacy are delivered or administered.
- 28. Practice setting.** “Practice setting” includes, but is not limited to, the place, area, site, or manner in which the practice of pharmacy may normally occur or transpire.

29. **Pharmacy technician (advanced).** "Pharmacy technician (advanced)" is a pharmacy technician who has demonstrated to the board that he/she:
- ~~(1) Holds the designation of Certified Pharmacy Technician (CPhT) issued by the Pharmacy Technician Certification Board, and has maintained the certification in full force and effect; or~~
 - ~~(2) Has successfully completed the National Community Pharmacy Technician Training Program and passed the corresponding National Pharmacy Technician examination. [deleted]~~
30. **Prescription filling area.** "Prescription filling area" is the area used for compounding prescription legend drugs, for storing all drugs and devices which may be sold by prescription only, and for any other activities necessary to the practice of pharmacy.
31. **Printout.** "Printout" is a hard copy produced by computer that is readable without the aid of any special device.
32. **Retail drug outlet pharmacy.** "Retail drug outlet pharmacy" is:
- (1). A drug outlet pharmacy located in a retail store; or
 - (2). A specialty drug outlet pharmacy not located in a retail store, including but not limited to a nuclear drug outlet or a drug outlet that compounds sterile pharmaceuticals, that dispenses a drug upon a prescription drug order for a specific patient closed-shop pharmacy, sterile compounding pharmacy, extended hospital pharmacy, opioid treatment program and retail supplier of medical oxygen.
- 32-A. Retail supplier of medical oxygen.** "Retail supplier of medical oxygen" means a person who sells or dispenses medical oxygen to a consumer—
- 1. Pursuant to a prescription from a practitioner; or
 - 2. In circumstances where a prescription is required by federal law.
33. **Sight-readable.** "Sight-readable" refers to a record that may be read from a computer screen, microfiche, microfilm, printout, or other method approved by the Board.
34. **Sterile pharmaceutical.** ~~"Sterile pharmaceutical" is a dosage form free from living microorganisms (aseptic).~~ "Sterile pharmaceutical" is any dosage form of a drug, including but not limited to, parenterals (e.g., injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.
- 34-A. Sterile compounding pharmacy.** "Sterile compounding pharmacy" is a pharmacy that engages in the compounding of sterile pharmaceuticals.

[NOTE: "Compounding" is defined in 32 MRSA §13702-A(4).]

35. **Stop date.** "Stop date" is the length of time to administer medication. In institutional settings, the physician normally notes the length of time to administer medication on the drug order. In the absence of this notation, the policy of the institution shall determine the length of time various categories of drugs may be administered.
- 35-A. **VAWD.** "VAWD" is the Verified-Accredited Wholesale Distributor program administered by NABP.
36. **Wholesale distribution.** "Wholesale distribution" is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, but does not include:
- (1). Intracompany sales, which include any internal sales transaction or transfer with any division, subsidiary, parent and affiliated or related company under the common ownership and control as the transferor;
 - (2). The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 - (3). The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 - (4). The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
 - (5). The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
 - (6). The sale of a drug by a retail ~~drug outlet~~pharmacy to licensed practitioners for office use when the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five (5) percent of that ~~drug outlet's~~pharmacy's total annual prescription drug sales;
 - (7). The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
 - (8). The distribution of drug samples by manufacturers' representatives or distributors' representatives;
 - (9). The sale, purchase or trade of blood and blood components intended for transfusion; or

(10). Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23.

37. **Wholesale distributor.** "Wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A wholesale distributor includes a wholesaler as defined in 32 M.R.S.A. §13702-A(34).

STATUTORY AUTHORITY: 32 M.R.S.A. §§-13720, 13723

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

Part 1-General Information

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1: DEFINITIONS

Summary: As used in the board's rules, unless the context otherwise indicates, the following words have the following meanings:

[NOTE: Additional definitions are found in 32 M.R.S.A. §13702-A.]

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1-A. APPE. "APPE" is the advanced pharmacy practice experience.

- 1. Authorized person.** An "authorized person" is a person other than a pharmacy technician (e.g., computer technician, bookkeeper) who the pharmacist in charge has designated to be present in the prescription filling area in the absence of a pharmacist pursuant to Chapter 13, Section 6(8).
- 2.** [deleted]
- 3.** [deleted]
- 4. Blood.** "Blood" is whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- 5. Blood component.** "Blood component" is that part of blood separated by physical or mechanical means.
- 6. Central fill pharmacy.** "Central fill pharmacy" is a pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to it by a retail pharmacy, rural health center or free clinic; or by a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and returns the labeled and filled prescriptions to the retail pharmacy or other source of origin for delivery to the patient or the authorized agent of the patient.

7. **Centralized prescription processing.** "Centralized prescription processing" refers to the functions and activities of a central fill pharmacy and a central processing center. A central fill pharmacy and central processing center may, but need not, operate in the same facility.
8. **Central processing center.** "Central processing center" is a pharmacy that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail pharmacy, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board.
- 8-A. **Certified midwife.** "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.
9. [deleted]
10. [deleted]
- 10-A. **Closed-shop pharmacy.** "Closed-shop pharmacy" is a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population such as residents of a long term care facility, assisted living program, residential care facility, intermediate care facility for persons with mental retardation, or residential mental health facility.
11. **Contact hour.** A "contact hour" is 60 minutes of participation in a continuing professional education activity described in 32 MRSA §13735 or Chapter 5 of the board's rules.
12. [deleted]
13. **DEA.** "DEA" is the United States Department of Justice, Drug Enforcement Administration.
14. **Direct supervision.** "Direct supervision" is the ability of a pharmacist to:
 1. Oversee the activities of a pharmacy intern or pharmacy technician by being physically present within the same work area as the technician being supervised;
 2. Direct the activities of a pharmacy intern or pharmacy technician who has no fixed workstation (e.g., visits individual patient rooms); or
 3. Oversee the activities of a pharmacy intern or pharmacy technician at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician.

"Direct supervision" includes activities performed by a pharmacy intern or pharmacy technician during the supervising pharmacist's short-term absence from the workplace for meals or breaks.

- 14-A. [deleted]
- 14-B. **DHHS.** "DHHS" means the Maine Department of Health and Human Services.
15. **Drug sample.** "Drug sample" is a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
16. **Electronic device.** An "electronic device" includes, but is not limited to, a facsimile machine, computer system, portable device, or any other system or equipment approved by the Board.
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- 17-A. **Electronic prescription.** "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.
18. [deleted]
- 18-A. **Extended hospital pharmacy.** "Extended hospital pharmacy" means a pharmacy owned by and located in a hospital licensed by the Maine Department of Health and Human Services that is further licensed by the board to dispense drugs as set forth in Chapter 35 of the board's rules.
19. **FDA.** "FDA" is the United States Department of Health and Human Services, Food and Drug Administration.
20. **Hard copy.** "Hard copy" is a prescription drug order which has been transferred to paper, whether by hand or by equipment, and is readable without the aid of any special devices.
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- 20-B. **Medical oxygen.** "Medical oxygen" means oxygen in liquid or gaseous form intended for therapeutic use.
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23. **NAPLEX(r).** "NAPLEX" is the North American Pharmacist Licensure Examination.
- 23-A. **Non-sterile compounding pharmacy.** "Non-sterile compounding pharmacy" means a pharmacy that engages in the compounding of drug products in a non-sterile environment.
- [NOTE: "Compounding" is defined in 32 MRSA §13702-A(4).
24. **Nuclear pharmacy.** "Nuclear pharmacy" is a pharmacy that compounds, stores, dispenses, labels or delivers any radioactive drug.

25. **Parenteral.** "Parenteral" means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous, or intramuscular routes.
26. **Pharmacist on duty.** "Pharmacist on duty" is a pharmacist who performs the duties of a pharmacist at any given time.
27. **Pharmacy intern.** "Pharmacy intern" is a pharmacy student, recent graduate or foreign graduate engaged in the practice of pharmacy under the direct supervision of a pharmacist while enrolled in the internship program described in Chapter 6-A of the board's rules.
- 27-A. **Point of care location.** "Point of care location" means the premises where prescriptions filled by an automated pharmacy system that is not wholly located in a retail pharmacy are delivered or administered.
28. **Practice setting.** "Practice setting" includes, but is not limited to, the place, area, site, or manner in which the practice of pharmacy may normally occur or transpire.
29. [deleted]
30. **Prescription filling area.** "Prescription filling area" is the area used for compounding prescription legend drugs, for storing all drugs and devices which may be sold by prescription only, and for any other activities necessary to the practice of pharmacy.
31. **Printout.** "Printout" is a hard copy produced by computer that is readable without the aid of any special device.
32. **Retail pharmacy.** "Retail pharmacy" is:
1. A pharmacy located in a retail store; or
 2. A specialty pharmacy not located in a retail store, including but not limited to a closed-shop pharmacy, sterile compounding pharmacy, extended hospital pharmacy, opioid treatment program and retail supplier of medical oxygen.
- 32-A. **Retail supplier of medical oxygen.** "Retail supplier of medical oxygen" means a person who sells or dispenses medical oxygen to a consumer—
1. Pursuant to a prescription from a practitioner; or
 2. In circumstances where a prescription is required by federal law.
33. **Sight-readable.** "Sight-readable" refers to a record that may be read from a computer screen, microfiche, microfilm, printout, or other method approved by the Board.
34. **Sterile pharmaceutical.** "Sterile pharmaceutical" is any dosage form of a drug, including but not limited to, parenterals (e.g., injectables, surgical irrigants, and ophthalmics) devoid of viable microorganisms.

- 34-A. Sterile compounding pharmacy.** “Sterile compounding pharmacy” is a pharmacy that engages in the compounding of sterile pharmaceuticals.

[NOTE: “Compounding” is defined in 32 MRSA §13702-A(4).]

- 35. Stop date.** “Stop date” is the length of time to administer medication. In institutional settings, the physician normally notes the length of time to administer medication on the drug order. In the absence of this notation, the policy of the institution shall determine the length of time various categories of drugs may be administered.
- 35-A. VAWD.** “VAWD” is the Verified-Accredited Wholesale Distributor program administered by NABP.
- 36. Wholesale distribution.** “Wholesale distribution” is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, but does not include:
1. Intracompany sales, which include any internal sales transaction or transfer with any division, subsidiary, parent and affiliated or related company under the common ownership and control as the transferor;
 2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 3. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 4. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, “common control” means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
 5. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, “emergency medical reasons” includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
 6. The sale of a drug by a retail pharmacy to licensed practitioners for office use when the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five (5) percent of that pharmacy’s total annual prescription drug sales;
 7. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

8. The distribution of drug samples by manufacturers' representatives or distributors' representatives;
 9. The sale, purchase or trade of blood and blood components intended for transfusion; or
 10. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23.
37. **Wholesale distributor.** "Wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A wholesale distributor includes a wholesaler as defined in 32 MRSA §13702-A(34).
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STATUTORY AUTHORITY: 32 MRSA §§13720, 13723

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS

CHAPTER 1

DEFINITIONS

ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter defines certain words and terms used throughout the board's rules. In the amendments to this chapter the board made the following changes:

- Adopted new definitions of "affiliated" (see Chapter 35), "closed-shop pharmacy" (see Chapter 38), "electronic prescription" (see Chapter 19, Sections 3 and 4), "extended hospital pharmacy" (see Chapter 35), "medical oxygen" (relocated from Chapter 34), "non-sterile compounding pharmacy" (see Chapter 13, Section 7), "retail supplier of medical oxygen" (relocated from Chapter 34), and "sterile compounding pharmacy" (see Chapter 37).
- Deleted the definition of "authorized pharmacy technician" in light of the amendment of Chapter 13 to permit any pharmacy technician to be present in the prescription filling area in the absence of a pharmacist.
- Deleted the definitions of "biological safety cabinet," "Class 100 environment," "Class 1000 environment," "cytotoxic" and "enteral" due to the repeal of Chapter 18.
- Deleted the definition of "pharmacy technician (advanced)" due to the elimination of that license category in Chapter 7.
- Deleted the definition of "drug administration clinic" (content folded into Chapter 4-A).
- Amended the definition of "direct supervision" to allow for meals and breaks of pharmacists.
- Amended the definitions of "parenteral" and "sterile pharmaceutical" to conform to NABP definitions (see Chapter 37).
- Amended the definition of "sterile compounding pharmacy" (see Chapter 37).

These revised definitions and related comments are discussed as necessary in the substantive chapters that follow.

Response to Comments

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Part 2 - Licenses and Registrations

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 4: LICENSURE OF PHARMACISTS

Summary: This chapter sets forth the application procedure for persons applying for licensure as a pharmacist pursuant to 32 M.R.S.A. §§-13732 and 13733.

1. Applications

1. Generally

The applicant shall complete the application supplied by the board and provide such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant.

2. Completion of Application Process

~~A. Applications submitted on or after the effective date of this chapter~~

An applicant must satisfy all qualifications for licensure in an expeditious manner following submission of the application. Qualifications include but are not limited to the achievement and submission of passing examination scores. Application files that show no activity by the applicant to satisfy the qualifications for licensure over a period of ~~1~~one year will be discarded.

~~B. Applications submitted prior to the effective date of this chapter~~

~~For applications submitted prior to the effective date of this chapter, all materials required to qualify the applicant for licensure, including but not limited to passing examination scores, must be submitted to the board no later than 1 year from the effective date of this chapter. Application files that do not contain all qualifying materials after this date will be discarded. Upon adoption of this chapter, the board shall notify pending applicants of this requirement via first class mail sent to the last known address of the applicant on file with the board.~~

~~C. Governing rules Applications pending on the effective date of this chapter that have been substantively reviewed by the board prior to the effective date of this chapter shall be determined under the licensing criteria in effect at the~~

~~time the first substantive review took place. All other applications pending on the effective date of this chapter shall be determined under the licensing criteria in effect for new applications. For purposes of this paragraph, a review for completeness is not a substantive review, and an application that has been returned to the applicant as incomplete is not a pending application.~~

3. Designation of Examinations

All applicants for licensure must demonstrate passing scores on the NAPLEX and the MPJE or their predecessors, or any successor to either of them recognized by the board.

4. Applicants for Licensure by Examination

The applicant shall submit with the application-

- A. An official transcript from the pharmacy school accredited by the American Council on Pharmaceutical Education or Canadian Council for Accreditation of Pharmacy Programs where the applicant earned his/hersa first pharmacy degree. For purposes of this chapter, "accredited" includes pre-candidate and candidate status;
- B. Written verification from a regulatory body with jurisdiction over the practice of pharmacy that the applicant has completed an internship that meets the requirements of Chapter ~~6-6-A~~ of the board's rules;
- C. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of ~~Licensing and Registration~~ Professional and Occupational Regulation, entitled "Establishment of License Fees."

A NAPLEX score transfer presented in support of an application for licensure by examination is only valid for ~~+~~one year from the date the applicant achieved the passing score.

5. Applicants for Licensure by Reciprocity

An applicant who has taken the NAPLEX in another state may transfer the scores on that examination to Maine for consideration by the board for licensure in this state. The applicant shall contact the Score Transfer Program administered by the NABP for this purpose.

The applicant shall submit with the application-

- A. An official transcript from the pharmacy school from which the applicant graduated;

[NOTE: See 32 M.R.S.A. §13733(1)(D) for circumstances as to when accreditation of the pharmacy degree program is not required.]

- B. Verification of employment in a manner required by the board for the period of time required by 32 M.R.S.A. §13733(1)(D) (5 years within the 10 years preceding application) or 32 M.R.S.A. §13733(1)(E) (at least ~~+~~one year), as applicable;
- C. For applicants electing to demonstrate completion of internship pursuant to 32 M.R.S.A. §13733(1)(E) in lieu of employment, written verification from a regulatory body with jurisdiction over the practice of pharmacy that the applicant has completed an internship that meets the requirements of Chapter ~~6-6-A~~ of the board's rules; and
- D. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of ~~Licensing and Registration~~Professional and Occupational Regulation, entitled "Establishment of License Fees."

6. Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate

An applicant who has earned a first pharmacy degree outside the United States from a college which is not subject to accreditation by the American Association of Colleges of Pharmacy or the Canadian Council for Accreditation of Pharmacy Programs and presents a Foreign Pharmacy Graduate Examination Committee Certificate issued by the NABP is eligible for licensure.

An applicant subject to this subsection must meet all other requirements of law and rule in order to qualify for licensure.

7. Verification of Licensure; Effect of Prior Disciplinary Action or Criminal Conviction on Application

The applicant shall supply verification of licensure for all jurisdictions in which the applicant has at any time been licensed or registered as a pharmacist, pharmacy intern or pharmacy technician. The board may refuse to license and may refuse to renew the license of an applicant-

- A. Whose pharmacy license or registration as a pharmacy intern or pharmacy technician has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving controlled substances. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacist.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for ~~registration~~licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 M.R.S.A. §5301 *et seq.*]

2. Term of License

All pharmacist licenses expire on December 31 of each year. ~~Registrations~~ Licenses may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee.

3. Notice of Change of Contact Address

A pharmacist shall notify the board of a change of contact address via letter, fax, ~~or email~~ or on line within 30 days after the change.

4. Notice of Employment and Non-Employment

The board encourages a pharmacist to voluntarily notify the board via letter, fax, email or on line of the pharmacist's commencement or cessation of employment as a pharmacist.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), 13723, 13732, 13733, 13734

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

Part 2 - Licenses and Registrations
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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 4: LICENSURE OF PHARMACISTS

Summary: This chapter sets forth the application procedure for persons applying for licensure as a pharmacist pursuant to 32 MRSA §§13732 and 13733.

1. Applications

1. Generally

The applicant shall complete the application supplied by the board and provide such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant.

2. Completion of Application Process

An applicant must satisfy all qualifications for licensure in an expeditious manner following submission of the application. Qualifications include but are not limited to the achievement and submission of passing examination scores. Application files that show no activity by the applicant to satisfy the qualifications for licensure over a period of one year will be discarded.

3. Designation of Examinations

All applicants for licensure must demonstrate passing scores on the NAPLEX and the MPJE or their predecessors, or any successor to either of them recognized by the board.

4. Applicants for Licensure by Examination

The applicant shall submit with the application-

- A. An official transcript from the pharmacy school accredited by the American Council on Pharmaceutical Education or Canadian Council for Accreditation of Pharmacy Programs where the applicant earned a first pharmacy degree. For purposes of this chapter, “accredited” includes pre-candidate and candidate status;

- B. Written verification from a regulatory body with jurisdiction over the practice of pharmacy that the applicant has completed an internship that meets the requirements of Chapter 6-A of the board's rules;
- C. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

A NAPLEX score transfer presented in support of an application for licensure by examination is only valid for one year from the date the applicant achieved the passing score.

5. Applicants for Licensure by Reciprocity

An applicant who has taken the NAPLEX in another state may transfer the scores on that examination to Maine for consideration by the board for licensure in this state. The applicant shall contact the Score Transfer Program administered by the NABP for this purpose.

The applicant shall submit with the application-

- A. An official transcript from the pharmacy school from which the applicant graduated;

[NOTE: See 32 MRSA §13733(1)(D) for circumstances as to when accreditation of the pharmacy degree program is not required.]

- B. Verification of employment in a manner required by the board for the period of time required by 32 MRSA §13733(1)(D) (5 years within the 10 years preceding application) or 32 MRSA §13733(1)(E) (at least one year), as applicable;
- C. For applicants electing to demonstrate completion of internship pursuant to 32 MRSA §13733(1)(E) in lieu of employment, written verification from a regulatory body with jurisdiction over the practice of pharmacy that the applicant has completed an internship that meets the requirements of Chapter 6-A of the board's rules; and
- D. The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

6. Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate

An applicant who has earned a first pharmacy degree outside the United States from a college which is not subject to accreditation by the American Association of Colleges of Pharmacy or the Canadian Council for Accreditation of Pharmacy Programs and presents a Foreign Pharmacy Graduate Examination Committee Certificate issued by the NABP is eligible for licensure.

An applicant subject to this subsection must meet all other requirements of law and rule in order to qualify for licensure.

7. Verification of Licensure; Effect of Prior Disciplinary Action or Criminal Conviction on Application

The applicant shall supply verification of licensure for all jurisdictions in which the applicant has at any time been licensed or registered as a pharmacist, pharmacy intern or pharmacy technician. The board may refuse to license and may refuse to renew the license of an applicant-

- A. Whose pharmacy license or registration as a pharmacy intern or pharmacy technician has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving controlled substances. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacist.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSA §5301 *et seq.*]

2. Term of License

All pharmacist licenses expire on December 31 of each year. Licenses may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee.

3. Notice of Change of Contact Address

A pharmacist shall notify the board of a change of contact address via letter, fax, email or on line within 30 days after the change.

4. Notice of Employment and Non-Employment

The board encourages a pharmacist to voluntarily notify the board via letter, fax, email or on line of the pharmacist's commencement or cessation of employment as a pharmacist.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), 13723, 13732, 13733, 13734

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 4
LICENSURE OF PHARMACISTS
ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter sets forth the application procedure for persons applying for licensure as a pharmacist pursuant to 32 MRSA §§13732 and 13733. In the amendments to this chapter the board made the following changes:

- Deleted obsolete text relating to submission of applications.
- Defined "accredited" to include pre-candidate and candidate status.
- Encouraged pharmacists to voluntarily notify the board of their commencement or cessation of employment as a pharmacist.

The broader definition of "accredited" recognizes that for new pharmacy programs, accreditation is a gradual process. The notification requirement will enable the board to more easily locate a pharmacist who may have changed employment prior to the board's receipt of a complaint against the pharmacist.

Response to Comments

Stanley L. Tenenman
55 Rockwood Lane
Poland, ME 04274
(written)

- Section 4. "A proposed regulation is that a pharmacist must give notice within 10 days of a change or ceasing of employment. How will this be interpreted for a pharmacist who 1) works part time for more than one pharmacy, 2) a pharmacist who floats to multiple stores within the same company, and 3) a pharmacist who may work very occasionally, perhaps a few days a year, to help other pharmacists. Will he/she have to [be in] constant with the Board?

- ◆ *Board Response:* The board shares the commenter's concerns about the uncertainty of the reporting obligation. Moreover, the reporting obligation is not necessary: In investigating complaints, the board has never been unable to identify and locate the pharmacist on duty at the time the alleged violation occurred. A mandatory reporting obligation will be an administrative burden on pharmacies that will only lead to additional fines.

For these reasons the board has amended proposed Section 4 to read:

4. Notice of Employment and Non-Employment

The board encourages A a pharmacist shall to voluntarily notify the board via letter, fax, email or on line ~~within 10 days after~~ of the pharmacist's commencement or cessation of employment as a pharmacist.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-300

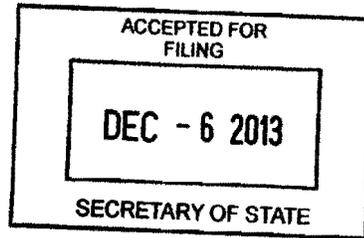
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Administration of Drugs and Vaccines

4. Chapter number assigned to the rule: 4-A
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 4-A: ADMINISTRATION OF DRUGS AND IMMUNIZATIONS VACCINES**

Summary: This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the operation of drug administration clinics.

1. Minimum Requirements for Treatment Protocol Issued Pursuant to 32 MRSA §13833

For purposes of this section, a treatment protocol is a written collaborative agreement between a practitioner as described in 32 MRSA §13833 and a pharmacist who holds a certificate of administration or pharmacy as described in this section. A treatment protocol authorizes the administration of drugs and ~~immunizations~~ vaccines by a pharmacist who holds a certificate of administration pursuant to 32 MRSA §13831-13835 and must include, at a minimum, the following provisions:

1. Authorized Practitioner

The treatment protocol must state the name, professional title, license number and contact information of the authorized practitioner issuing the protocol.

2. Time Period

The treatment protocol must state the beginning and ending dates of the period of time during which the protocol will be in effect, and the date on which the treatment protocol was issued. The treatment protocol may not have a beginning date prior to the date of issuance.

3. Scope of Coverage – Pharmacists

The treatment protocol may cover specific, named pharmacists who hold a certificate of administration, or may cover on a blanket basis all pharmacists holding a certificate of administration who are employed by or under contract to a specific pharmacy or pharmacies. Thus, the protocol must either:

- A. State the name and contact information of the individual pharmacists holding a certificate of administration who are covered by the treatment protocol; or
- B. State the name and physical address of the pharmacy or pharmacies whose employee or contract certified pharmacists holding a certificate of administration will be covered by the treatment protocol without further identification.

A treatment protocol that covers on a blanket basis all pharmacists who hold a certificate of administration and are employed by or under contract to a specific pharmacy or pharmacies only applies to the administration of drugs and ~~immunizations~~ vaccines by such pharmacists in the course of the pharmacists' employment or performance of contractual duties for a pharmacy identified in the treatment protocol.

4. **Scope of Coverage – Drugs and ~~Immunizations~~ Vaccines**

The treatment protocol must identify the drugs and ~~immunizations~~ vaccines that may be administered pursuant to the protocol. For each drug and ~~immunization~~ vaccine named, the protocol must specify the maximum permitted dose and the route of administration.

~~Only the following drugs and immunizations may be included in the treatment protocol:~~

- ~~_____ Influenza vaccines, including intranasal vaccine~~
- ~~_____ Pneumococcal vaccine~~
- ~~_____ Shingles or herpes zoster vaccine~~
- ~~_____ Tetanus-diphtheria-pertussis vaccine~~
- ~~_____ Tetanus-diphtheria vaccine~~
- ~~_____ Booster tetanus-diphtheria vaccine~~

[NOTE: Vaccines that may be administered pursuant to this chapter are described in 32 MRSA §13831.]

5. **Standards for Observation**

The treatment protocol must include standards for observation of the person receiving the drug or ~~immunization~~ vaccine to determine whether the person has an adverse reaction. The treatment protocol must specify a minimum post-administration patient retention period.

6. **Adverse Reactions**

The treatment protocol must include procedures to be followed by the pharmacist who holds a certificate of administration when administering epinephrine, diphenhydramine, or both, to a person who has an adverse reaction to an ~~immunization~~ vaccine administered by the pharmacist. The treatment protocol must include guidelines as to when contact with the local emergency services system or other follow-up health care providers is necessary or recommended.

7. **Notification**

- A. The treatment protocol must require a pharmacist holding a certificate of administration who administers a drug or ~~immunization~~ vaccine pursuant to this treatment protocol to provide notice of the administration within 3 business days to the authorized practitioner who issued a prescription, treatment protocol or written standing order pursuant to 32 MRSA §13831(2)

which authorized administration to the patient or to the patient population of which the patient is a member;

B. The treatment protocol must require a pharmacist who holds a certificate of administration to provide notice of an adverse reaction to a drug or ~~immunization~~ vaccine administered by the pharmacist of which the pharmacist is aware, including a statement as to whether epinephrine or diphenhydramine was administered, within 3 business days to:

- (1) The authorized practitioner who issued the prescription, treatment protocol or written standing order which authorized administration to the patient or to the patient population of which the patient is a member;
- (2) The Vaccine Adverse Events Reporting System co-sponsored by the Centers for Disease Control and the Federal Drug Administration; and
- (3) The Maine Center for Disease Control and Prevention.

[NOTE: A prescription, treatment protocol or written standing order from an authorized practitioner is not required for administration of influenza vaccines.]

8. **Submission to Board**

The pharmacist holding a certificate of administration or the pharmacy or pharmacies to which the treatment protocol is issued shall submit a copy of the protocol to the board no later than 20 calendar days after the effective date of the protocol. If the protocol is changed, a copy of the revised protocol must be submitted to the board no later than 20 calendar days after the effective date of the change.

2. **Administration Requirements**

A pharmacist who holds a certificate of administration shall observe the following administration requirements in addition to requirements contained in:

- An applicable prescription, treatment protocol or written standing order issued pursuant to 32 MRSA §13831(2); and
- The applicable treatment protocol issued pursuant to 32 MRSA §13833 and Section 1 of this chapter.

1. **Verification**

A. For administration of influenza vaccines, the pharmacist who holds a certificate of administration shall verify as necessary that the patient is 9 years of age or older.

B. For administration of ~~pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus diphtheria pertussis vaccine, tetanus diphtheria vaccine or booster tetanus diphtheria~~ all other vaccines pursuant to a prescription, the pharmacist who holds a certificate of administration shall verify

~~(1) that~~ That the patient is the person to whom the prescription was issued;

(2) That the patient is 18 years of age or older.

C. For administration of ~~pneumococcal vaccine, shingles or herpes zoster vaccine, tetanus diphtheria pertussis vaccine, tetanus diphtheria vaccine or booster tetanus diphtheria~~ all other vaccines pursuant to a treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:

(1) That the patient is a member of the patient population (e.g., employee of designated employer, resident of designated municipality) covered by the treatment protocol or standing written order; and

(2) That the patient is 18 years of age or older.

2. **Assessment**

Prior to administering a drug or ~~immunization~~ vaccine, a pharmacist who holds a certificate of administration shall assess the patient for contraindications that would preclude vaccination.

3. **Vaccine Information Statement**

A pharmacist who holds a certificate of administration, prior to administration, shall give each patient or the patient's legal representative the appropriate vaccine information statement for the drug or ~~immunization~~ vaccine to be administered. The pharmacist shall orally review with the patient or patient's legal representative the portions of the statement describing the risks of the ~~vaccination~~ vaccine and what to look for and what to do in the event of a severe reaction.

4. **Informed Consent**

After providing the vaccine information statement, but prior to administration, the pharmacist who holds a certificate of administration shall obtain in writing the informed consent of the patient or the patient's legal representative to administration of the drug or ~~immunization~~ vaccine and to emergency administration of epinephrine, diphenhydramine or both if the patient has an adverse reaction to the drug or ~~immunization~~ vaccine administered.

5. **Certificate of ~~Immunization~~ Vaccination**

A pharmacist holding a certificate of administration who administers a drug or ~~immunization~~ vaccine shall issue a certificate of ~~immunization~~ vaccination to the

patient or patient's representative at the time the drug or ~~immunization vaccine~~ is administered. The certificate shall be signed by the pharmacist and shall include the patient's name, date of ~~immunization vaccination~~ and the location where the drug or ~~immunization vaccine~~ was administered.

6. Record of Individual Administration—~~Influenza Vaccines~~

~~For influenza vaccines, including intranasal vaccine, the~~ A pharmacist who holds a certificate of administration shall record the administration of a vaccine in a computerized or non-computerized recordkeeping system that includes, at a minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:

A. For both influenza and non-influenza vaccines:

- ~~A.~~(1) The name, date of birth, gender and contact information of the patient;
- ~~B.~~(2) The name of the pharmacist holding a certificate of administration who administered the drug or ~~immunization vaccine~~;
- ~~C.~~(3) The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;
- ~~D.~~(4) The date of administration;
- ~~E.~~(5) The street address or location of the building where the drug or ~~immunization vaccine~~ was administered;
- ~~F.~~(6) The name of the drug or ~~immunization vaccine~~ administered, including the dose, route of administration, expiration date, manufacturer and lot number; and
- ~~G.~~(7) In the event that epinephrine or diphenhydramine is administered pursuant to 32 MRSA §13831(3),
 - (1a) The name of the pharmacist holding a certificate of administration who administered the drug;
 - (2b) The date of administration;
 - (3c) The street address or location of the building where the drug was administered; and
 - (4d) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number.

B. For non-influenza vaccines:

- (1) For vaccinations authorized by prescription, the prescription; and
- (2) For vaccinations authorized by a treatment protocol or standing written order, the name of the authorized practitioner who issued the treatment protocol or standing written order and the date of issuance.

7. ~~Record of Individual Administration— Non-Influenza Vaccines~~

~~For pneumococcal vaccine, shingles or herpes-zoster vaccine, tetanus-diphtheria-pertussis vaccine, tetanus-diphtheria vaccine or booster tetanus-diphtheria vaccine, the pharmacist who holds a certificate of administration shall record the administration in a computerized recordkeeping system that includes, at a minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:~~

- ~~A. The name, date of birth, gender and contact information of the patient;~~
- ~~B. The name of the pharmacist holding a certificate of administration who administered the drug or immunization;~~
- ~~C. The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;~~
- ~~D. The date of administration;~~
- ~~E. The street address or location of the building where the drug or immunization was administered;~~
- ~~F. The name of the drug or immunization administered, including the dose, route of administration, expiration date, manufacturer and lot number;~~
- ~~G. For administrations authorized by prescription, the prescription;~~
- ~~H. For administrations authorized by a treatment protocol or standing written order, the name of the authorized practitioner who issued the treatment protocol or standing written order and the date of issuance; and~~
- ~~I. In the event that epinephrine or diphenhydramine is administered pursuant to 32 MRSA §13831(3) and the treatment protocol,~~
 - ~~(1) The name of the pharmacist holding a certificate of administration who administered the drug;~~
 - ~~(2) The date of administration;~~
 - ~~(3) The street address or location of the building where the drug was administered; and~~
 - ~~(4) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number. [deleted]~~

3. Operation of Drug-Vaccine Administration Clinics; One-Time Approval by Board

1. Site Suitability

A drug-vaccine administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

2. Written Plan of Operation

The pharmacist holding a certificate of administration or pharmacy that operates a drug-vaccine administration clinic shall develop a written plan of operation prior to conducting the clinic, and shall ensure that the plan is complied with during operation. The plan may cover multiple pharmacies under common ownership, provided that each such pharmacy adheres to the plan. A clinic may not be conducted until the written plan of operation has been approved by the board pursuant to subsection 5 of this Section. The plan must, at a minimum:

- A. Require that any non-health care personnel who assist at the clinic have no contact whatsoever with drugs, ~~immunizations~~vaccines, needles or syringes;
- B. Include a specific protocol for prevention of administration errors (e.g., administration of incorrect drug or incorrect dose to patient; administration of drug to wrong patient);
- C. Include procedures for the orderly management and flow of patients through the clinic both pre- and post-administration;
- D. Include a specific protocol for performing the following procedures
 - (1) Verification (Section 2(1));
 - (2) Assessment (Section 2(2));
 - (3) Provision of vaccine information statement and discussion of possible adverse reactions (Section 2(3));
 - (4) Obtaining written informed consent (Section 2(4)); and
 - (5) Issuance of certificate of ~~immunization~~vaccination (Section 2(5));
- E. Incorporate the protocol for observing patients following administration required by Section 1(5) of this chapter. Clinic staff shall strongly recommend that all patients remain in the immediate vicinity of the vaccination site for the post-administration observation period specified in the treatment protocol. To facilitate patient compliance, the operator of the clinic shall make a comfortable sitting area available in the immediate vicinity of

the administration site. The sitting area must be of adequate size and must be suitably equipped to accommodate the flow of patients for the full duration of the post-administration observation period;

- F. Include a protocol for the safe storage and transportation of drugs and ~~immunizations~~ vaccines to ensure that the vaccine remains viable until the point of administration;
- G. Include procedures to ensure that an adequate number of epinephrine and diphenhydramine syringes and other emergency medical supplies will be available for use in case a patient has an adverse reaction to the drug or ~~vaccination~~ vaccine administered; and
- H. Include a protocol for infection control. Standard precautions to minimize the risks of spreading disease during vaccine administration must be in place. The protocol must include, at a minimum, the following provisions:
 - (1) *Handwashing.* Hands must be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled;
 - (2) *Gloving.* Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. It is important to remember that gloves cannot prevent needlestick injuries;
 - (3) *Needlestick Injuries.* Needlestick injuries must be reported immediately to a lead person, with appropriate care and follow-up given. Safety needles or needle-free injection devices should be used if available to reduce the risk of injury;

[NOTE: For more information on needle-free injection technology, see the CDC website:
[http://www.cdc.gov/vaccinesafety/vaxtech/nfit/.](http://www.cdc.gov/vaccinesafety/vaxtech/nfit/)]

- (4) *Equipment Disposal.* Used needles may not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices must be placed in puncture-proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and are subject to Chapter 900 of the rules of the Department of Environmental Protection, “Biomedical Waste Management Rules;” and

[NOTE: The operator of a drug administration clinic may be required to register as a biomedical waste generator with the Department of Environmental Protection.]

- (5) *Vaccine Preparation.* Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

3. Clinic Personnel

At the conclusion of a drug administration clinic the pharmacist holding a certificate of ~~immunization~~administration or pharmacy that conducted the clinic shall attach to the written plan of operation for that clinic a list that identifies, by name and position:

- A. The lead person or persons who were responsible for operation of the clinic; and
- B. All pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who staffed or assisted at the clinic.

4. Retention of Records

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

5. One-Time Approval of Written Plan of Operation

The written plan of operation described in subsection 2 of this Section must be submitted to the board for approval no less than 30 days prior to initial operation of a vaccine administration clinic pursuant to the plan. The duration of approval is indefinite, provided that in the event of any change to the plan, or any change in operation of a clinic that is not documented by or is inconsistent with the approved plan, the entire written plan of operation must be re-submitted to the board for approval.

4. Administration of Drugs and Vaccines by Pharmacy Intern

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13723, 13831, 13832, 13833, 13834(1), 13835;
PL 2009, c. 308

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 4-A: ADMINISTRATION OF DRUGS AND VACCINES**

Summary: This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the operation of drug administration clinics.

1. Minimum Requirements for Treatment Protocol Issued Pursuant to 32 MRSA §13833

For purposes of this section, a treatment protocol is a written collaborative agreement between a practitioner as described in 32 MRSA §13833 and a pharmacist who holds a certificate of administration or pharmacy as described in this section. A treatment protocol authorizes the administration of drugs and vaccines by a pharmacist who holds a certificate of administration pursuant to 32 MRSA §13831-13835 and must include, at a minimum, the following provisions:

1. Authorized Practitioner

The treatment protocol must state the name, professional title, license number and contact information of the authorized practitioner issuing the protocol.

2. Time Period

The treatment protocol must state the beginning and ending dates of the period of time during which the protocol will be in effect, and the date on which the treatment protocol was issued. The treatment protocol may not have a beginning date prior to the date of issuance.

3. Scope of Coverage – Pharmacists

The treatment protocol may cover specific, named pharmacists who hold a certificate of administration, or may cover on a blanket basis all pharmacists holding a certificate of administration who are employed by or under contract to a specific pharmacy or pharmacies. Thus, the protocol must either:

- A. State the name and contact information of the individual pharmacists holding a certificate of administration who are covered by the treatment protocol; or
- B. State the name and physical address of the pharmacy or pharmacies whose employee or contract certified pharmacists holding a certificate of administration will be covered by the treatment protocol without further identification.

A treatment protocol that covers on a blanket basis all pharmacists who hold a certificate of administration and are employed by or under contract to a specific pharmacy or pharmacies only applies to the administration of drugs and vaccines by such pharmacists in the course of the pharmacists' employment or performance of contractual duties for a pharmacy identified in the treatment protocol.

4. Scope of Coverage – Drugs and Vaccines

The treatment protocol must identify the drugs and vaccines that may be administered pursuant to the protocol. For each drug and vaccine named, the protocol must specify the maximum permitted dose and the route of administration.

[NOTE: Vaccines that may be administered pursuant to this chapter are described in 32 MRSA §13831.]

5. Standards for Observation

The treatment protocol must include standards for observation of the person receiving the drug or vaccine to determine whether the person has an adverse reaction. The treatment protocol must specify a minimum post-administration patient retention period.

6. Adverse Reactions

The treatment protocol must include procedures to be followed by the pharmacist who holds a certificate of administration when administering epinephrine, diphenhydramine, or both, to a person who has an adverse reaction to a vaccine administered by the pharmacist. The treatment protocol must include guidelines as to when contact with the local emergency services system or other follow-up health care providers is necessary or recommended.

7. Notification

- A. The treatment protocol must require a pharmacist holding a certificate of administration who administers a drug or vaccine pursuant to this treatment protocol to provide notice of the administration within 3 business days to the authorized practitioner who issued a prescription, treatment protocol or written standing order pursuant to 32 MRSA §13831(2) which authorized administration to the patient or to the patient population of which the patient is a member;
- B. The treatment protocol must require a pharmacist who holds a certificate of administration to provide notice of an adverse reaction to a drug or vaccine administered by the pharmacist of which the pharmacist is aware, including a statement as to whether epinephrine or diphenhydramine was administered, within 3 business days to:
 - (1) The authorized practitioner who issued the prescription, treatment protocol or written standing order which authorized administration to

the patient or to the patient population of which the patient is a member;

- (2) The Vaccine Adverse Events Reporting System co-sponsored by the Centers for Disease Control and the Federal Drug Administration; and
- (3) The Maine Center for Disease Control and Prevention.

[NOTE: A prescription, treatment protocol or written standing order from an authorized practitioner is not required for administration of influenza vaccines.]

8. Submission to Board

The pharmacist holding a certificate of administration or the pharmacy or pharmacies to which the treatment protocol is issued shall submit a copy of the protocol to the board no later than 20 calendar days after the effective date of the protocol. If the protocol is changed, a copy of the revised protocol must be submitted to the board no later than 20 calendar days after the effective date of the change.

2. Administration Requirements

A pharmacist who holds a certificate of administration shall observe the following administration requirements in addition to requirements contained in:

- An applicable prescription, treatment protocol or written standing order issued pursuant to 32 MRSA §13831(2); and
- The applicable treatment protocol issued pursuant to 32 MRSA §13833 and Section 1 of this chapter.

1. Verification

- A. For administration of influenza vaccines, the pharmacist who holds a certificate of administration shall verify as necessary that the patient is 9 years of age or older.
- B. For administration of all other vaccines pursuant to a prescription, the pharmacist who holds a certificate of administration shall verify
 - (1) That the patient is the person to whom the prescription was issued;
 - (2) That the patient is 18 years of age or older.
- C. For administration of all other vaccines pursuant to a treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:

- (1) That the patient is a member of the patient population (e.g., employee of designated employer, resident of designated municipality) covered by the treatment protocol or standing written order; and
- (2) That the patient is 18 years of age or older.

2. **Assessment**

Prior to administering a drug or vaccine, a pharmacist who holds a certificate of administration shall assess the patient for contraindications that would preclude vaccination.

3. **Vaccine Information Statement**

A pharmacist who holds a certificate of administration, prior to administration, shall give each patient or the patient's legal representative the appropriate vaccine information statement for the drug or vaccine to be administered. The pharmacist shall orally review with the patient or patient's legal representative the portions of the statement describing the risks of the vaccine and what to look for and what to do in the event of a severe reaction.

4. **Informed Consent**

After providing the vaccine information statement, but prior to administration, the pharmacist who holds a certificate of administration shall obtain in writing the informed consent of the patient or the patient's legal representative to administration of the drug or vaccine and to emergency administration of epinephrine, diphenhydramine or both if the patient has an adverse reaction to the drug or vaccine administered.

5. **Certificate of Vaccination**

A pharmacist holding a certificate of administration who administers a drug or vaccine shall issue a certificate of vaccination to the patient or patient's representative at the time the drug or vaccine is administered. The certificate shall be signed by the pharmacist and shall include the patient's name, date of vaccination and the location where the drug or vaccine was administered.

6. **Record of Individual Administration**

A pharmacist who holds a certificate of administration shall record the administration of a vaccine in a computerized or non-computerized recordkeeping system that includes, at a minimum, the following information. The recordkeeping system may be a pharmacy's patient profile record system:

A. For both influenza and non-influenza vaccines:

- (1) The name, date of birth, gender and contact information of the patient;

- (2) The name of the pharmacist holding a certificate of administration who administered the drug or vaccine;
- (3) The written informed consent required by Section 2(4) of this chapter, or an electronic copy of the document;
- (4) The date of administration;
- (5) The street address or location of the building where the drug or vaccine was administered;
- (6) The name of the drug or vaccine administered, including the dose, route of administration, expiration date, manufacturer and lot number; and
- (7) In the event that epinephrine or diphenhydramine is administered pursuant to 32 MRSA §13831(3),
 - (a) The name of the pharmacist holding a certificate of administration who administered the drug;
 - (b) The date of administration;
 - (c) The street address or location of the building where the drug was administered; and
 - (d) The name of the drug administered, including the dose, route of administration, expiration date, manufacturer and lot number.

B. For non-influenza vaccines:

- (1) For vaccinations authorized by prescription, the prescription; and
- (2) For vaccinations authorized by a treatment protocol or standing written order, the name of the authorized practitioner who issued the treatment protocol or standing written order and the date of issuance.

7. [deleted]

3. Operation of Vaccine Administration Clinics; One-Time Approval by Board

1. Site Suitability

A vaccine administration clinic must be located in a sanitary, well-maintained, adequately-equipped space that is appropriately sized for the expected patient volume and facilitates interaction among clinic staff and patients.

2. **Written Plan of Operation**

The pharmacist holding a certificate of administration or pharmacy that operates a vaccine administration clinic shall develop a written plan of operation prior to conducting the clinic, and shall ensure that the plan is complied with during operation. The plan may cover multiple pharmacies under common ownership, provided that each such pharmacy adheres to the plan. A clinic may not be conducted until the written plan of operation has been approved by the board pursuant to subsection 5 of this Section. The plan must, at a minimum:

- A. Require that any non-health care personnel who assist at the clinic have no contact whatsoever with drugs, vaccines, needles or syringes;
- B. Include a specific protocol for prevention of administration errors (e.g., administration of incorrect drug or incorrect dose to patient; administration of drug to wrong patient);
- C. Include procedures for the orderly management and flow of patients through the clinic both pre- and post-administration;
- D. Include a specific protocol for performing the following procedures
 - (1) Verification (Section 2(1));
 - (2) Assessment (Section 2(2));
 - (3) Provision of vaccine information statement and discussion of possible adverse reactions (Section 2(3));
 - (4) Obtaining written informed consent (Section 2(4)); and
 - (5) Issuance of certificate of vaccination (Section 2(5));
- E. Incorporate the protocol for observing patients following administration required by Section 1(5) of this chapter. Clinic staff shall strongly recommend that all patients remain in the immediate vicinity of the vaccination site for the post-administration observation period specified in the treatment protocol. To facilitate patient compliance, the operator of the clinic shall make a comfortable sitting area available in the immediate vicinity of the administration site. The sitting area must be of adequate size and must be suitably equipped to accommodate the flow of patients for the full duration of the post-administration observation period;
- F. Include a protocol for the safe storage and transportation of drugs and vaccines to ensure that the vaccine remains viable until the point of administration;

- G. Include procedures to ensure that an adequate number of epinephrine and diphenhydramine syringes and other emergency medical supplies will be available for use in case a patient has an adverse reaction to the drug or vaccine administered; and
- H. Include a protocol for infection control. Standard precautions to minimize the risks of spreading disease during vaccine administration must be in place. The protocol must include, at a minimum, the following provisions:
- (1) *Handwashing.* Hands must be washed thoroughly with soap and water or cleansed with an alcohol-based waterless antiseptic between patients, before vaccine preparation or any time hands become soiled;
 - (2) *Gloving.* Gloves are not required to be worn when administering vaccines unless the person administering the vaccine is likely to come into contact with potentially infectious body fluids or has open lesions on the hands. It is important to remember that gloves cannot prevent needlestick injuries;
 - (3) *Needlestick Injuries.* Needlestick injuries must be reported immediately to a lead person, with appropriate care and follow-up given. Safety needles or needle-free injection devices should be used if available to reduce the risk of injury;
 - (4) *Equipment Disposal.* Used needles may not be detached from syringes, recapped or cut before disposal. All used syringe/needle devices must be placed in puncture-proof containers to prevent accidental needlesticks and reuse. Empty or expired vaccine vials are considered medical waste and are subject to Chapter 900 of the rules of the Department of Environmental Protection, “Biomedical Waste Management Rules;” and

[NOTE: The operator of a drug administration clinic may be required to register as a biomedical waste generator with the Department of Environmental Protection.]

- (5) *Vaccine Preparation.* Proper vaccine handling and preparation is critical in maintaining the integrity of the vaccine during transfer from the manufacturer's vial to the syringe and ultimately to the patient.

3. Clinic Personnel

At the conclusion of a drug administration clinic the pharmacist holding a certificate of administration or pharmacy that conducted the clinic shall attach to the written plan of operation for that clinic a list that identifies, by name and position:

- A. The lead person or persons who were responsible for operation of the clinic; and

- B. All pharmacists holding a certificate of administration, pharmacy technicians, student interns, other health care personnel and non-health care personnel who staffed or assisted at the clinic.

4. Retention of Records

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

5. One-Time Approval of Written Plan of Operation

The written plan of operation described in subsection 2 of this Section must be submitted to the board for approval no less than 30 days prior to initial operation of a vaccine administration clinic pursuant to the plan. The duration of approval is indefinite, provided that in the event of any change to the plan, or any change in operation of a clinic that is not documented by or is inconsistent with the approved plan, the entire written plan of operation must be re-submitted to the board for approval.

4. Administration of Drugs and Vaccines by Pharmacy Intern

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13723, 13831, 13832, 13833, 13834(1), 13835

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 4-A
ADMINISTRATION OF DRUGS AND VACCINES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth minimum requirements for treatment protocols, administration and recordkeeping requirements, and standards for the operation of drug administration clinics. The immediate impetus for the changes to this chapter was the enactment of PL 2011, c. 577 (and later, PL 2013, c. 6). Chapter 577 amended the pharmacist immunization law by:

- Broadening the types of vaccines that pharmacists can administer.
- Clarifying that a pharmacy can operate a vaccine clinic off-premises
- Requiring a pharmacy that operates a vaccine clinic to submit its plan of operation to the board for a one-time approval.
- Changing the word "immunization" to "vaccine" throughout.

In the amendments to this chapter the board made the following changes:

- Substituted the phrase "drugs and vaccinations" for "drugs and immunizations" pursuant to PL 2011, c. 577.
- Broadened the scope of drugs and vaccinations that may be administered by a pharmacist to conform to PL 2011, c. 577 and PL 2013, c. 6.
- Required a pharmacist or pharmacy to submit to the board any change to a treatment protocol that was previously submitted to the board.
- Consolidated the provisions of the current chapter regarding the Record of Individual Administration.
- Provided that a written plan of operation may cover multiple pharmacies under common ownership.
- Implemented the requirement of one-time board approval of a vaccination clinic's written plan of operation as required by PL 2011, c. 577. The board interprets this legislation as also requiring approval in the event of any change to the plan, and Section 5 of this chapter so provides.
- Re-stated the statutory authorization of a pharmacy intern to administer drugs and vaccines. (See the Board Finding below.)

The board also deleted the definition of "drug administration clinic" that formerly appeared in Chapter 1, Section 14-A. In the board's view, this definition didn't add anything of value to Section 3 of this chapter, "Operation of Vaccine Administration Clinic; One-Time Approval by Board."

In developing the amendments to this chapter, the board sought input from the Maine Center for Disease Control and Prevention and Board of Licensure in Medicine as required by 32 MRSA §13835. The board received a response from MCDPC but not from BOLIM.

Board Finding

PL 2013, c. 98 amended 32 MRSA §13834(1) to permit a pharmacist to delegate the pharmacist's authority to administer drugs and vaccines to persons 18 years of age or older. In the comments

to Chapter 6-A, Pharmacy Student Internship Program, commenter Robert Morrissette recommended that the board recognize in rule a pharmacy intern's statutory authorization to administer drugs and vaccines. The board agreed, and finds that the same statement should be added to this chapter. The board has accordingly adopted new Section 4 to read:

4. Administration of Drugs and Vaccines by Pharmacy Intern

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

Response to Comments

Mark Polli, R.Ph., Director, Pharmacy Government & Regulatory Affairs
Delhaize America Shared Services Group, LLC
145 Pleasant Hill Rd.
Scarborough ME 04074
(written)

- Section 3(2)(H)(3) (needlestick injuries). The phrase "appropriate care" is ambiguous; the board should define what is meant by "appropriate care."
 - ◆ *Board Response:* The board declines to adopt a more specific requirement for responding to needlestick injuries. There are generally accepted protocols in place for dealing with needlestick injuries. The necessary response to a needlestick injury will depend on the circumstances.

Rule-Making Cover Sheet

2013-301

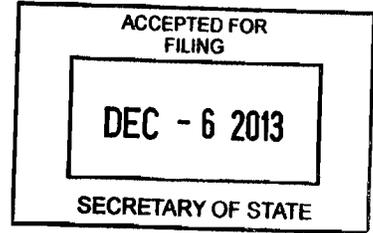
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Pharmacy Student Internship Programs (sunsetting)

4. Chapter number assigned to the rule: 6
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [X] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 6: PHARMACY STUDENT INTERNSHIP PROGRAMS (*sunsetting*)**

Summary: This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules.

1. Purpose

~~A pharmacy student internship consists of 1500 hours of pharmacy practice at one or more drug outlets under the direct supervision of working pharmacists. The pharmacy intern program provides pharmacy students with practical preprofessional experience in a supervised setting and prepares them for licensure as pharmacists. At least 500 hours of the required 1500 hours must be completed in the United States.~~

2. Qualifications**1. Academic Completion**

~~A pharmacy student shall have completed the second year of the six-year pharmacy curriculum or its equivalent at a pharmacy degree program described in 32 M.R.S.A. §13732(1)(D) prior to commencing an internship.~~

2. Registration as Pharmacy Technician

~~A pharmacy student must be registered as a pharmacy technician pursuant to Chapter 7 of the board's rules prior to commencing an internship. The student intern is subject to all the requirements of Chapter 7 on an ongoing basis, including the requirement of annual renewal, except that the limitation of duties contained in Chapter 7 does not apply to student interns.~~

3. Duration of Internship

~~Except in cases of hardship approved by the board, internship must be completed no later than one year after the intern's graduation from the pharmacy degree program. The intern is subject to the limitation of duties contained in Chapter 7 upon either completion of the 1500-hour internship or expiration of the maximum one-year time for completion, whichever first occurs.~~

4. Preceptor

~~The pharmacist in charge shall designate one or more preceptor pharmacists for each pharmacy intern employed at the drug outlet. The preceptor shall direct the training of the intern to whom the preceptor is assigned. The preceptor shall have been engaged in the practice of pharmacy for at least 2 years on a full-time basis immediately prior to serving as preceptor. A preceptor may be responsible for the training of multiple pharmacy interns.~~

5. Training Program

~~The drug outlet at which a pharmacy intern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by a pharmacy intern. The drug outlet shall develop a training program for pharmacy interns employed at that drug outlet. The drug outlet shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. Preceptor pharmacists shall follow the program in training interns.~~

~~Internship programs in non-traditional practice settings (e.g., industry-sponsored programs, manufacturer sales representative, physician's office) must be specially approved by the board upon a consideration of the criteria set forth in this section. The board may, in its discretion, approve a non-traditional practice setting for only a portion of the required 1500 hours.~~

6. Scope of Duties

~~A student intern who has completed the training program required by Section 5 may assist the preceptor pharmacist in the practice of pharmacy while under the direct supervision of the preceptor.~~

7. Completion of Internship

~~An intern employed in Maine shall report completion of the internship to the board on forms supplied by the board and provide such other information as the board may require.~~

8. Sunset

~~A student internship completed according to the requirements of this chapter will not qualify an applicant for licensure as a pharmacist for applications received after June 30, 2012, [repealed]~~

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(G), 13723, 13732(3)

EFFECTIVE DATE:

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version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 6: PHARMACY STUDENT INTERNSHIP PROGRAMS *(sunsetting)*

Summary: This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules.

[repealed]

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(G), 13723, 13732(3)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 6
PHARMACY STUDENT INTERNSHIP PROGRAMS (SUNSETTED)
ADOPTED OCTOBER 3, 2013**

Basis Statement

The board repealed this chapter, which was sunsetted as of June 30, 2012 in the board's most recent prior rulemaking proceeding and is now obsolete.

Response to Comments

No comments were received on the proposed rule.

Rule-Making Cover Sheet

2013-302

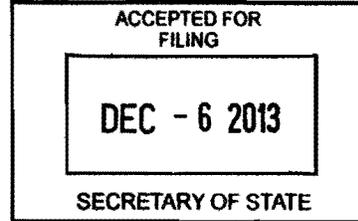
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Pharmacy Student Internship Programs

4. Chapter number assigned to the rule: 6-A
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
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8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

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[] Emergency adoption of major-substantive rule

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Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-21-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 6-A: PHARMACY STUDENT INTERNSHIP PROGRAMS**

Summary: This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules.

SUBCHAPTER 1

PHARMACY STUDENTS-INTERNS EDUCATED IN THE UNITED STATES AND CANADA
PHARMACY SCHOOLS ACCREDITED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION OR CANADIAN COUNCIL FOR ACCREDITATION OF PHARMACY PROGRAMS

1. Scope

The provisions of this subchapter apply to pharmacy internships for pharmacy students educated in pharmacy schools accredited by the Accreditation Council for Pharmacy Education (United States) or the Canadian Council for Accreditation of Pharmacy Programs the United States and (Canada), or a successor organization. For purposes of this chapter, "accredited" includes precandidate and candidate status.

2. Student Internship Program

The pharmacy student internship consists of an IPPE and APPE administered by one or more pharmacy schools accredited by the Accreditation Council for Pharmacy Education, the Canadian Council for Accreditation of Pharmacy Programs, or a successor organization. The internship must be completed as part of the professional curriculum leading to the Doctor of Pharmacy degree. The minimum duration of the IPPE and APPE combined is 1,500 hours.

3. Application for Student Internship in Maine Licensure as a Pharmacy Intern

A student matriculated in a professional academic program leading to the Doctor of Pharmacy degree shall apply to the board for licensure as a pharmacy technician-intern as set forth in Chapter 7, Section 1(1) of the board's rules prior to commencement of an IPPE or APPE in Maine. A student may not participate in either pharmacy practice experience until the board has actually issued a pharmacy intern license to the student. It is the student's obligation to at all times be aware of his or her licensure status. The student shall include with the application the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees." To apply, the pharmacy student shall:

1. Complete the application supplied by the board;
2. Provide the verifications required by Section 4 of this subchapter;
3. Remit the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled “Establishment of License Fees;” and
4. Provide such other information as the board may require.

Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

~~A student may not participate in either pharmacy practice experience until the board has actually issued a pharmacy technician intern license to the student. It is the student’s obligation to at all times be aware of his or her licensure status.~~

4. **Qualifications for Licensure**

1. Matriculation

~~The applicant shall meet the qualifications for licensure as a pharmacy technician set forth in Chapter 7, Section 1(2) of the board’s rules. In addition, As part of the application, the applicant shall present to the board written verification of matriculation in a professional academic degree program described in Section 2 of this subchapter. Maintenance of matriculation is an ongoing requirement of licensure. A license issued under this chapter automatically terminates upon a student’s dropping out of or expulsion from pharmacy school.~~

2. Disciplinary History; Criminal Convictions Involving Controlled Substances

The applicant shall supply verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational license. The board may refuse to license and may refuse to renew the license of an applicant:

- A. Whose professional or occupational license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy intern.

[NOTE: The effect of a criminal conviction on an applicant’s eligibility for licensure is governed generally by the Occupational

License Disqualification on Basis of Criminal Record law, 5
MRSA §5301 et seq.]

5. Issuance and Renewal of License

The initial license and all renewal licenses expire on December 31 annually. The license may be renewed for successive 1-year periods upon completion of a renewal application supplied by the board and certification by the licensee that he or she continues to be enrolled in a professional academic degree program as described in Section 1 of this subchapter. There is no fee to renew the license. A licensee who fails to timely renew the license must apply for a new pharmacy intern license and pay a reinstatement fee. A ~~student-pharmacy~~ pharmacy intern may not practice with an expired or invalid license.

6. Final Renewal Period; Expiration

The licensee shall notify the board of the licensee's graduation within 10 days as required by 10 MRSA §8003-G(2)(D). A pharmacy ~~technician~~-intern license automatically expires on the second renewal subsequent to the licensee's graduation and may not be further renewed. The licensee shall also notify the board within 10 days if the licensee has dropped out of or been expelled from pharmacy school.

7. Scope of Licensure; Supervision; Responsibility

A pharmacy ~~technician~~-intern license issued under this Chapter authorizes the licensee to work as a student intern in an IPPE or APPE or in any other practice environment. The pharmacy ~~technician~~-intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy ~~technician~~-intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

8. Preceptor Pharmacists

A preceptor pharmacist must meet the qualifications established by the pharmacy school administering the IPPE or APPE in which the preceptor participates. For an IPPE or APPE administered in Maine, a preceptor pharmacist must also ~~be licensed in good standing by~~ hold a valid license from the board and have at least 2 years of practice experience as a licensed pharmacist in any state.

8-A. Non-Traditional Practice Setting

The board may recognize for purposes of Section 2 above internship hours completed outside of an IPPE or APPE in a non-traditional practice setting (e.g., industry-sponsored programs, manufacturer's sales representative, physician's office) upon a consideration of the complexity and diversity of the work performed, the nature and amount of supervision provided, the recommendation of the pharmacist in charge or supervising pharmacist, and the overall suitability of the non-traditional practice setting as preparation for the practice of pharmacy. The number of non-traditional hours to be recognized lies in the discretion of the board.

9. Reporting**A1. Completion of IPPE/APPE**

A pharmacy ~~technician~~-intern's completion of an IPPE or APPE, including the number of hours worked, must be verified by the preceptor pharmacist in a manner acceptable to the board.

B2. Non-IPPE/APPE Hours

No later than January 31 of each year, a pharmacy ~~technician~~-intern (~~or former pharmacy technician intern~~) shall report on forms provided by the board all hours worked during the preceding calendar year outside of an IPPE or APPE. All reported hours must be verified by the pharmacist in charge or supervising pharmacist.

10. Theft or Drug-Related Misconduct of Pharmacy Intern

The preceptor shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons, provided that the report shall be made by a pharmacist in charge or supervising pharmacist if the reason for the resignation, discharge or termination arose outside of the IPPE/APPE. Notice shall be provided within 48 hours after the termination:

1. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
2. Theft of non-drug merchandise; or
3. Theft of cash or credit/debit card data.

SUBCHAPTER 2

PHARMACY ~~STUDENTS-INTERNS~~ EDUCATED IN A FOREIGN COUNTRY OTHER THAN CANADA

1. Scope

This subchapter applies to pharmacy internships completed by pharmacy students educated in a foreign country other than Canada.

2. Student Internship Program

A pharmacy ~~student~~ internship consists of 1500 hours of pharmacy practice at one or more pharmacies under the direct supervision of working pharmacists. The pharmacy internship program provides foreign-educated pharmacy ~~students-graduates~~ with practical preprofessional experience in a supervised setting and prepares them for licensure as pharmacists. At least 500 hours of the required 1,500 hours must be completed in the United States.

3. Application for Student Internship

~~A pharmacy student~~An applicant shall have completed the second year of~~graduated from the a 6-year pharmacy curriculum or its equivalent at a pharmacy degree program or its equivalent described in~~approved by the board pursuant to 32 MRSA §13732(1)(D) prior to commencing~~applying for an internship. The student graduate shall apply to the board for licensure as a pharmacy technician intern as set forth in Chapter 7, Section 1(1) of the board's rules. A graduate may not commence the internship until the board has actually issued a pharmacy intern license to the graduate. It is the graduate's obligation to at all times be aware of his or her licensure status. The student shall include with the application the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees."~~To apply, the pharmacy graduate shall:

1. Complete the application supplied by the board;
2. Provide the transcript, FPGEC certificate and verifications required by Section 4 of this subchapter;
3. Remit the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees;" and
4. Provide such other information as the board may require.

Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

~~A student may not commence the internship until the board has actually issued a pharmacy technician intern license to the student. It is the student's obligation to all times be aware of her or her licensure status.~~

4. Qualifications for Licensure

1. Graduation

~~The applicant shall meet the qualifications for licensure as a pharmacy technician set forth in Chapter 7, Section 1(2) of the board's rules. In addition, the~~
The applicant shall present to the board written verification of matriculation in or graduation provide an official transcript showing that the applicant has graduated from a professional academic degree program described in Section 3 of this subchapter. For an applicant who has not yet graduated, maintenance of matriculation is an ongoing requirement of licensure. A license issued under this chapter automatically terminates upon a student's dropping out of or expulsion from pharmacy school.

2. Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate

The applicant shall provide a Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate issued by NABP.

3. Disciplinary History; Criminal Convictions Involving Controlled Substances

The applicant shall provide verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational license. The board may refuse to license and may refuse to renew the license of an applicant:

- A. Whose professional or occupational license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy intern.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSA §5301 et seq.]

5. Issuance and Renewal of License

The initial license and all renewal licenses expire on December 31 annually. The license may be renewed for successive 1-year periods upon completion of a renewal application supplied

by the board and certification by the licensee that he or she continues to be enrolled in a professional academic degree program as described in Section 1 of this subchapter, or has graduated. There is no fee to renew the license. A licensee who fails to timely renew the license must apply for a new pharmacy intern license and pay a reinstatement fee. A student pharmacy intern may not practice with an expired or invalid license.

6. **Final Renewal Period; ~~Expiration~~**

~~The licensee shall notify the board of the licensee's graduation within 10 days as required by 10 MRSA §8003-G(2)(D).~~ A pharmacy technician intern license automatically expires on the second renewal subsequent to the licensee's graduation initial issuance and may not be further renewed. The licensee shall also notify the board within 10 days if the licensee has dropped out of or been expelled from pharmacy school.

7. **Scope of Licensure; Supervision; Responsibility**

A pharmacy technician intern license issued under this Chapter authorizes the licensee to work as a student intern in an internship or in any other practice environment. The pharmacy technician intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy technician intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

8. **Preceptor Pharmacists**

The pharmacist in charge shall designate one or more preceptor pharmacists for each pharmacy intern employed at the pharmacy. The preceptor shall direct the training of the intern to whom the preceptor is assigned. The For an internship administered in Maine, a preceptor pharmacist must also hold a valid license from the board and must have at least 2 years of practice experience as a licensed pharmacist in any state. A preceptor may be responsible for the training of multiple pharmacy interns.

9. **Training Program**

The pharmacy at which a pharmacy intern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by a pharmacy intern. The pharmacy shall develop a training program for pharmacy interns employed at that pharmacy. The pharmacy shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. Preceptor pharmacists shall follow the program in training interns.

~~Internship programs in non-traditional practice settings (e.g., industry-sponsored programs, manufacturer sales representative, physician's office) must be specially approved by the board upon a consideration of the criteria set forth in this section. The board may, in its discretion, approve a non-traditional practice setting for only a portion of the required 1500 hours.~~

9-A. Non-Traditional Practice Settings

The board may recognize for purposes of Section 2 above internship hours completed outside of an IPPE or APPE in a non-traditional practice setting (e.g., industry-sponsored programs, manufacturer's sales representative, physician's office) upon a consideration of the complexity and diversity of the work performed, the nature and amount of supervision provided, the recommendation of the pharmacist in charge or supervising pharmacist, and the overall suitability of the non-traditional practice setting as preparation for the practice of pharmacy. The number of non-traditional hours to be recognized lies in the discretion of the board.

10. Reporting

A1. Completion of Internship

A pharmacy ~~technician~~-intern's completion of a ~~student~~ internship, including the number of hours worked, must be verified by the preceptor pharmacist in a manner acceptable to the board.

B2. Non-Internship Hours

No later than January 31 of each year, a pharmacy ~~technician~~-intern (~~or former pharmacy technician intern~~) shall report on forms provided by the board all hours worked during the preceding calendar year outside of an internship. All reported hours must be verified by the pharmacist in charge or supervising pharmacist.

11. Theft or Drug-Related Misconduct of Pharmacy Intern

The pharmacist in charge or preceptor pharmacist shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons. Notice shall be provided within 48 hours after the termination:

1. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
2. Theft of non-drug merchandise; or
3. Theft of cash or credit/debit card data.

| STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(G), 13723, 13732(3), 13834(1)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 6-A: PHARMACY STUDENT INTERNSHIP PROGRAMS**

Summary: This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules.

SUBCHAPTER 1**PHARMACY INTERNS EDUCATED IN PHARMACY SCHOOLS ACCREDITED BY THE ACCREDITATION COUNCIL FOR PHARMACY EDUCATION OR CANADIAN COUNCIL FOR ACCREDITATION OF PHARMACY PROGRAMS****1. Scope**

The provisions of this subchapter apply to pharmacy internships for pharmacy students educated in pharmacy schools accredited by the Accreditation Council for Pharmacy Education (United States) or the Canadian Council for Accreditation of Pharmacy Programs (Canada), or a successor organization. For purposes of this chapter, “accredited” includes precandidate and candidate status.

2. Student Internship Program

The pharmacy student internship consists of an IPPE and APPE administered by one or more pharmacy schools accredited by the Accreditation Council for Pharmacy Education, the Canadian Council for Accreditation of Pharmacy Programs, or a successor organization. The internship must be completed as part of the professional curriculum leading to the Doctor of Pharmacy degree. The minimum duration of the IPPE and APPE combined is 1,500 hours.

3. Application for Licensure as a Pharmacy Intern

A student matriculated in a professional academic program leading to the Doctor of Pharmacy degree shall apply to the board for licensure as a pharmacy intern prior to commencement of an IPPE or APPE in Maine. A student may not participate in either pharmacy practice experience until the board has actually issued a pharmacy intern license to the student. It is the student’s obligation to at all times be aware of his or her licensure status. To apply, the pharmacy student shall:

1. Complete the application supplied by the board;
2. Provide the verifications required by Section 4 of this subchapter;

3. Remit the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled “Establishment of License Fees;” and
4. Provide such other information as the board may require.

Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

4. Qualifications for Licensure

1. Matriculation

As part of the application, the applicant shall present to the board written verification of matriculation in a professional academic degree program described in Section 2 of this subchapter. Maintenance of matriculation is an ongoing requirement of licensure. A license issued under this chapter automatically terminates upon a student’s dropping out of or expulsion from pharmacy school.

2. Disciplinary History; Criminal Convictions Involving Controlled Substances

The applicant shall supply verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational license. The board may refuse to license and may refuse to renew the license of an applicant:

- A. Whose professional or occupational license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy intern.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSa §5301 *et seq.*]

5. Issuance and Renewal of License

The initial license and all renewal licenses expire on December 31 annually. The license may be renewed for successive 1-year periods upon completion of a renewal application supplied by the board and certification by the licensee that he or she continues to be enrolled in a professional academic degree program as described in Section 1 of this subchapter. There is

no fee to renew the license. A licensee who fails to timely renew the license must apply for a new pharmacy intern license and pay a reinstatement fee. A pharmacy intern may not practice with an expired or invalid license.

6. Final Renewal Period; Expiration

The licensee shall notify the board of the licensee's graduation within 10 days as required by 10 MRSA §8003-G(2)(D). A pharmacy intern license automatically expires on the second renewal subsequent to the licensee's graduation and may not be further renewed. The licensee shall also notify the board within 10 days if the licensee has dropped out of or been expelled from pharmacy school.

7. Scope of Licensure; Supervision; Responsibility

A pharmacy intern license issued under this Chapter authorizes the licensee to work as a student intern in an IPPE or APPE or in any other practice environment. The pharmacy intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

8. Preceptor Pharmacists

A preceptor pharmacist must meet the qualifications established by the pharmacy school administering the IPPE or APPE in which the preceptor participates. For an IPPE or APPE administered in Maine, a preceptor pharmacist must also hold a valid license from the board and have at least 2 years of practice experience as a licensed pharmacist in any state.

8-A. Non-Traditional Practice Setting

The board may recognize for purposes of Section 2 above internship hours completed outside of an IPPE or APPE in a non-traditional practice setting (e.g., industry-sponsored programs, manufacturer's sales representative, physician's office) upon a consideration of the complexity and diversity of the work performed, the nature and amount of supervision provided, the recommendation of the pharmacist in charge or supervising pharmacist, and the overall suitability of the non-traditional practice setting as preparation for the practice of pharmacy. The number of non-traditional hours to be recognized lies in the discretion of the board.

9. Reporting**1. Completion of IPPE/APPE**

A pharmacy intern's completion of an IPPE or APPE, including the number of hours worked, must be verified by the preceptor pharmacist in a manner acceptable to the board.

2. Non-IPPE/APPE Hours

No later than January 31 of each year, a pharmacy intern shall report on forms provided by the board all hours worked during the preceding calendar year outside of an IPPE or APPE. All reported hours must be verified by the pharmacist in charge or supervising pharmacist.

10. Theft or Drug-Related Misconduct of Pharmacy Intern

The preceptor shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons, provided that the report shall be made by a pharmacist in charge or supervising pharmacist if the reason for the resignation, discharge or termination arose outside of the IPPE/APPE.

Notice shall be provided within 48 hours after the termination:

1. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
2. Theft of non-drug merchandise; or
3. Theft of cash or credit/debit card data.

SUBCHAPTER 2

PHARMACY INTERNS EDUCATED IN A FOREIGN COUNTRY OTHER THAN CANADA

1. Scope

This subchapter applies to pharmacy internships completed by pharmacy students educated in a foreign country other than Canada.

2. Internship Program

A pharmacy internship consists of 1500 hours of pharmacy practice at one or more pharmacies under the direct supervision of working pharmacists. The pharmacy internship program provides foreign-educated pharmacy graduates with practical preprofessional experience in a supervised setting and prepares them for licensure as pharmacists. At least 500 hours of the required 1,500 hours must be completed in the United States.

3. Application for Internship

An applicant shall have graduated from a 6-year pharmacy degree program or its equivalent approved by the board pursuant to 32 MRSA §13732(1)(D) prior to applying for an internship. The graduate shall apply to the board for licensure as a pharmacy intern. A graduate may not commence the internship until the board has actually issued a pharmacy intern license to the graduate. It is the graduate's obligation to at all times be aware of his or her licensure status. To apply, the pharmacy graduate shall:

1. Complete the application supplied by the board;
2. Provide the transcript, FPGEC certificate and verifications required by Section 4 of this subchapter;
3. Remit the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees;" and
4. Provide such other information as the board may require.

Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

4. Qualifications for Licensure

1. Graduation

The applicant shall provide an official transcript showing that the applicant has graduated from a professional academic degree program described in Section 3 of this subchapter.

2. **Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate**

The applicant shall provide a Foreign Pharmacy Graduate Examination Committee ("FPGEC") Certificate issued by NABP.

3. **Disciplinary History; Criminal Convictions Involving Controlled Substances**

The applicant shall provide verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational license. The board may refuse to license and may refuse to renew the license of an applicant:

- A. Whose professional or occupational license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy intern.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSA §5301 *et seq.*]

5. **Issuance and Renewal of License**

The initial license and all renewal licenses expire on December 31 annually. The license may be renewed for successive 1-year periods upon completion of a renewal application supplied by the board. There is no fee to renew the license. A licensee who fails to timely renew the license must apply for a new pharmacy intern license and pay a reinstatement fee. A pharmacy intern may not practice with an expired or invalid license.

6. **Final Renewal Period**

A pharmacy intern license automatically expires on the second renewal subsequent to initial issuance and may not be further renewed.

7. **Scope of Licensure; Supervision; Responsibility**

A pharmacy intern license issued under this Chapter authorizes the licensee to work as a student intern in an internship or in any other practice environment. The pharmacy intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

8. Preceptor Pharmacists

The pharmacist in charge shall designate one or more preceptor pharmacists for each pharmacy intern employed at the pharmacy. The preceptor shall direct the training of the intern to whom the preceptor is assigned. For an internship administered in Maine, a preceptor pharmacist must also hold a valid license from the board and must have at least 2 years of practice experience as a licensed pharmacist in any state. A preceptor may be responsible for the training of multiple pharmacy interns.

9. Training Program

The pharmacy at which a pharmacy intern is being trained shall provide an environment that is conducive to the learning of the practice of pharmacy by a pharmacy intern. The pharmacy shall develop a training program for pharmacy interns employed at that pharmacy. The pharmacy shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. Preceptor pharmacists shall follow the program in training interns.

9-A. Non-Traditional Practice Settings

The board may recognize for purposes of Section 2 above internship hours completed outside of an IPPE or APPE in a non-traditional practice setting (e.g., industry-sponsored programs, manufacturer's sales representative, physician's office) upon a consideration of the complexity and diversity of the work performed, the nature and amount of supervision provided, the recommendation of the pharmacist in charge or supervising pharmacist, and the overall suitability of the non-traditional practice setting as preparation for the practice of pharmacy. The number of non-traditional hours to be recognized lies in the discretion of the board.

10. Reporting

1. Completion of Internship

A pharmacy intern's completion of an internship, including the number of hours worked, must be verified by the preceptor pharmacist in a manner acceptable to the board.

2. Non-Internship Hours

No later than January 31 of each year, a pharmacy intern shall report on forms provided by the board all hours worked during the preceding calendar year outside of an internship. All reported hours must be verified by the pharmacist in charge or supervising pharmacist.

11. Theft or Drug-Related Misconduct of Pharmacy Intern

The pharmacist in charge or preceptor pharmacist shall notify the board via letter, fax or email of any resignation or discharge from an internship program or termination of employment for any of the following reasons. Notice shall be provided within 48 hours after the termination:

1. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
2. Theft of non-drug merchandise; or
3. Theft of cash or credit/debit card data.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(G), 13723, 13732(3), 13834(1)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 6-A
PHARMACY STUDENT INTERNSHIP PROGRAM
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth requirements of the pharmacy student internship required for licensure by Chapter 4, Section 1(4)(B) of the board's rules. In the amendments to this chapter the board made the following changes:

- Provided for the licensure of pharmacy interns as authorized by PL 2011, c. 496.
- Defined "accredited" to include pre-candidate and candidate status. (See the discussion in the Basis Statement to Chapter 4.)
- Emphasized that a pharmacy intern may not participate in an IPPE or APPE until the intern license has actually been issued to the student.
- Revised application procedures.
- Permitted the board to consider an applicant's disciplinary history and certain types of criminal convictions.
- Permitted the board to consider non-traditional practice settings, which were inadvertently omitted from this chapter in the board's most recent prior rulemaking proceeding.
- Required the preceptor, pharmacist in charge or supervising pharmacist to notify the board of the resignation, discharge or termination of a pharmacy intern due to theft or drug-related misconduct.
- Required applicants educated in a foreign country other than Canada to have graduated from a 6-year pharmacy degree program and passed the FPGEC examination in order to be eligible for the pharmacy intern license.
- Re-stated the statutory authorization of a pharmacy intern to administer drugs and vaccines. (See the Response to Comments below.)

Until enactment of PL 2011, c. 496, there was no statutory authority for the licensure of pharmacy interns per se. Rather, pharmacy interns were licensed as a type of pharmacy technician—a category in which they didn't belong. In this rulemaking proceeding, both this chapter and Chapter 7, "Licensure and Employment of Pharmacy Technicians," were re-written to reflect the board's new ability to directly license pharmacy interns.

Subchapter 2 of this chapter formerly provided that graduates of 6 year pharmacy programs located in countries other than the United States and Canada could apply for an internship upon completion of their second year of studies. In this rulemaking proceeding the board amended subchapter 2 to require that applicants have graduated in order to be eligible for an internship. This change conforms to the board's experience: Without exception, all applicants from foreign countries have already graduated before applying to the board for an internship.

The board now also requires foreign graduates to present a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate as a prerequisite to internship. Chapter 4, Section 6 of the board's rules currently requires that graduates of foreign schools present an FPGEC certificate as a prerequisite to licensure as a pharmacist. Because pharmacy interns interact extensively with preceptors and members of the public, English language proficiency is equally important in the internship phase.

This chapter contains standardized language relating to the application process, disciplinary history, criminal convictions involving controlled substances, and theft or drug-related misconduct. Similar provisions, as applicable, appear in Chapter 7 for pharmacy technicians, Chapter 8 for retail pharmacists and Chapter 29, Section 1(26) (requirement of pharmacy to notify board of termination of pharmacist for theft or drug-related misconduct).

Response to Comments

Mark Polli, R.Ph., Director, Pharmacy Government & Regulatory Affairs
Delhaize America Shared Services Group, LLC
145 Pleasant Hill Rd.
Scarborough ME 04074
(written)

- Subchapter 1, Section 10 and Subchapter 2, Section 11. The commenter suggested that the board add “mishandling or theft of patient health information” to the list of reportable conduct in Section 10/11, “Theft or Drug-Related Misconduct of Pharmacy Intern.”
 - ◆ *Board Response:* The board declines to amend the rule as requested. The addition requested by the commenter was not part of the proposed rule. The mishandling or theft of patient health information can be addressed as unprofessional conduct under 32 MRSA §13742-A(C) and would likely violate 22 MRSA §1711-C and HIPAA.

Douglas S. Carr
Carr Consulting
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
(oral and written)

- Subchapter 2, Section 3. The commenter is concerned that Subchapter 2 does not permit graduates of 5-year pharmacy programs to apply for internships. The commenter suggested that students currently enrolled in foreign 5-year programs be grandparented for purposes of internship eligibility. The commenter also suggested that the board create some mechanism whereby graduates of foreign 5-year programs could somehow obtain credit for a sixth year of study so as to be eligible for internships.
 - ◆ *Board Response:* The board declines to amend the rule as requested. The addition requested by the commenter was not part of the proposed rule. In addition, the board has authority under Subchapter 2, Section 3 to recognize an equivalent of a 6-year pharmacy degree program.

Robert A. Morrissette, R.Ph., BSPHarm
University of New England
Department of Pharmacy Practice
(oral and written)

“We would like to see the following statement added under ‘scope of licensure’ as documented in LD 148 and signed into law on May 17, 2013:”

A pharmacy intern who is under the pharmacist’s direct supervision and who has obtained drug administration training may administer drugs and vaccines to a person 18 years of age or older.

- ◆ *Board Response:* PL 2013, c. 98 amended 32 MRSA §13834(1) to permit a pharmacist to delegate the pharmacist’s authority to administer drugs and vaccines to persons 18 years of age or older. The board agrees that it would

be helpful to reiterate in rule the statutory authorization for a pharmacy intern to administer drugs and vaccines. The board has accordingly amended Section 7 of Subchapters 1 and 2 to read:

Subchapter 1

7. Scope of Licensure; Supervision; Responsibility

A pharmacy intern license issued under this Chapter authorizes the licensee to work as a student intern in an IPEE or APPE or in any other practice environment. The pharmacy intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

Subchapter 2

7. Scope of Licensure; Supervision; Responsibility

A pharmacy intern license issued under this Chapter authorizes the licensee to work as a student intern in an internship or in any other practice environment. The pharmacy intern may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor pharmacist or pharmacist on duty is responsible for all actions performed by the pharmacy intern.

A pharmacy intern who is under the direct supervision of a pharmacist holding a certificate of administration and has obtained the drug administration training required by 32 MRSA §13832(3) may administer drugs and vaccines to a person 18 years of age or older.

The identical amendment was also added to Chapter 4-A, Administration of Drugs and Vaccinations, as new Section 4.

Post-Adoption Correction

On November 20, 2013 the Attorney General's office completed its review of the adopted rules as to form and legality. The reviewing Assistant Attorney General identified one provision of this chapter as adopted that is inconsistent with 32 MRSA §13732(1)(D).

As adopted by the board, the heading to Subchapter 2, and Section 1 of Subchapter 2, read as follows:

SUBCHAPTER 2

**PHARMACY STUDENTS-INTERNS EDUCATED IN A FOREIGN COUNTRY ~~OTHER THAN~~
CANADA**

1. Scope

This subchapter applies to pharmacy internships completed by pharmacy students educated in a foreign country ~~other than Canada~~, or educated in a United States pharmacy school that has not been accredited by the Accreditation Council for Pharmacy Education or a successor organization, or in a Canadian

pharmacy school that has not been accredited by the Council for Accreditation of Pharmacy Programs or a successor organization.

Title 32 MRSA §13732(1)(D) provides that an applicant for licensure by examination must:

D. Have graduated and received the first professional undergraduate degree from a pharmacy degree program accredited by the American Council on Pharmaceutical Education or have received a degree from an equivalent program, which has been approved by the board, from a school outside the United States;

Section 13732(1)(D) does not permit the board to allow a graduate of an unaccredited pharmacy school located in the United States to apply for licensure by examination. For this reason the amendment to Subchapter 2, Section 1 has been struck in full and the heading to Subchapter 2 has been struck in part. The revised text and heading now read as follows:

SUBCHAPTER 2

PHARMACY ~~STUDENTS~~ INTERNS EDUCATED IN A FOREIGN COUNTRY

1. Scope

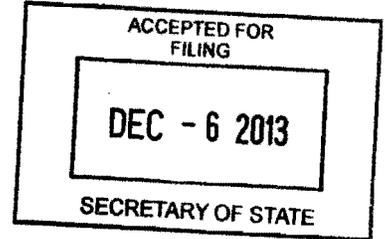
This subchapter applies to pharmacy internships completed by pharmacy students educated in a foreign country other than Canada.

Rule-Making Cover Sheet

2013-303

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Licensure and Employment of Pharmacy Technicians
4. Chapter number assigned to the rule: 7
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 7: REGISTRATION LICENSURE AND EMPLOYMENT OF PHARMACY TECHNICIANS**

Summary: This chapter sets forth the qualifications, permissible duties and supervision responsibilities of the pharmacist in charge with respect to ~~registered~~ licensed pharmacy technicians.

1-A. License Requirement

No person other than a pharmacist or pharmacy intern may perform any of the following duties unless such other person holds a valid pharmacy technician license from the board:

1. Acceptance of an original or renewal prescription drug order;
2. Receipt of a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board's rules;
3. Prescription data entry;
4. Prescription drug selection from inventory; or
5. Counting, packaging and labeling of prescription drugs for delivery.

The assignment of any of the above duties to a pharmacy technician lies within the discretion of the pharmacist on duty.

1. Registration Licensure**1. Application**

The pharmacy technician shall complete the application supplied by the board and provide such other information as the board may require, along with the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of ~~Licensing and Registration~~ Professional and Occupational Regulation, entitled "Establishment of License Fees." Applications will not be considered for approval until they are complete. ~~Incomplete applications will be returned to the applicant.~~ Applications that remain incomplete for more than 60 days will be discarded.

2. Qualifications

The applicant shall supply verification of licensure or registration for all states in which the applicant has at any time ~~been licensed or registered as a pharmacy technician~~ held any type of professional or occupational license. The board may refuse to register and may refuse to renew the registration of an applicant:

- A. Whose pharmacy technician license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving ~~controlled substances~~ alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy technician.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for ~~registration~~ licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 M.R.S.A. §5301 *et seq.*]

~~An applicant who meets the qualifications of pharmacy technician (advanced) as defined in Chapter 1, Section 29 of the board's rules shall be registered as such by the board.~~

3. ~~Applicability of Chapter to Pharmacy Students and Graduates~~

~~Pharmacy school students, and pharmacy school graduates who have not yet been licensed as professional pharmacists, must register as pharmacy technicians before assisting a pharmacist in the practice of pharmacy. This registration requirement extends to student interns and to pharmacy students or pharmacy graduates participating in a residency or fellowship program. Persons registered as pharmacy technicians pursuant to this subsection are subject to all requirements of this chapter and to all requirements of the board's rules relating to pharmacy technicians, except that student interns and pharmacy graduates participating in a residency or fellowship program are not subject to the limitation of duties contained in this chapter. [deleted]~~

4. ~~Term of Registration~~ License

The ~~registration~~ license term is 1 year. ~~Registrations~~ Licenses may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee. No applicant may commence training or employment as a pharmacy technician until the ~~registration~~ license has been issued by the board.

5. ~~Notice of Change of Work Site, or Contact Address or Enrollment Status~~

A pharmacy technician shall notify the board of a change in work site, cessation of employment as a pharmacy technician or a change of contact address via letter, fax or email within 30 days after the change. ~~A pharmacy technician who is also a pharmacy student shall notify the board of any change in enrollment status other than graduation via letter, fax or email within 30 days after the change.~~

2. Training

A ~~drug outlet~~pharmacy that employs a pharmacy technician shall develop or deploy a training program for pharmacy technicians employed at that ~~drug outlet~~pharmacy. The ~~drug outlet~~pharmacy shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. The pharmacist in charge or other Maine-licensed pharmacist designated by the ~~retail drug outlet~~pharmacy shall train each pharmacy technician in accordance with the ~~drug outlet's~~pharmacy's training program or shall ensure that each pharmacy technician satisfactorily completes the training program offered by the ~~drug outlet~~pharmacy. The training program shall accommodate the needs of the individual technician being trained.

The training program shall include specific instruction relating to the limited scope of practice of a pharmacy technician and shall clearly delineate functions that may only be performed by a pharmacist and may not be performed by a pharmacy technician.

3. Administrative Responsibilities

~~1. Verification of Registration~~

~~The pharmacist in charge shall ensure that each pharmacy technician employed at the drug outlet for which the pharmacist in charge is responsible is registered with the board. A pharmacy technician shall carry the wallet-sized registration card issued by the board at all times the technician is on duty and shall produce the card upon request of the pharmacist in charge, a pharmacist on duty or an inspector of the board. No pharmacist in charge or pharmacist on duty shall permit a person who is not registered pursuant to the terms of this chapter to perform the duties of a pharmacy technician.~~

~~2. Display of Registration Certificate~~

~~The pharmacist in charge shall prominently display for public view the registration certificates of all pharmacy technicians employed at the drug outlet for which the pharmacist in charge is responsible. If the pharmacy technician works at multiple sites, the certificate shall be displayed at the technician's primary work site.~~

~~3. Notice of Employment and Non-Employment of Pharmacy Technicians~~

~~The pharmacist in charge shall notify the board via letter, fax or email within 14 days after the commencement or cessation of employment of any pharmacy technician at a retail drug outlet for which the pharmacist in charge is responsible:~~

~~4. Notice of Termination of Employment for Drug-Related Reason~~

~~The pharmacist in charge shall notify the board via letter, fax or email of the termination of employment of a pharmacy technician for any drug-related reason, including but not limited to adulteration, abuse, theft and diversion, and shall include in the notice the~~

reason for the termination. Notice shall be provided within 7 days after the termination. ~~[deleted]~~

4. Supervision by Pharmacist in Charge

1. Generally

The pharmacist in charge shall supervise pharmacy technicians employed at the ~~drug outlet~~pharmacy for which the pharmacist in charge is responsible. In the absence of the pharmacist in charge, a pharmacist on duty shall be the supervisor.

2. ~~Retail Drug Outlets~~Direct Supervision

A pharmacy technician may engage in the practice of pharmacy at a ~~retail drug outlet~~pharmacy only under the direct supervision of a pharmacist as defined in Chapter 1, Section ~~14(A)~~14 of the board's rules. The pharmacist shall physically review each prescription drug order prepared by a pharmacy technician before the product is delivered to the patient or the authorized agent of the patient. The pharmacist is responsible for the work of each pharmacy technician working under the direct supervision of the pharmacist.

3. Automated Pharmacy Systems At Remote Sites

~~[deleted]~~

5. Permissible Duties

1. Generally

The pharmacist in charge or the ~~retail drug outlet~~pharmacy shall determine the duties of pharmacy technicians based upon the needs of the ~~drug outlet~~pharmacy. At time of employment the pharmacist in charge shall provide the technician with a description of the tasks that the technician may perform.

Pharmacy technicians are limited to performing tasks in the ~~preparation-dispensing~~ of prescription legend drugs and nonjudgmental support services as set forth in Section 1-A above. ~~Permissible duties include the dispensing of drugs under the direct supervision of a pharmacist.~~ Pharmacy technicians may also have access to a facsimile machine or computer used to receive original prescription drug orders via facsimile.

2. Automated Pharmacy Systems

~~[deleted]~~ A pharmacy technician on duty at an institutional pharmacy as described in Chapter 20, Subchapter 2, Section 1 of the board's rules may perform the duties relating to an automated pharmacy system described in Chapter 20, Subchapter 2, Section 4(2) of the board's rules only under the direct supervision of a pharmacist as

defined in Chapter 1, Section 14(3) of the board's rules. The pharmacist in charge or pharmacist on duty at an automated pharmacy system is responsible for the work of each pharmacy technician at a point of care location served by the automated pharmacy system.

3. **Limitations**

~~Except as set forth in Section 7 of this chapter, a~~ pharmacy technician may not perform any of the following tasks:

- A. ~~Accept an original prescription drug order by telephone~~[deleted];
- B. Clinically evaluate a patient profile relative to drugs that have or will be dispensed;
- C. Perform patient counseling;
- D. Make decisions that require the education and professional training of a pharmacist; or
- E. Sign any federally-required controlled substance or inventory form.

4. **Responsibility of Pharmacist**

The pharmacist shall verify and confirm the correctness, exactness, accuracy and completeness of the acts, tasks and functions undertaken by the pharmacy technician to assist the pharmacist in the practice of pharmacy. The pharmacist in charge, or a pharmacist on duty, is responsible for all actions performed by the pharmacy technician.

6. **Limitation on Deployment of Pharmacy Technicians**

~~Except as set forth in this section or in Section 7(2) of this chapter, no drug outlet may permit more than 3 pharmacy technicians per working pharmacist to be actively involved in the prescription filling process at any time, provided that a pharmacy technician who is a pharmacy student or a pharmacy graduate need not be included in the calculation of this ratio.~~

~~A drug outlet may request the board to permit a greater ratio of pharmacy technicians to pharmacists only upon a clear and convincing demonstration that a pharmacist at the drug outlet can supervise more than 3 pharmacy technicians without compromising the health and safety of the patients served. Any waiver of the 3:1 ratio granted by the board pursuant to this paragraph may be limited in scope or duration or made subject to such conditions as the board deems necessary for the protection of the public.~~[deleted]

7. **Pharmacy Technician (Advanced)**

1. **Authorization for Performance of Additional Duties**

A pharmacy technician (advanced) may perform the following duties in addition to those permitted by Section 5 of this chapter:

- A. ~~A pharmacy technician (advanced) may receive a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board's rules.~~
- B. ~~A pharmacy technician (advanced) on duty at an institutional pharmacy as described in Chapter 20, Subchapter 2, Section 1 of the board's rules may perform the duties relating to an automated pharmacy system described in Chapter 20, Subchapter 2, section 4(2) of the board's rules only under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(A), (B) or (C) of the board's rules. The pharmacist in charge or pharmacist on duty at an automated pharmacy system is responsible for the work of each pharmacy technician (advanced) at a point of care location served by the automated pharmacy system.~~

~~2. Deployment of Additional Pharmacy Technicians~~

~~A drug outlet may permit a pharmacist to directly supervise up to 4 pharmacy technicians who are not pharmacy students or pharmacy graduates without need of the waiver otherwise required by Section 6 if at least 1 of the pharmacy technicians supervised by the pharmacist is a pharmacy technician (advanced).~~

~~A drug outlet may request the board to permit a greater ratio of pharmacy technicians to pharmacists if additional pharmacy technicians supervised by the pharmacist are pharmacy technicians (advanced) and the drug outlet makes a clear and convincing showing that a pharmacist at the drug outlet can supervise more than 4 pharmacy technicians without compromising the health and safety of the patients served. Any waiver of the 4:1 ratio granted by the board pursuant to this paragraph may be limited in scope or duration or made subject to such conditions as the board deems necessary for the protection of the public. [deleted]~~

7-A. Limitation on Deployment of Pharmacy Technicians

A pharmacy and pharmacist in charge are responsible at all times for providing appropriate quality control over the work of pharmacy technicians employed at the pharmacy. A pharmacy is responsible for ensuring at all times that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist in charge and the pharmacists on duty.

7-B. Administrative Responsibilities

31. Verification of Status

~~The pharmacist in charge is responsible for verifying the registration status of each pharmacy technician (advanced) employed at the drug outlet for which the pharmacist in charge is responsible. No pharmacist in charge or pharmacist on duty shall:~~

~~A. Permit a pharmacy technician who is not registered as a pharmacy technician (advanced) to perform technician duties that may only be performed by a pharmacy technician (advanced); or~~

~~B. Supervise pharmacy technicians in a ratio permitted by Section 7(2) of this chapter where 1 or more of the pharmacy technicians, as the case may be, is not a pharmacy technician (advanced).~~

The pharmacist in charge shall ensure that each pharmacy technician employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board. A pharmacy technician shall carry the wallet-sized license card issued by the board at all times the technician is on duty and shall produce the card upon request of the pharmacist in charge, a pharmacist on duty or an agent of the board. No pharmacist in charge or pharmacist on duty shall permit a person who is not licensed pursuant to the terms of this chapter to perform the duties of a pharmacy technician.

2. Notice of Employment and Non-Employment of Pharmacy Technicians

The pharmacist in charge shall notify the board via letter, fax, email or on line within 10 days after the commencement or cessation of employment of any pharmacy technician at a pharmacy for which the pharmacist in charge is responsible.

3. Notice of Termination of Employment For Drug-Related Reasons or Theft

The pharmacist in charge or a designee of the pharmacist in charge shall notify the board via letter, fax, email or on line of the termination of employment of a pharmacy technician for any of the following reasons and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination:

A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;

B. Theft of non-drug merchandise; or

C. Theft of cash or credit/debit card data.

8. Exemption

Nursing personnel with access to hospital pharmacy medications at times when the pharmacy is not open need not register as pharmacy technicians.

9. Discipline

Pharmacy technicians are subject to the disciplinary provisions of 10 MRSA §8003(5-A), 32 MRSA §§ 13742-A and 13743 and Chapters 30, 31 and 32 of the board's rules.

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

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 7: LICENSURE AND EMPLOYMENT OF PHARMACY TECHNICIANS**

Summary: This chapter sets forth the qualifications, permissible duties and supervision responsibilities of the pharmacist in charge with respect to licensed pharmacy technicians.

1-A. License Requirement

No person other than a pharmacist or pharmacy intern may perform any of the following duties unless such other person holds a valid pharmacy technician license from the board:

1. Acceptance of an original or renewal prescription drug order;
2. Receipt of a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board's rules;
3. Prescription data entry;
4. Prescription drug selection from inventory; or
5. Counting, packaging and labeling of prescription drugs for delivery.

The assignment of any of the above duties to a pharmacy technician lies within the discretion of the pharmacist on duty.

1. Licensure**1. Application**

The pharmacy technician shall complete the application supplied by the board and provide such other information as the board may require, along with the fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Applications will not be considered for approval until they are complete. Applications that remain incomplete for more than 60 days will be discarded.

2. Qualifications

The applicant shall supply verification of licensure or registration for all states in which the applicant has at any time held any type of professional or occupational

license. The board may refuse to register and may refuse to renew the registration of an applicant:

- A. Whose pharmacy technician license or registration has been denied, revoked, suspended or restricted in any jurisdiction for disciplinary reasons; or
- B. Who has been convicted of a crime involving alcohol or drugs. This restriction is subject to consideration and waiver by the board upon presentation of satisfactory evidence that the conviction does not impair the ability of the person to conduct, with safety to the public, the duties of a pharmacy technician.

[NOTE: The effect of a criminal conviction on an applicant's eligibility for licensure is governed generally by the Occupational License Disqualification on Basis of Criminal Record law, 5 MRSA §5301 *et seq.*]

3. [deleted]

4. Term of License

The license term is 1 year. Licenses may be renewed annually upon completion of a renewal application form supplied by the board and payment of the prescribed fee. No applicant may commence training or employment as a pharmacy technician until the license has been issued by the board.

5. Notice of Change of Work Site or Contact Address

A pharmacy technician shall notify the board of a change in work site, cessation of employment as a pharmacy technician or a change of contact address via letter, fax or email within 10 days after the change.

2. Training

A pharmacy that employs a pharmacy technician shall develop or deploy a training program for pharmacy technicians employed at that pharmacy. The pharmacy shall keep a copy of the training program on site at all times and shall furnish the training program to the board upon inspection or upon request. The pharmacist in charge or other Maine-licensed pharmacist designated by the pharmacy shall train each pharmacy technician in accordance with the pharmacy's training program or shall ensure that each pharmacy technician satisfactorily completes the training program offered by the pharmacy. The training program shall accommodate the needs of the individual technician being trained.

The training program shall include specific instruction relating to the limited scope of practice of a pharmacy technician and shall clearly delineate functions that may only be performed by a pharmacist and may not be performed by a pharmacy technician.

3. [deleted]

4. **Supervision by Pharmacist in Charge**

1. **Generally**

The pharmacist in charge shall supervise pharmacy technicians employed at the pharmacy for which the pharmacist in charge is responsible. In the absence of the pharmacist in charge, a pharmacist on duty shall be the supervisor.

2. **Direct Supervision**

A pharmacy technician may engage in the practice of pharmacy at a pharmacy only under the direct supervision of a pharmacist as defined in Chapter 1, Section 14 of the board's rules. The pharmacist shall physically review each prescription drug order prepared by a pharmacy technician before the product is delivered to the patient or the authorized agent of the patient. The pharmacist is responsible for the work of each pharmacy technician working under the direct supervision of the pharmacist.

3. **Automated Pharmacy Systems At Remote Sites**

[deleted]

5. **Permissible Duties**

1. **Generally**

The pharmacist in charge or the pharmacy shall determine the duties of pharmacy technicians based upon the needs of the pharmacy. At time of employment the pharmacist in charge shall provide the technician with a description of the tasks that the technician may perform.

Pharmacy technicians are limited to performing tasks in the dispensing of prescription legend drugs and nonjudgmental support services as set forth in Section 1-A above. Pharmacy technicians may also have access to a facsimile machine or computer used to receive original prescription drug orders via facsimile.

2. **Automated Pharmacy Systems**

A pharmacy technician on duty at an institutional pharmacy as described in Chapter 20, Subchapter 2, Section 1 of the board's rules may perform the duties relating to an automated pharmacy system described in Chapter 20, Subchapter 2, Section 4(2) of the board's rules only under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(3) of the board's rules. The pharmacist in charge or pharmacist on duty at an automated pharmacy system is responsible for the work of each pharmacy technician at a point of care location served by the automated pharmacy system.

3. Limitations

A pharmacy technician may not perform any of the following tasks:

- A. [deleted];
- B. Clinically evaluate a patient profile relative to drugs that have or will be dispensed;
- C. Perform patient counseling;
- D. Make decisions that require the education and professional training of a pharmacist; or
- E. Sign any federally-required controlled substance or inventory form.

4. Responsibility of Pharmacist

The pharmacist shall verify and confirm the correctness, exactness, accuracy and completeness of the acts, tasks and functions undertaken by the pharmacy technician to assist the pharmacist in the practice of pharmacy. The pharmacist in charge, or a pharmacist on duty, is responsible for all actions performed by the pharmacy technician.

6. [deleted]

7. [deleted]

7-A. Limitation on Deployment of Pharmacy Technicians

A pharmacy and pharmacist in charge are responsible at all times for providing appropriate quality control over the work of pharmacy technicians employed at the pharmacy. A pharmacy is responsible for ensuring at all times that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist in charge and the pharmacists on duty.

7-B. Administrative Responsibilities**1. Verification of Status**

The pharmacist in charge shall ensure that each pharmacy technician employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board. A pharmacy technician shall carry the wallet-sized license card issued by the board at all times the technician is on duty and shall produce the card upon request of the

pharmacist in charge, a pharmacist on duty or an agent of the board. No pharmacist in charge or pharmacist on duty shall permit a person who is not licensed pursuant to the terms of this chapter to perform the duties of a pharmacy technician.

2. Notice of Employment and Non-Employment of Pharmacy Technicians

The pharmacist in charge shall notify the board via letter, fax, email or on line within 10 days after the commencement or cessation of employment of any pharmacy technician at a pharmacy for which the pharmacist in charge is responsible.

3. Notice of Termination of Employment For Drug-Related Reasons or Theft

The pharmacist in charge or a designee of the pharmacist in charge shall notify the board via letter, fax, email or on line of the termination of employment of a pharmacy technician for any of the following reasons and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination:

- A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
- B. Theft of non-drug merchandise; or
- C. Theft of cash or credit/debit card data.

8. Exemption

Nursing personnel with access to hospital pharmacy medications at times when the pharmacy is not open need not register as pharmacy technicians.

9. Discipline

Pharmacy technicians are subject to the disciplinary provisions of 10 MRSA §8003(5-A), 32 MRSA §§ 13742-A and 13743 and Chapters 30, 31 and 32 of the board's rules.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(H), 13723

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 7
LICENSURE AND EMPLOYMENT OF PHARMACY TECHNICIANS
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth the qualifications, permissible duties and supervision responsibilities of the pharmacist in charge with respect to licensed pharmacy technicians. In the amendments to this chapter the board made the following changes:

- More specifically delineated the permissible duties of pharmacy technicians.
- Deleted the license category of pharmacy technician (advanced).
- Deleted the ratios governing the maximum number of pharmacy technicians permitted to work under the supervision of a pharmacist.
- Required the pharmacist in charge to notify the board of termination due to theft as well as drug-related reasons. (See the discussion in the Basis Statement to Chapter 6-A.)
- Reorganized this chapter to reflect the direct licensure of pharmacy interns pursuant to Chapter 6-A, as opposed to licensure as a type of pharmacy technician. (See the discussion in the Basis Statement to Chapter 6-A.)
- Reorganized this chapter to reflect the elimination of the pharmacy technician (advanced) license category.

The predecessor rule provided in Section 5(1) of this chapter that “[p]harmacy technicians are limited to performing tasks in the preparation of prescription legend drugs and nonjudgmental support services. Permissible duties include the dispensing of drugs under the direct supervision of a pharmacist.” Specific additional tasks were also authorized for pharmacy technicians (advanced).

Conversely, Section 5(3(1) of this chapter listed professional tasks that were off limits to pharmacy technicians. But a wide gap nonetheless existed between the delineation of permissible vs. non-permissible activities. The chapter as a whole failed to provide adequate guidance as to what specific activities in modern pharmacy practice would trigger the licensure requirement. This uncertainty was exacerbated in large retail settings, where employees frequently rotate or fill in as needed in the pharmacy and non-pharmacy areas of the store. For example, must a supermarket check-out clerk be licensed as a pharmacy technician if that employee sometimes checks out customers in the pharmacy department?

In new Section 1-A of this chapter the board attempts to dispel this uncertainty by clearly listing the following activities for which licensure is required:

- Acceptances of an original or renewal prescription drug order.
- Receipt of a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board’s rules.
- Prescription data entry.
- Prescription drug selection from inventory.
- Counting, packaging and labeling of prescription drugs for delivery.

The common thread of these tasks is their unique connection to the prescription process. Activities that are similar in kind to functions performed elsewhere in a store, or activities that are peripheral to the prescription process, can be performed by unlicensed personnel. For example, in the rule development process the board declined to require licensure for:

- Pharmaceutical ordering.
- Shelf stocking in the prescription department.
- Delivery of filled prescriptions to customers in the prescription department, including customer assistance and customer check-out.
- Obtaining patient profile, medical, insurance or demographic information from customers.
- Performing outbound refill calls to providers or customers.
- Billing insurers, investigating insurance benefits, or coordinating copayment/coinsurance and order delivery.
- Packing, shipment or delivery of prescription drugs on behalf of the pharmacy.

Section 5(3)(A) of the predecessor rule expressly prohibited a pharmacy technician from accepting an original prescription drug order by telephone. In this rulemaking proceeding the board deleted this prohibition and instead provided in Section 1-A of this chapter that a pharmacy technician may accept an original or renewal prescription drug order without restriction. A parallel change was made to Chapter 19, Section 3(1), Telephone Prescription Drug Orders. In the board's view, the need for flexibility in staffing—i.e., who can answer the telephone—demands this change. See also the discussion in the Response to Comments.

Chapter 1, Section 29 of the predecessor rules defined "pharmacy technician (advanced)" as a pharmacy technician who had achieved either of two nationally-recognized certifications. Under former Section 7(1) of this chapter, a pharmacy technician (advanced) was authorized to perform certain tasks that could not be performed by ordinary pharmacy technicians. In addition, pursuant to former Section 7(2) of this chapter, the former 1:3 maximum pharmacist/pharmacy technician ratio was increased to 1:4 if one of the technicians was a pharmacy technician (advanced).

In the amended rule the board has repealed the definition of pharmacy technician (advanced), and the amended rule now permits ordinary pharmacy technicians to perform the duties formerly reserved to pharmacy technicians (advanced). In the board's view, certification has not been a predictor of success as a pharmacy technician. This may partly reflect the fact that certification from the Pharmacy Technician Certification Board could be earned solely by passing an examination: no real-world experience in a pharmacy environment was required. Pharmacists should be free to assign tasks to a technician based on the pharmacist's assessment of the technician's capabilities.

Similar reasoning underlies the board's repeal of the 1:3 and 1:4 deployment ratios of pharmacy technicians. The pharmacy and pharmacist are the best judges of how many technicians a given pharmacist can competently supervise. However, this discretion is not without limit. New Section 7-A of this chapter emphasizes that "a pharmacy is responsible for ensuring at all times that the number of pharmacy technicians on duty can be satisfactorily supervised by the pharmacist in charge and the pharmacists on duty."

Response to Comments

Douglas S. Carr
Carr Consulting
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
(oral and written)

- The commenter supports the elimination of the pharmacist/pharmacy technician ratio and allow the pharmacist in charge to determine the appropriate number of technicians. This change will improve patient care and allow the pharmacist to devote more time to clinical interaction with patients. Also, this change is consistent with a number of states that are similarly headed in this direction.
- The commenter strongly supports authorization for pharmacy technicians to accept original prescription drug orders by telephone. The commenter commends the board for recognizing the value of pharmacy technicians and the “dynamic working relationship between pharmacists and pharmacy technicians as an integral part of the healthcare system seeking to improve patient outcomes and help reduce healthcare costs.” The commenter believes that this change will enable retail pharmacists to devote time with patients in the area of MTM, immunization, counseling and other patient needs.

Anne Fellows, Regional State Director
 National Association of Chain Drug Stores
 413 North Lee St., PO Box 1417-D49
 Alexandria VA 22313-1480
 (oral and written)

- The NACDS commends the board for its considerable work in this overall rulemaking proposal and in particular NACDS extends support in eliminating the pharmacist/pharmacy technician ratio and for “allowing the pharmacy and the pharmacist in charge to determine the appropriate number of pharmacy technicians that may be supervised by the pharmacist on duty and the pharmacist in charge.” NACDS also supports the board’s proposal to expand the duties of a pharmacy technician to allow taking original telephone prescription order and for eliminating the advanced pharmacy technician license level that requires national certification. NACDS reports that seventeen states no longer have pharmacy technician ratios; twelve states allow pharmacy technicians to take new prescription orders by telephone under the pharmacist’s supervision or discretion and that several states do not require certification of pharmacy technicians. Through pharmacy based training programs and program examinations, pharmacy technicians are equipped to perform expected duties.

Stephen Drapeau, R.Ph.
 Clinical Pharmacist
 (written)

- The commenter supports the proposed modification of the existing pharmacy technician ratio, but recommends that the board add language that “the ratios would only be eliminated if the technician has attained a Certified Technician License or has an advanced degree/license in the medical field such as a Registered Nurse, Nurse Practitioner, Physician Assistant” or another similar type health care degree or license. Irrespective of certification or advanced degree, the board should not permit a pharmacy technician to take an original or renewal prescription drug order as ‘many medications that require an enhanced knowledge of a medications specific dosing, dosing pattern, supportive regimens, weight-based dosing information and other clinically pertinent information” for proper dosing and for which a pharmacist is educated and trained to perform.

Mary Pierskalla, R.Ph. MBA
 Director of Pharmacy
 New England Life Care
 108a Industry Way
 Portland, ME 04103
 (written)

- "...I believe that there are different levels of expertise required to do different duties in the pharmacy. Some duties are strictly clerical in nature while others are highly technical in nature...So too should remain the distinction between the pharmacy tech and the advanced tech and all the criteria required to maintain this advanced status. Even with this distinction however I feel it is crucial that technician[s] not be allowed to take original prescriptions by phone...Technicians (even highly trained technicians) do not have the clinical training and expertise to judge the appropriateness of the prescriptions they are receiving. There are often subtle nuances in the conversation that a pharmacist can pick up on to trigger further clarification. Technicians are ill equipped to make these clinical determinations."
- The commenter also opposes elimination of the pharmacist/pharmacy technician ratio and fears that if the ratio is rescinded employers will take advantage of pharmacists by bringing in as many technicians as possible to work under a given pharmacist's license.

Mark McAuliffe, Managing Partner
Apothecary by Design
84 Marginal Way, Suite 100
Portland, ME 04101
(written)

- The commenter supports the elimination of the pharmacist/pharmacy technician ratio, but only if the pharmacy technicians have obtained nationally-recognized certification or hold an active nursing, physician assistant or nurse practitioner degree. Also, only nationally-certified pharmacy technicians should be permitted to take prescriptions by telephone.

Philip W. Rioux, R.Ph., FASCP
Health System Director of Pharmacy
Central Maine Healthcare
300 Main St
Lewiston ME 04240
(written and oral)

- The proposed elimination of the Pharmacy Technician (Advanced) will result in a dangerous situation whereby an entry level pharmacy technician will be allowed to accept an order for a new prescription by telephone that "may very well [have been] given by a person on the end of the phone who also may have little training...It is hard enough to obtain a correct order as it is with a pharmacist taking the order." The commenter would not have a non-certified pharmacy technician take a new prescription by telephone in either a hospital or retail setting. The board should either retain the Pharmacy Technician (Advanced) level, or increase the entry level requirements for pharmacy technicians to include national certification and "a minimum amount of experience working in a pharmacy of two years or more."

Christine O'Connor, Sr. Counsel, Regulatory Government Affairs
(oral comment on behalf of
Ronald E. Hanchar, Executive Director
National Healthcareer Association Certification Programs
11161 Overbrook Rd
Leawood, KS 66211
(written comment from Mr. Hanchar filed post hearing)

- At the hearing Ms. O'Connor testified that thirty-eight states require some or all of the pharmacy technicians take a certification examination with legislation pending in NY and MI. The board's proposal to eliminate recognition of a pharmacy technician who take a certification examination is a step in the "opposite direction taken by the vast majority of boards..." in the U.S. The board should consider the following proposal.

1. To add and define the term "Certified Pharmacy Technician" in Chapter 1.

2. Require all pharmacy technicians to become certified before the third anniversary of the issuance of his/her licensewith a grace period or grandfathering provision for current license holders.
 3. Allow the Certified Pharmacy Technician ("CPhTs"), and no other pharmacy technician to perform: a) the additional duties previously permitted to the Pharmacy Technician(Advanced) in Chapter 7-7-1 (now, designated for deletion); b) to accept an original prescription drug order by telephone (previously not permitted by any pharmacy technician but now, by deletion at Chapter 7-5-3-A, would be a permitted duty of all pharmacy technicians); and c) to perform such other functions that, for the safety of the public, the board determines are properly delegated to pharmacy technicians that have demonstrated through certification the required competency.
 4. Reinstate the pharmacy technician to pharmacist ratio reflected in the original text of Chapter 7-6 and the first paragraph of Chapter 7-7-2 (both now designated as a proposed deletion), substituting "Certified Pharmacy Technician" for "pharmacy technician (advanced)" and allow a pharmacy technician to pharmacist ratio of 6:1, if at least 2 of the pharmacy technicians supervised by the pharmacist are CPhTs.
 5. The board should require for licensure as a pharmacy technician: 1) high school diploma or its equivalent; and 2) successful passage of a national certification examination approved by the board (currently there are two, the examination for the Certification of Pharmacy Technicians ("ExCPT") offered by National Healthcareer Association and the Pharmacy Technician Certification Examination ("PTCE") offered by the Pharmacy Technician Certification Board.
- Certified technicians make a personal investment and a commitment to their profession. This leads to a greater sense of public safety. Employers place a lot of stock that someone has taken that extra step. Certification creates a more loyal relationship between the pharmacy, pharmacist and persons supporting the pharmacist. Certification also enables a broader ratio of pharmacists to technicians. (O'Connor)

Stanley L. Tetenman
 55 Rockwood Lane
 Poland, ME 04274
 (written)

- The board should not eliminate the Pharmacy Technician (Advanced) credential. The advanced training prepares technicians to undertake more responsibilities, such as transfer or renewal of a medication, than they would otherwise be qualified to perform.
- No pharmacy technician, even a pharmacy technician (advanced), is qualified to accept a telephone order for a new prescription. The pharmacy technician may not pick up on an error made by the person calling, and an unlicensed person in many cases will be doing the calling. "Once the order is written and entered into the computer the error will most likely never be recognized unless there is a problem reported by the patient or physician."
- The 1:3 pharmacist/pharmacy technician ratio should not be eliminated. This ratio represents the workload that a pharmacist can reasonably be expected to handle. If the ratio is eliminated, management may assign whatever number of technicians it desires and the pharmacist will either have to accept this policy or look for another position.

Robert A. Morrissette, R.Ph., BSPHarm
 University of New England
 Department of Pharmacy Practice
 (oral and written)

Kenneth L. McCall III, BSPHarm, PharmD
 President, Maine Pharmacy Association
 (oral and written)

- The commenters agree with expanding the scope of practice of a pharmacy technician to accept an original prescription drug order by phone, but for safety reasons this task should only be extended to a pharmacy technician with a designation of Certified Pharmacy Technician (CPhT). The Maine Pharmacy Association conducted a phone survey of its membership about pharmacy technicians accepting original prescription orders by phone; 109 voted, yes and 470 voted, no. The board should “[retain] the pharmacy technician definition in Chapter 1, 29.1.2 Pharmacy Technician definition eliminating the word ‘advanced’ and replacing it with ‘certified’ and under Chapter 7, [5.3.A.B.] adding the word ‘certified’ along with pharmacy technician when stating who may accept new prescription phone orders.” (Morrissette)

In a survey of the MPA membership, 256 favored the proposed elimination of the pharmacist/pharmacy technician ratios with 323 opposing elimination due to concerns over “span of control, adequate supervision of five or more pharmacy technicians per pharmacist, and public safety.” (McCall) Based on the minimum qualifications to become a pharmacy technician in Maine, the Maine Pharmacy Association proposes that “a pharmacist may supervise no more than 3 pharmacy technicians actively involved in the prescription filling process at any time. However, we also propose that this ratio does not apply to ‘certified pharmacy technicians.’” (McCall)

While under the supervision of a pharmacist, performing compounding duties should be restricted to a “certified pharmacy technician” as it relates to the delineation of duties between a “certified pharmacy technician” and a “pharmacy technician” in the NABP Model Rules.

- ◆ *Board Response to the foregoing comments:* The commenters (i.e., all but Carr and Fellows) have not convinced the board to make any changes to the proposed rule with respect to pharmacy/pharmacy technician ratios, the taking of new prescription drug orders by telephone, elimination of the license category of Pharmacy Technician (Advanced), or recognition of Certified Pharmacy Technicians.

The number of pharmacy technicians that a pharmacist on duty may supervise is a business decision to be made by a pharmacy in consultation with the pharmacist in charge. The board should not be legislating this aspect of pharmacy practice. Even under the current system the board has frequently granted waivers, up to a ratio of one pharmacist supervising 6 pharmacy technicians. Some commenters expressed concern that a pharmacy may overload pharmacists with too many technicians for the pharmacist to competently supervise. If this happens, the board wants to hear about it. But in the meantime, the board cannot allow its rules to mirror these fears.

Section 2 of this chapter currently requires every pharmacy that employs a pharmacy technician to develop or deploy a training program for pharmacy technicians. Under this framework, each pharmacy has the discretion to train its technicians in a manner that best prepares technicians to participate in the workflow of that particular facility. In the board's view, such individualized training programs are far more effective in preparing pharmacy technicians for employment than third-party certification, which, as noted in the Basis Statement, can be obtained on the basis of examination alone with no actual pharmacy experience.

The board is not opposed to certification of pharmacy technicians. Pharmacies are free to require that all technicians, or all newly-hired technicians, be certified, and some pharmacies have adopted this policy. Many pharmacies foot the bill for certification and/or offer technicians a pay increase upon obtaining certification. On the other hand, some highly-competent and committed technicians do not desire certification, and access to certified pharmacy technicians may be difficult in remote areas of the state.

For these reasons the board adheres to its decision to abandon the two-tiered licensure of pharmacy technicians, under which certain duties were reserved to pharmacy technicians (advanced). The pharmacist in charge can decide which technicians are best capable of performing which duties. Like the pharmacist/pharmacy technician ratios discussed above, the degree to which a given pharmacy wishes to avail itself of pharmacy technicians (advanced) is a business decision that this board need not be a part of. For similar reasons the board also rejects the suggestion, which was not part of the proposed rule, that all pharmacy technicians be required to obtain certification within a certain period of time.

The commenters have not persuaded the board that permitting pharmacy technicians to accept new prescription drug orders by telephone will result in misidentifications or misfills. The board does not accept the premise that a properly-trained pharmacy technician is incapable of evaluating the information given over the telephone for gross error or misunderstanding. The board expects that the pharmacist in charge will instruct technicians to check the prescription with the pharmacist in the event of any doubt. And again, each PIC will be free to determine which (if any) of the pharmacy technicians on staff have achieved the level of competence necessary to accept new prescription drug orders by telephone.

A large volume of prescriptions that were formerly called in to a pharmacy are now submitted electronically. Pharmacy technicians perform the initial review of those prescriptions, which has not led to any widespread prescribing error of which the board is aware. The board concurs in the comment (Carr) that permitting technicians to accept telephone orders will allow the pharmacy team to work more efficiently and will enable retail pharmacists to devote more time to patient interaction and patient needs.

Commenters Morrissette and McCall suggested that only certified pharmacy technicians be permitted to accept a new prescription drug order by telephone. As discussed above, the board is not requiring third-party certification in its rules. However, certification may be a factor that a pharmacist in charge may wish to consider in assigning responsibilities to pharmacy technicians under the PIC's supervision.

Douglas S. Carr
Carr Consulting
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
(oral and written)

- Section 7-B(3). Seven days may be insufficient time for the pharmacist-in-charge to notify the board of the termination of a pharmacy technician for a drug-related reason or theft. If the pharmacy technician was working in the front end when the termination occurred, the

termination may not come to the attention of the PIC until much later – perhaps weeks, or until the employee is next scheduled to work in the pharmacy.

- ◆ *Board Response:* The board declines to amend the rule as requested. The pharmacy can make provisions to bring such terminations to the prompt attention of the pharmacist in charge.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-304

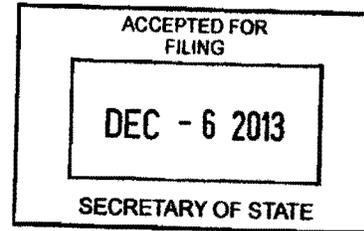
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #)

3. **Title of rule:** Licensure of Retail Pharmacies

4. **Chapter number assigned to the rule:** 8
(must be 3 digits or less)



5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. **Date(s)/place(s) of hearing(s):** June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

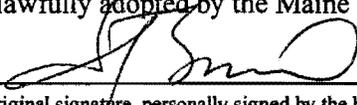
7-A. **Type:** new rule partial amendment(s) of existing rule
 suspension of existing rule repeal of rule emergency rule
 repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625

9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**

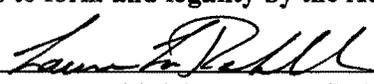
- Provisional adoption (prior to Legislative review) Final adoption
 Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: 
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. **Approved as to form and legality by the Attorney General on** 11-18-13
(date)

Signature: 
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 8: REGISTRATION LICENSURE OF RETAIL DRUG
OUTLETS/PHARMACIES**

Summary: This chapter sets forth registration license requirements for retail drug outlets/pharmacies.

1. Application; Fees

~~The retail drug outlet shall provide the following information on forms supplied by the board, along with such other information as the board may require. Applications will not be considered for approval until they are complete. Incomplete applications will be returned to the applicant. An application for licensure as a retail pharmacy must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:~~

1. The name, address, telephone number and email address of the person responsible for submission of the application;
2. The name under which the retail ~~drug outlet~~pharmacy will operate, and the physical address, contact address, telephone number, email address and world wide web address of the retail ~~drug outlet~~pharmacy;
3. All trade or business names used by the retail ~~drug outlet~~pharmacy;
4. The name(s) of the owner and/or operator of the retail drug ~~outlet~~pharmacy, including:
 - A. If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - B. If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for

corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;

C. If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board;

CD. If a sole proprietor, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity.

5. The hours of operation of the retail ~~drug outlet~~pharmacy during which a pharmacist will be on duty;
6. If the ~~drug outlet~~pharmacy is located within a retail store, the hours of operation of the retail store;
7. The DEA number, when obtained;
8. The name and license number of the pharmacist in charge of the retail ~~drug outlet~~pharmacy;
9. Verification of the following facilities, apparatus and equipment:
 - * Adequate lighting
 - * Sink with hot and cold running water
 - * Rest room facilities
 - * Refrigerator
 - * Rx weights (if required by type of Rx balance used)
 - * Rx balance
 - * Spatula, non-metal (1)
 - * Spatula, metal (2)
 - * Mortar and pestle (2)
 - * Graduates assorted (4)
 - * Safety cap Rx containers
 - * Appropriate Rx labels
 - * Professional reference library, including drug interactions (in any format)
 - * Current Maine pharmacy laws and rules (in any format)
10. A scaled drawing and floor plan of the retail ~~drug outlet~~pharmacy which details the usage of each area. If the ~~registered licensed~~ area is part of a larger retail store, the applicant shall include an additional scaled drawing and floor plan of the entire establishment showing the relative position of the ~~registered licensed~~ area and the location of all entrances, bathrooms, and storage areas;

11. ~~Demonstration on the scaled drawing that the prescription filling area will measure no less than 200 square feet;~~~~[deleted]~~
12. Demonstration of compliance with the security barrier, alarm and security camera requirements of Chapter 13, Section 6 of the board's rules;
13. Demonstration of compliance with the signage requirement of Chapter 13, Section 7 8 of the board's rules;
14. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
15. ~~The fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Licensing and Registration, entitled "Establishment of License Fees."~~Such other information as the board may require.

2. Waiver Requests

For good cause shown, the board may waive or modify any of the following requirements for operation of a retail ~~drug outlet~~pharmacy:

1. ~~Minimum 200 square foot prescription filling area (Section 1(11) of this chapter);~~~~[deleted]~~
2. Minimum 40 hours per week of operation (Chapter 13, Section 2(1) of the board's rules); and
3. Practice by the pharmacist in charge at the ~~drug outlet~~pharmacy for which he or she has registered for a minimum of 30 hours per week or 50% of the hours that the retail ~~drug outlet~~pharmacy is open, whichever is less. (Chapter 13, Section 3(3) of the board's rules)

3. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for ~~registration~~licensure as a retail ~~drug outlet~~pharmacy:

1. The applicant's past experience in the ~~dispensation~~dispensing of prescription drugs;
2. The furnishing by the applicant of false or fraudulent material in any application made in connection with the ~~dispensation~~dispensing of prescription drugs;
3. Suspension, ~~or~~revocation or other disciplinary action taken by a federal, state or local government~~governmental body of~~with respect to any type of pharmacy license currently or previously held by the applicant ~~for the dispensation of prescription drugs;~~

3-A. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and

4. ~~Compliance with previously granted licenses of any kind; and~~[deleted]

5. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by retail ~~drug outlets~~pharmacies.

4. Processing of Application

1. Review of Application

The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail ~~drug outlet~~pharmacy will be in the best interest of the public health and welfare.

2. Action on Application

Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

5. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

1. Submit an application with modifications requested by the board;
2. Furnish additional information requested by the board;
3. Make site modifications requested by the board;
4. Request a hearing to contest a preliminary denial; or
5. Request a hearing to contest a condition imposed by the board.

Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

6. Change of Owner, Location, or Pharmacist in Charge; Change in Other Registration Information

Upon a change of ownership, a retail ~~drug outlet~~pharmacy shall file a new application with the board by registered mail no less than 7 days prior to the change. Upon a change of location, a retail ~~drug outlet~~pharmacy shall file a new application with the board by first class mail no less than 7 days prior to the change. Upon a change of pharmacist in charge, the retail ~~drug outlet~~pharmacy shall file a new application with the board by registered mail no later than 7 days after the change. Upon any other change in the information provided by the retail ~~drug outlet~~pharmacy in its most recent application, the retail ~~drug outlet~~pharmacy shall notify the board via letter, fax or email within 7 days after the change.

Upon a change of pharmacist in charge, the incoming pharmacist in charge shall immediately conduct an audit of Schedule II drugs and report to the board any ~~discrepancies in or in excess of the minimum quantities~~ significant loss as described in Chapter 23, Section ~~3(2)(B)~~3 of the board's rules, irrespective of time period.

6-A. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A retail pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

7. Alteration of Prescription Filling Area

~~No~~ A retail ~~drug outlet~~pharmacy shall may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The ~~drug outlet~~pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

8. Operation of Retail ~~Drug Outlet~~Pharmacy

A retail ~~drug outlet~~pharmacy shall comply with the rules of operation contained in Chapter 13, "Operation of ~~Retail Drug Outlets~~Pharmacies," and Chapter 17, "Operation of Nuclear Drug Outlets," and Chapter 18, "Sterile Pharmaceuticals" of the board's rules."

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751, 13752, 13752-A, 13753

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 8: LICENSURE OF RETAIL PHARMACIES**

Summary: This chapter sets forth license requirements for retail pharmacies.

1. Application; Fees

An application for licensure as a retail pharmacy must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

1. The name, address, telephone number and email address of the person responsible for submission of the application;
2. The name under which the retail pharmacy will operate, and the physical address, contact address, telephone number, email address and world wide web address of the retail pharmacy;
3. All trade or business names used by the retail pharmacy;
4. The name(s) of the owner and/or operator of the retail drug pharmacy, including:
 - A. If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - B. If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - C. If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each

- member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board;
- D. If a sole proprietor, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity.
5. The hours of operation of the retail pharmacy during which a pharmacist will be on duty;
 6. If the pharmacy is located within a retail store, the hours of operation of the retail store;
 7. The DEA number, when obtained;
 8. The name and license number of the pharmacist in charge of the retail pharmacy;
 9. Verification of the following facilities, apparatus and equipment:
 - * Adequate lighting
 - * Sink with hot and cold running water
 - * Rest room facilities
 - * Refrigerator
 - * Rx weights (if required by type of Rx balance used)
 - * Rx balance
 - * Spatula, non-metal (1)
 - * Spatula, metal (2)
 - * Mortar and pestle (2)
 - * Graduates assorted (4)
 - * Safety cap Rx containers
 - * Appropriate Rx labels
 - * Professional reference library, including drug interactions (in any format)
 - * Current Maine pharmacy laws and rules (in any format)
 10. A scaled drawing and floor plan of the retail pharmacy which details the usage of each area. If the licensed area is part of a larger retail store, the applicant shall include an additional scaled drawing and floor plan of the entire establishment showing the relative position of the licensed area and the location of all entrances, bathrooms, and storage areas;
 11. [deleted]
 12. Demonstration of compliance with the security barrier, alarm and security camera requirements of Chapter 13, Section 6 of the board's rules;
 13. Demonstration of compliance with the signage requirement of Chapter 13, Section 8 of the board's rules;

14. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
15. Such other information as the board may require.

2. Waiver Requests

For good cause shown, the board may waive or modify any of the following requirements for operation of a retail pharmacy:

1. [deleted]
2. Minimum 40 hours per week of operation (Chapter 13, Section 2(1) of the board's rules); and
3. Practice by the pharmacist in charge at the pharmacy for which he or she has registered for a minimum of 30 hours per week or 50% of the hours that the retail pharmacy is open, whichever is less. (Chapter 13, Section 3(3) of the board's rules)

3. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as a retail pharmacy:

1. The applicant's past experience in the dispensing of prescription drugs;
2. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing of prescription drugs;
3. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
- 3-A. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
4. [deleted]
5. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by retail pharmacies.

4. Processing of Application

1. Review of Application

The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail pharmacy will be in the best interest of the public health and welfare.

2. Action on Application

Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

5. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

1. Submit an application with modifications requested by the board;
2. Furnish additional information requested by the board;
3. Make site modifications requested by the board;
4. Request a hearing to contest a preliminary denial; or
5. Request a hearing to contest a condition imposed by the board.

Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

6. Change of Owner, Location, or Pharmacist in Charge; Change in Other Registration Information

Upon a change of ownership, a retail pharmacy shall file a new application with the board by registered mail no less than 7 days prior to the change. Upon a change of location, a retail pharmacy shall file a new application with the board by first class mail no less than 7 days prior to the change. Upon a change of pharmacist in charge, the retail pharmacy shall file a new application with the board by registered mail no later than 7 days after the change. Upon any other change in the information provided by the retail pharmacy in its most recent application, the retail pharmacy shall notify the board via letter, fax or email within 7 days after the change.

Upon a change of pharmacist in charge, the incoming pharmacist in charge shall immediately conduct an audit of Schedule II drugs and report to the board any significant loss as described in Chapter 23, Section 3 of the board's rules, irrespective of time period.

6-A. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A retail pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

7. Alteration of Prescription Filling Area

A retail pharmacy may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

8. Operation of Retail Pharmacy

A retail pharmacy shall comply with the rules of operation contained in Chapter 13, "Operation of Pharmacies" and Chapter 17, "Operation of Nuclear Drug Outlets."

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751, 13752, 13752-A, 13753

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 8
LICENSURE OF RETAIL PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth license requirements for retail pharmacies. In the amendments to this chapter the board made the following changes:

- Standardized license application and processing language for consistency among retail pharmacies (this chapter), retail suppliers of medical oxygen (Chapter 34), extended hospital pharmacies (Chapter 35), opioid treatment programs (Chapter 36), sterile compounding pharmacies (chapter 37) and closed-shop pharmacies (Chapter 38), to the extent practicable.
- Deleted the minimum size requirement for prescription filling areas, which is no longer meaningful.
- Better described the disciplinary and regulatory action that the board may consider in acting on a license application.
- Clarified the nature of alterations to the prescription filling area that require prior board approval.

Response to Comments

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-305

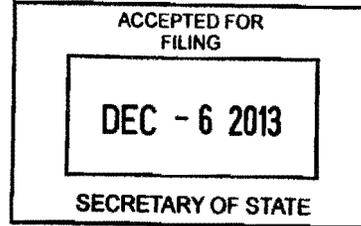
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Operation of Retail Pharmacies

4. Chapter number assigned to the rule: 13
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-19-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

Part 3 - Operation of Drug Outlets**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 13: OPERATION OF RETAIL DRUG OUTLETS PHARMACIES**

Summary: This chapter sets forth operation requirements for retail ~~drug outlets~~ registered pharmacies licensed by the board.

1. Cleanliness and Sanitation

The pharmacy department shall at all times be operated in a clean and sanitary manner.

2. Hours of Operation; Posting of Hours**1. Minimum Hours of Operation**

A retail ~~drug outlet~~ pharmacy must be open to the public for a minimum of 40 hours per week unless waived by the board for good cause shown, and must be staffed by a pharmacist at all times that the ~~drug outlet~~ pharmacy is open.

2. Posting of Schedule

A retail ~~drug outlet~~ pharmacy shall prominently post in a public area of the store the days and hours that the ~~drug outlet~~ pharmacy is scheduled to be open to the public.

3. Adherence to Posted Schedule

A retail ~~drug outlet~~ pharmacy shall adhere to the schedule posted pursuant to Section 2(2) of this chapter.

4. Deviations From Posted Schedule

A retail ~~drug outlet~~ pharmacy shall prominently post in a public area of the store any deviation from its posted schedule as soon as the need to deviate from the posted schedule is known by the ~~drug outlet~~ pharmacy. This posting shall include the period of time the ~~drug outlet~~ pharmacy will be closed and the name, street address and telephone number of a nearby ~~drug outlet~~ pharmacy that is available to serve the public during the period of closure.

5. Reporting of Deviations to Board

Except as set forth in this subsection, a retail ~~drug outlet~~pharmacy shall report any deviation from its posted schedule to the board by fax or email no later than the next business day following the deviation. Each day on which a deviation occurs must be separately reported. Reporting may be made by mail if the ~~drug outlet~~pharmacy does not have fax or email capability.

No report need be filed for:

- A. A deviation of less than four hours duration;
- B. A deviation resulting from severe weather conditions, fire, flood, disaster or natural or man-made catastrophe beyond the control of the ~~drug outlet~~pharmacy; or
- C. Holiday closures.

6. Remedial Action by Board

In the event that a retail ~~drug outlet~~pharmacy deviates four or more times from its posted schedule within a calendar month, other than for reasons described in Section 2(5) of this chapter, the board, following notice and opportunity for hearing, may require the ~~drug outlet~~pharmacy to revise the schedule posted pursuant to Section 2(2) of this chapter as may be necessary to protect the public from injury or inconvenience due to the ~~drug outlet's~~pharmacy's inability to adhere to its posted schedule.

3. Pharmacist in Charge

1. Generally

The business of a retail ~~drug outlet~~pharmacy shall be conducted under the direct supervision of a licensed pharmacist who has registered as the pharmacist in charge of that ~~drug outlet~~pharmacy with the board. No retail ~~drug outlet~~pharmacy may operate without a pharmacist in charge.

2. Responsibilities

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the retail ~~drug outlet~~pharmacy for which the licensee is registered as pharmacist in charge, and for the ~~drug outlet's~~pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules. The responsibilities of the pharmacist in charge include, but are not limited to:

- A. The ~~drug outlet's~~pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;

- B. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
- C. The security of the prescription filling area and its contents;
- D. Ensuring that the prescription filling area is operated in conformance with good pharmaceutical practices;
- E. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination; ~~and~~
- F. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
- G. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

3. **Presence at Retail Drug Outlet**

Except as set forth in Section 3(4) of this chapter, or unless waived by the board for good cause shown, a pharmacist in charge of a retail ~~drug outlet~~pharmacy shall practice at that ~~drug outlet~~pharmacy for a minimum of 30 hours per week or 50% of the hours the ~~drug outlet~~pharmacy is open, whichever is less.

4. **Registration as Pharmacist in Charge for More Than One Retail ~~Drug Outlet~~Pharmacy**

Except as set forth in Section 3(5)(B) of this chapter, no pharmacist may register or serve as pharmacist in charge for more than one retail ~~drug outlet~~pharmacy prior to receiving approval from the board. All requests for approval, including requests for emergency approval made pursuant to Section 3(5) of this chapter, must be made via letter, email or fax. A request to serve as pharmacist in charge of an opioid treatment program and one other type of non-opioid pharmacy, or two opioid treatment programs and no other non-opioid pharmacy, will be approved automatically, subject to disciplinary review. A request to serve as pharmacist in charge of a retail pharmacy, closed-shop pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically, subject to disciplinary review. For all other requests, The the board may grant approval only in the following circumstances upon a consideration of the nature and extent of the risk posed to the public:

- A. Death, incapacity, emergency medical leave or unexpected resignation or discharge of a pharmacist in charge;
- B. Specialty practice setting which does not require a 30 hour/50% pharmacist in charge for reasonable protection of the population served (~~e.g., opiate treatment program~~); or

- C. Other situations where exigent circumstances warrant the registration of a sole pharmacist in charge of more than one retail ~~drug outlet~~pharmacy.

The board's order of approval may be of fixed or of indeterminate duration and shall contain such coverage requirements and other provisions as may be necessary to protect the public health and safety at all locations to be served by a sole pharmacist in charge.

5. Emergency Requests

A request for approval pursuant to Section 3(4)(A) of this chapter must be made within 7 days after the death, incapacity, commencement of emergency medical leave or unexpected resignation or discharge of a pharmacist in charge. Providing that the request was made within this time period,

- A. The board administrator or the administrator's designee may rule on the request on an interim basis until the board is able to address it; and
- B. The retail ~~drug outlet~~pharmacy may operate under the supervision of a pharmacist pending the interim ruling of the board administrator or the administrator's designee.

4. Death, Incapacity or Sudden Unavailability of Pharmacist on Duty

A retail ~~drug outlet~~pharmacy shall immediately cease filling and dispensing prescription drug orders upon the death, incapacity or sudden unavailability of a sole pharmacist on duty until a replacement pharmacist arrives at the ~~drug outlet~~pharmacy.

5. Prescriptions to be Filled Only in Prescription Filling Area

Prescriptions may only be filled and dispensed in the prescription filling area of the retail ~~drug outlet~~pharmacy. A retail ~~drug outlet~~pharmacy may request a waiver of this limitation from the board by demonstrating, to the satisfaction of the board, that a lack of convenient public access to a retail ~~drug outlet~~pharmacy exists and that the public health and safety requires that drugs be dispensed at a location remote from the retail ~~drug outlet~~pharmacy.

Nothing in this section shall prevent a retail ~~drug outlet~~pharmacy from delivering a prescription to the home or business of a patient under arrangements supervised by a pharmacist.

6. Security of Prescription Filling Area

1. Absence of Pharmacist From Prescription Filling Area

A retail ~~drug outlet~~pharmacy and pharmacist on duty shall ensure that no person remains in the prescription filling area during the absence of a pharmacist from the

prescription filling area other than an ~~authorized~~ pharmacy technician, pharmacy intern or an authorized person.

2. Dispensing of Prescriptions in the Absence of a Pharmacist

~~No A retail drug outlet~~ pharmacy may not dispense prescription drugs pursuant to an original prescription drug order in the absence of a pharmacist from the prescription filling area. ~~No A retail drug outlet~~ pharmacy may not dispense prescription drugs pursuant to a renewal prescription drug order in the absence of a pharmacist from the store premises.

3. Acceptance of Walk-In Prescription Drug Orders in the Absence of a Pharmacist

~~An A authorized~~ pharmacy technician may accept prescription drug orders from walk-in patients in the absence of a pharmacist from the prescription filling area only when the pharmacist-

- A. Is taking a customary and reasonable work break;
- B. Is in the vicinity of the store in which the retail ~~drug outlet~~ pharmacy is located; or is in a closed-shop pharmacy at the same location as the retail pharmacy;
- C. Is not engaged in any activity that would interfere with his/her immediate availability; and
- D. Is reachable by the ~~authorized~~ pharmacy technician during the absence.

4. Deployment of Barrier

During the absence of a pharmacist or ~~authorized~~ pharmacy technician from the prescription filling area, the prescription filling area shall be secured with a barrier that extends from the floor or counter to the ceiling. The barrier must be constructed of a material of sufficient strength so that the barrier cannot be readily removed, penetrated or bent. If the barrier is constructed of non-solid material, any openings or interstices must be small enough to prevent the removal, by any means, of items from the prescription filling area. If, in addition, there is no authorized person in the prescription filling area, the barrier shall also be locked. The retail ~~drug outlet~~ pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the lock.

5. Alarm

The prescription filling area, drug storage areas and compounding area (if applicable) shall must be protected by an electronic security system. The electronic security system must be separate from any other electronic security system that may be installed at the retail ~~drug outlet~~ pharmacy, and must be capable of activation/deactivation separately from any other electronic security system that may

be installed at the retail ~~drug outlet~~pharmacy. The ~~drug outlet~~pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The retail ~~drug outlet~~pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

6. Security Cameras

A retail ~~drug outlet~~pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy department, including, at a minimum, the prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, ~~the narcotics safe~~controlled drug storage areas, ~~and the checkout area~~ and compounding area (if applicable). The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A retail ~~drug outlet~~pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the compounding area (if applicable) and controlled drug storage areas goes into effect on July 1, 2014.

7. ~~Implementation of Barrier, Alarm and Security Camera Requirements~~

~~A retail drug outlet that is not in compliance with the barrier, alarm and security camera requirements of Section 6, subsections 4, 5 and 6 shall bring itself into full compliance upon any alteration of the prescription filling area that requires approval of the board pursuant to Chapter 8, Section 7 or by June 30, 2010, whichever first occurs. [deleted]~~

8. Designation of Authorized Persons and Authorized Pharmacy Technicians

A pharmacist in charge shall report on a form supplied by the board the name and other identifying information of all authorized persons and ~~authorized pharmacy technicians~~ designated by the pharmacist in charge.

9. Deliveries and Delivery Logs

A. All shipments containing only prescription drugs ~~shall~~ must be delivered in unopened containers to a pharmacist, ~~authorized pharmacy technician or authorized person~~. Only a pharmacist, ~~authorized pharmacy technician or authorized person~~ may sign for the delivery.

B. A retail ~~drug outlet~~pharmacy shall maintain a log of all prescription drugs delivered to rural health centers and free clinics; and to dispensaries, hospital pharmacies, extended care facilities, boarding homes, nursing homes, drug abuse treatment centers, penal institutions, family planning centers, medical clinics and all other facilities that are not registered or licensed by the board. The log shall show the date and time of delivery, the name of the person

making delivery on behalf of the retail ~~drug outlet~~pharmacy, the drugs delivered, the name and address of the institution receiving the drugs, and the name of the person accepting delivery on behalf of the institution.

- C. A rural health center or free clinic; or a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board; shall maintain a log of all prescription drugs delivered to it by a retail ~~drug outlet~~pharmacy. The log shall show the date and time of delivery, the name of the retail ~~drug outlet~~pharmacy making delivery, the name of the person making delivery on behalf of the retail ~~drug outlet~~pharmacy, the drugs received, and the name of the person accepting delivery on behalf of the institution.

7. Compounding

1. Scope

This section applies to non-sterile compounding pharmacies, for which no separate license or endorsement is required other than the general retail pharmacy license or closed-shop pharmacy license. A sterile compounding pharmacy must be separately licensed pursuant to Chapter 37 of the board's rules.

2. Operational Requirements

- A. USP Chapter 795 – A non-sterile compounding pharmacy shall comply in all respects with United States Pharmacopeia USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations, 2013-14 edition, Vol. 1, p. 355. (“Chapter 795”). The board incorporates Chapter 795 into this chapter by reference. Chapter 795 may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

3. Activity Records

At the request of the board, a non-sterile compounding pharmacy shall generate within 3 business days a report showing the number and type of prescriptions dispensed during the period of time specified by the board. The contents and format of the report shall be determined by the board. The reporting period is subject to the record retention requirements contained in Chapter 24 of the board's rules.

78. Signs

All retail ~~drug outlets~~pharmacies shall identify their location by an interior or exterior sign that identifies the establishment as a ~~drug outlet~~pharmacy through the word or words "pharmacy," "druggist," "drugs," "drug store," "Rx," "apothecary," or the like. The ~~drug outlet~~pharmacy may display the sign upon issuance of the ~~drug outlet's~~pharmacy's certificate of registrationlicense by the board. The sign must be immediately removed or covered upon the nonrenewal, surrender or revocation of the establishment's ~~registration as a drug outlet~~license, or upon the permanent closing of the ~~drug outlet~~pharmacy.

89. Permanent Closing of a Retail ~~Drug Outlet~~Pharmacy**1. Notification**

- A. A retail ~~drug outlet~~pharmacy shall notify the board of the ~~drug outlet's~~pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name and address of the ~~drug outlet~~pharmacy to be closed; the date of closure; the name and address of the ~~drug outlet~~pharmacy acquiring the prescription inventory; and the name and address of the ~~drug outlet~~pharmacy acquiring the prescription files and patient profiles.
- B. A retail ~~drug outlet~~pharmacy shall notify the DEA of the ~~drug outlet's~~pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name, address, and DEA registration number of the ~~drug outlet~~pharmacy to be closed; the name, address, and DEA registration number of the ~~drug outlet~~pharmacy acquiring the controlled substances; and the date on which the transfer will occur.
- C. A retail ~~drug outlet~~pharmacy shall notify the general public of the ~~drug outlet's~~pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the date of closure and the new location of the ~~drug outlet's~~pharmacy's patient prescription files. Notice shall be given by prominent posting in a public area of the store and by display advertisement in a newspaper of general circulation in the area served by the ~~drug outlet~~pharmacy.

2. Closing day procedures

- A. The retail ~~drug outlet~~pharmacy shall take a complete inventory of all controlled substances.
- B. The retail ~~drug outlet~~pharmacy shall dispose of controlled substances as follows:
 - (1) If the controlled substances are being sold or given to another DEA registrant-

- (a) The transfer of Schedule II controlled substances shall be made on closing day and memorialized by a properly executed DEA Form 222; and
 - (b) The transfer of Schedule III, IV, and V controlled substances shall be made on closing day and memorialized by invoice, with copies to each party and the board.
- (2) If the controlled substances are not being sold or given to another DEA registrant, the retail ~~drug outlet~~pharmacy shall turn over to the board on closing day for safekeeping, at the sole expense of the ~~drug outlet~~pharmacy, all controlled substances in its possession, custody or control, together with appropriate inventory information. The ~~drug outlet~~pharmacy shall lawfully sell or dispose of these drugs within 60 days after closure. If the ~~drug outlet~~pharmacy fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the ~~drug outlet~~pharmacy. In the event of forfeiture as set forth herein, the retail ~~drug outlet~~pharmacy remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- C. The retail ~~drug outlet~~pharmacy shall dispose of prescription legend drugs as follows:
- (1) If the prescription legend drugs are being sold or given to another ~~drug outlet~~pharmacy, the bulk transfer of such drugs shall be made on closing day and memorialized by invoice, with copies to each party.
 - (2) If the prescription legend drugs are not being sold or given to another ~~drug outlet~~pharmacy, the retail ~~drug outlet~~pharmacy shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all prescription legend drugs in its possession, custody or control, together with appropriate inventory information. The ~~drug outlet~~pharmacy shall lawfully sell or dispose of these drugs within 60 days after closure. If the ~~drug outlet~~pharmacy fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the ~~drug outlet~~pharmacy. In the event of forfeiture as set forth herein, the retail ~~drug outlet~~pharmacy remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- D. Disposition of prescription files and patient profiles

- (1) If the prescription files and patient profiles are being sold to another ~~drug outlet~~pharmacy or are being transferred to another ~~drug outlet~~pharmacy in the same chain, the retail ~~drug outlet~~pharmacy that is closing shall transfer the files and profiles on closing day. The recipient ~~drug outlet~~pharmacy must keep the files and profiles for the time required by Chapter 24 of the board's rules.
 - (2) If the prescription files and patient profiles are not being sold or transferred, the retail ~~drug outlet~~pharmacy shall find a ~~drug outlet~~pharmacy within a reasonable distance that is willing to be custodian of the records. The custodian ~~drug outlet~~pharmacy must keep the files and profiles for the time required by Chapter 24 of the board's rules.
- E. Security. The retail ~~drug outlet~~pharmacy shall ensure the security of its drug supply at all times during the closing procedures.

3. Reports and Returns Due After Closing

Within 30 days after closing, the retail ~~drug outlet~~pharmacy shall make the following reports and returns:

A. To DEA -

- (1) Name, address, and DEA number of the closed ~~drug outlet~~pharmacy;
- (2) Return of any unused DEA Form 222s;
- (3) Copy of the controlled substances inventory and all schedules; and
- (4) Copies of DEA Form 222 completed pursuant to Section 8(2)(B)(1)(a) of this chapter.

B. To the board -

- (1) Return of the license for the closed retail ~~drug outlet~~pharmacy;
- (2) Report that all signs indicating the presence of the closed ~~drug outlet~~pharmacy have been removed;
- (3) Report that all labels and blank prescriptions have been destroyed;
- (4) Report that the DEA license and all unused DEA Form 222s have been returned to the DEA;
- (5) Report as to the disposition of controlled substances and prescription legend drugs made pursuant to Section 8(2)(B) and (C) of this chapter; and

- (6) Report as to the disposition of prescription files and patient profiles made pursuant to Section 8(2)(D) of this chapter.

4. Chemicals and Hazardous Materials

The retail ~~drug outlet~~pharmacy shall remove and dispose of all chemicals and hazardous materials prior to closing in accordance with the Hazardous Waste Management Rules of the Department of Environmental Protection identified in Chapter 23, Section ~~2(1)~~2(2) of the board's rules (as applicable). The ~~drug outlet~~pharmacy is responsible for all costs directly and indirectly incurred by the board in removing and disposing of chemicals and hazardous materials that the licensee fails to remove from the premises.

STATUTORY AUTHORITY: 32 MRSA §13720, 13721(1), 13722, 13723, 13751

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

Part 3 - Operation of Drug Outlets

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 13: OPERATION OF RETAIL PHARMACIES

Summary: This chapter sets forth operation requirements for retail pharmacies licensed by the board.

1. Cleanliness and Sanitation

The pharmacy department shall at all times be operated in a clean and sanitary manner.

2. Hours of Operation; Posting of Hours

1. Minimum Hours of Operation

A retail pharmacy must be open to the public for a minimum of 40 hours per week unless waived by the board for good cause shown, and must be staffed by a pharmacist at all times that the pharmacy is open.

2. Posting of Schedule

A retail pharmacy shall prominently post in a public area of the store the days and hours that the pharmacy is scheduled to be open to the public.

3. Adherence to Posted Schedule

A retail pharmacy shall adhere to the schedule posted pursuant to Section 2(2) of this chapter.

4. Deviations From Posted Schedule

A retail pharmacy shall prominently post in a public area of the store any deviation from its posted schedule as soon as the need to deviate from the posted schedule is known by the pharmacy. This posting shall include the period of time the pharmacy will be closed and the name, street address and telephone number of a nearby pharmacy that is available to serve the public during the period of closure.

5. Reporting of Deviations to Board

Except as set forth in this subsection, a retail pharmacy shall report any deviation from its posted schedule to the board by fax or email no later than the next business day following the deviation. Each day on which a deviation occurs must be separately reported. Reporting may be made by mail if the pharmacy does not have fax or email capability.

No report need be filed for:

- A. A deviation of less than four hours duration;
- B. A deviation resulting from severe weather conditions, fire, flood, disaster or natural or man-made catastrophe beyond the control of the pharmacy; or
- C. Holiday closures.

6. Remedial Action by Board

In the event that a retail pharmacy deviates four or more times from its posted schedule within a calendar month, other than for reasons described in Section 2(5) of this chapter, the board, following notice and opportunity for hearing, may require the pharmacy to revise the schedule posted pursuant to Section 2(2) of this chapter as may be necessary to protect the public from injury or inconvenience due to the pharmacy's inability to adhere to its posted schedule.

3. Pharmacist in Charge

1. Generally

The business of a retail pharmacy shall be conducted under the direct supervision of a licensed pharmacist who has registered as the pharmacist in charge of that pharmacy with the board. No retail pharmacy may operate without a pharmacist in charge.

2. Responsibilities

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the retail pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules. The responsibilities of the pharmacist in charge include, but are not limited to:

- A. The pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;
- B. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;

- C. The security of the prescription filling area and its contents;
- D. Ensuring that the prescription filling area is operated in conformance with good pharmaceutical practices;
- E. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination;
- F. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
- G. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

3. Presence at Retail Drug Outlet

Except as set forth in Section 3(4) of this chapter, or unless waived by the board for good cause shown, a pharmacist in charge of a retail pharmacy shall practice at that pharmacy for a minimum of 30 hours per week or 50% of the hours the pharmacy is open, whichever is less.

4. Registration as Pharmacist in Charge for More Than One Retail Pharmacy

Except as set forth in Section 3(5)(B) of this chapter, no pharmacist may register or serve as pharmacist in charge for more than one retail pharmacy prior to receiving approval from the board. All requests for approval, including requests for emergency approval made pursuant to Section 3(5) of this chapter, must be made via letter, email or fax. A request to serve as pharmacist in charge of an opioid treatment program and one other type of non-opioid pharmacy, or two opioid treatment programs and no other non-opioid pharmacy, will be approved automatically, subject to disciplinary review. A request to serve as pharmacist in charge of a retail pharmacy, closed-shop pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically, subject to disciplinary review. For all other requests, the board may grant approval only in the following circumstances upon a consideration of the nature and extent of the risk posed to the public:

- A. Death, incapacity, emergency medical leave or unexpected resignation or discharge of a pharmacist in charge;
- B. Specialty practice setting which does not require a 30 hour/50% pharmacist in charge for reasonable protection of the population served; or
- C. Other situations where exigent circumstances warrant the registration of a sole pharmacist in charge of more than one retail pharmacy.

The board's order of approval may be of fixed or of indeterminate duration and shall contain such coverage requirements and other provisions as may be necessary to

protect the public health and safety at all locations to be served by a sole pharmacist in charge.

5. Emergency Requests

A request for approval pursuant to Section 3(4)(A) of this chapter must be made within 7 days after the death, incapacity, commencement of emergency medical leave or unexpected resignation or discharge of a pharmacist in charge. Providing that the request was made within this time period,

- A. The board administrator or the administrator's designee may rule on the request on an interim basis until the board is able to address it; and
- B. The retail pharmacy may operate under the supervision of a pharmacist pending the interim ruling of the board administrator or the administrator's designee.

4. Death, Incapacity or Sudden Unavailability of Pharmacist on Duty

A retail pharmacy shall immediately cease filling and dispensing prescription drug orders upon the death, incapacity or sudden unavailability of a sole pharmacist on duty until a replacement pharmacist arrives at the pharmacy.

5. Prescriptions to be Filled Only in Prescription Filling Area

Prescriptions may only be filled and dispensed in the prescription filling area of the retail pharmacy. A retail pharmacy may request a waiver of this limitation from the board by demonstrating, to the satisfaction of the board, that a lack of convenient public access to a retail pharmacy exists and that the public health and safety requires that drugs be dispensed at a location remote from the retail pharmacy.

Nothing in this section shall prevent a retail pharmacy from delivering a prescription to the home or business of a patient under arrangements supervised by a pharmacist.

6. Security of Prescription Filling Area

1. Absence of Pharmacist From Prescription Filling Area

A retail pharmacy and pharmacist on duty shall ensure that no person remains in the prescription filling area during the absence of a pharmacist from the prescription filling area other than a pharmacy technician, pharmacy intern or an authorized person.

2. Dispensing of Prescriptions in the Absence of a Pharmacist

A retail pharmacy may not dispense prescription drugs pursuant to an original prescription drug order in the absence of a pharmacist from the prescription filling area. A retail pharmacy may not dispense prescription drugs pursuant to a renewal prescription drug order in the absence of a pharmacist from the store premises.

3. Acceptance of Walk-In Prescription Drug Orders in the Absence of a Pharmacist

A pharmacy technician may accept prescription drug orders from walk-in patients in the absence of a pharmacist from the prescription filling area only when the pharmacist-

- A. Is taking a customary and reasonable work break;
- B. Is in the vicinity of the store in which the retail pharmacy is located or is in a closed-shop pharmacy at the same location as the retail pharmacy;
- C. Is not engaged in any activity that would interfere with his/her immediate availability; and
- D. Is reachable by the pharmacy technician during the absence.

4. Deployment of Barrier

During the absence of a pharmacist or pharmacy technician from the prescription filling area, the prescription filling area shall be secured with a barrier that extends from the floor or counter to the ceiling. The barrier must be constructed of a material of sufficient strength so that the barrier cannot be readily removed, penetrated or bent. If the barrier is constructed of non-solid material, any openings or interstices must be small enough to prevent the removal, by any means, of items from the prescription filling area. If, in addition, there is no authorized person in the prescription filling area, the barrier shall also be locked. The retail pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the lock.

5. Alarm

The prescription filling area, drug storage areas and compounding area (if applicable) must be protected by an electronic security system. The electronic security system must be separate from any other electronic security system that may be installed at the retail pharmacy, and must be capable of activation/deactivation separately from any other electronic security system that may be installed at the retail pharmacy. The pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The retail pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

6. Security Cameras

A retail pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy department, including, at a minimum, the prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, controlled drug storage areas, the checkout area and compounding area (if applicable). The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A retail pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the compounding area (if applicable) and controlled drug storage areas goes into effect on July 1, 2014.

7. [deleted]

8. Designation of Authorized Persons and Authorized Pharmacy Technicians

A pharmacist in charge shall report on a form supplied by the board the name and other identifying information of all authorized persons designated by the pharmacist in charge.

9. Deliveries and Delivery Logs

- A. All shipments containing only prescription drugs must be delivered in unopened containers to a pharmacist, pharmacy technician or authorized person. Only a pharmacist, pharmacy technician or authorized person may sign for the delivery.
- B. A retail pharmacy shall maintain a log of all prescription drugs delivered to rural health centers and free clinics; and to dispensaries, hospital pharmacies, extended care facilities, boarding homes, nursing homes, drug abuse treatment centers, penal institutions, family planning centers, medical clinics and all other facilities that are not registered or licensed by the board. The log shall show the date and time of delivery, the name of the person making delivery on behalf of the retail pharmacy, the drugs delivered, the name and address of the institution receiving the drugs, and the name of the person accepting delivery on behalf of the institution.
- C. A rural health center or free clinic; or a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board; shall maintain a log of all prescription drugs delivered to it by a retail pharmacy. The log shall show the date and time of delivery, the name of the retail pharmacy making delivery, the name of the person making delivery on behalf of the retail pharmacy, the drugs received, and the name of the person accepting delivery on behalf of the institution.

7. **Compounding**

1. **Scope**

This section applies to non-sterile compounding pharmacies, for which no separate license or endorsement is required other than the general retail pharmacy license or closed-shop pharmacy license. A sterile compounding pharmacy must be separately licensed pursuant to Chapter 37 of the board's rules.

2. **Operational Requirements**

- A. USP Chapter 795 – A non-sterile compounding pharmacy shall comply in all respects with United States Pharmacopeia USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations, 2013-14 edition, Vol. 1, p. 355. ("Chapter 795"). The board incorporates Chapter 795 into this chapter by reference. Chapter 795 may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

3. **Activity Records**

At the request of the board, a non-sterile compounding pharmacy shall generate within 3 business days a report showing the number and type of prescriptions dispensed during the period of time specified by the board. The contents and format of the report shall be determined by the board. The reporting period is subject to the record retention requirements contained in Chapter 24 of the board's rules.

8. **Signs**

All retail pharmacies shall identify their location by an interior or exterior sign that identifies the establishment as a pharmacy through the word or words "pharmacy," "druggist," "drugs," "drug store," "Rx," "apothecary," or the like. The pharmacy may display the sign upon issuance of the pharmacy's license by the board. The sign must be immediately removed or covered upon the nonrenewal, surrender or revocation of the establishment's license, or upon the permanent closing of the pharmacy.

9. **Permanent Closing of a Retail Pharmacy**

1. **Notification**

- A. A retail pharmacy shall notify the board of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name and address of the pharmacy to be closed; the date of closure; the name and address of the pharmacy acquiring the prescription inventory; and the name and address of the pharmacy acquiring the prescription files and patient profiles.
- B. A retail pharmacy shall notify the DEA of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name, address, and DEA registration number of the pharmacy to be closed; the name, address, and DEA registration number of the pharmacy acquiring the controlled substances; and the date on which the transfer will occur.
- C. A retail pharmacy shall notify the general public of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the date of closure and the new location of the pharmacy's patient prescription files. Notice shall be given by prominent posting in a public area of the store and by display advertisement in a newspaper of general circulation in the area served by the pharmacy.

2. Closing day procedures

- A. The retail pharmacy shall take a complete inventory of all controlled substances.
- B. The retail pharmacy shall dispose of controlled substances as follows:
 - (1) If the controlled substances are being sold or given to another DEA registrant-
 - (a) The transfer of Schedule II controlled substances shall be made on closing day and memorialized by a properly executed DEA Form 222; and
 - (b) The transfer of Schedule III, IV, and V controlled substances shall be made on closing day and memorialized by invoice, with copies to each party and the board.
 - (2) If the controlled substances are not being sold or given to another DEA registrant, the retail pharmacy shall turn over to the board on closing day for safekeeping, at the sole expense of the pharmacy, all controlled substances in its possession, custody or control, together with appropriate inventory information. The pharmacy shall lawfully sell or dispose of these drugs within 60 days after closure. If the pharmacy fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the pharmacy. In the event of forfeiture as set forth herein, the retail pharmacy remains

liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.

C. The retail pharmacy shall dispose of prescription legend drugs as follows:

- (1) If the prescription legend drugs are being sold or given to another pharmacy, the bulk transfer of such drugs shall be made on closing day and memorialized by invoice, with copies to each party.
- (2) If the prescription legend drugs are not being sold or given to another pharmacy, the retail pharmacy shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all prescription legend drugs in its possession, custody or control, together with appropriate inventory information. The pharmacy shall lawfully sell or dispose of these drugs within 60 days after closure. If the pharmacy fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the pharmacy. In the event of forfeiture as set forth herein, the retail pharmacy remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.

D. Disposition of prescription files and patient profiles

- (1) If the prescription files and patient profiles are being sold to another pharmacy or are being transferred to another pharmacy in the same chain, the retail pharmacy that is closing shall transfer the files and profiles on closing day. The recipient pharmacy must keep the files and profiles for the time required by Chapter 24 of the board's rules.
- (2) If the prescription files and patient profiles are not being sold or transferred, the retail pharmacy shall find a pharmacy within a reasonable distance that is willing to be custodian of the records. The custodian pharmacy must keep the files and profiles for the time required by Chapter 24 of the board's rules.

E. Security. The retail pharmacy shall ensure the security of its drug supply at all times during the closing procedures.

3. Reports and Returns Due After Closing

Within 30 days after closing, the retail pharmacy shall make the following reports and returns:

A. To DEA -

- (1) Name, address, and DEA number of the closed pharmacy;

- (2) Return of any unused DEA Form 222s;
- (3) Copy of the controlled substances inventory and all schedules; and
- (4) Copies of DEA Form 222 completed pursuant to Section 8(2)(B)(1)(a) of this chapter.

B. To the board -

- (1) Return of the license for the closed retail pharmacy;
- (2) Report that all signs indicating the presence of the closed pharmacy have been removed;
- (3) Report that all labels and blank prescriptions have been destroyed;
- (4) Report that the DEA license and all unused DEA Form 222s have been returned to the DEA;
- (5) Report as to the disposition of controlled substances and prescription legend drugs made pursuant to Section 8(2)(B) and (C) of this chapter; and
- (6) Report as to the disposition of prescription files and patient profiles made pursuant to Section 8(2)(D) of this chapter.

4. Chemicals and Hazardous Materials

The retail pharmacy shall remove and dispose of all chemicals and hazardous materials prior to closing in accordance with the Hazardous Waste Management Rules of the Department of Environmental Protection identified in Chapter 23, Section 2(2) of the board's rules (as applicable). The pharmacy is responsible for all costs directly and indirectly incurred by the board in removing and disposing of chemicals and hazardous materials that the licensee fails to remove from the premises.

STATUTORY AUTHORITY: 32 MRSA §13720, 13721(1), 13722, 13723, 13751

EFFECTIVE DATE:

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 13
OPERATION OF RETAIL PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth operational requirements for retail pharmacies licensed by the board. In the amendments to this chapter the board made the following changes:

- Excluded holiday closures from schedule deviations that need to be reported to the board.
- Required the pharmacist in charge to ensure that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed by the board. This amendment was prompted by investigations which revealed that several pharmacists were practicing under expired licenses.
- Expanded the scope of permissible waivers to the requirement that a pharmacist may serve as pharmacist in charge at no more than one retail pharmacy. This amendment is an outgrowth of the new limited purpose pharmacy licenses created in Chapter 36 (opioid treatment programs), Chapter 37 (sterile compounding pharmacies) and Chapter 38 (closed-shop pharmacies). Sterile compounding pharmacies and closed-shop pharmacies, for example, may operate in conjunction with a retail pharmacy.
- Required the drug compounding area (if applicable) and controlled drug storage areas to be protected by alarm.
- Required the drug compounding area (if applicable) and controlled drug storage areas to be protected by security camera. Chapter 13, Section 6 of the predecessor rules required the "narcotics safe" at retail pharmacies to be protected by security camera. The board was concerned that some pharmacies without an actual safe may have been avoiding deployment of a security camera. The proposed rule requires controlled drug storage areas to be protected by security camera beginning July 1, 2014. Pharmacies without a narcotics safe that do not currently monitor controlled drug storage areas will need to purchase an additional security camera. The cost of an additional camera is about \$500.
- Deleted obsolete text relating to the initial implementation of the barrier, alarm and security camera requirements.
- Required retail pharmacies that engage in non-sterile compounding to comply with USP Chapter 795.

...

The board's predecessor rules, in former Chapter 18, required licensure of sterile compounding pharmacies. There were no specific requirements, for licensure or otherwise, that pertained to the compounding of non-sterile pharmaceuticals.

Much of the board's energy in this rulemaking proceeding was devoted to the promulgation of new licensing standards for sterile compounding pharmacies contained in Chapter 37. The board considered but rejected a licensing requirement for non-sterile compounding pharmacies. Simply stated, the risk of process error, and possible harm to patients, is far lower in non-sterile than for sterile compounding.

Chapter 795 of the U.S. Pharmacopeia, "Pharmaceutical Compounding – Nonsterile Preparations" is a recognized industry standard for the compounding of non-sterile pharmaceuticals. Chapter 13, Section 7 of the board's rules incorporates USP 795 by reference as the regulatory standard for the compounding of non-sterile pharmaceuticals in Maine. The board sees no need to gild the lily by writing additional rules in this area.

Records of compounding activity must be produced upon request of the board. Such a request could arise in the context of a complaint or other investigation, or as a follow-up to an inspection.

Response to Comments

Douglas S. Carr
Carr Consulting
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
(oral and written)

- Section 6(5) requires that the drug storage area be protected by an alarm. Section 6(6) requires that controlled drug storage areas be protected by security cameras. Are both forms of protection necessary? Rite Aid does both, but this may not be the case for all retail pharmacies.

◆ *Board Response:* Both an alarm and security cameras are necessary to protect drug storage areas and controlled drug storage areas.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

...

The board received extensive comments relating to pharmacy compounding. The commenters did not differentiate between sterile compounding pharmacies, covered in Chapter 37, and non-sterile compounding pharmacies, covered in Section 7 of this chapter. The comments and responses relating to sterile and non-sterile compounding appear in the Response to Comments for Chapter 37. For the reasons discussed therein, the board has deleted Chapter 13, Sections 7(2) (NABP compounding records requirements) and 7(4)(B) (NABP good compounding practices) of the proposed rules from Chapter 13 as adopted. The board has reordered the surviving provisions of Chapter 13, Section 7 as adopted.

This chapter as proposed contained a Note relating to Chapter 30, Section 1(29) - (36). For the reason discussed in the response to comments for Chapter 30, the board has deleted Chapter 30, Section 1(29) - (36) of the proposed rules from Chapter 30 as adopted. The board has accordingly deleted the Note from this chapter as adopted.

Rule-Making Cover Sheet

2013-306

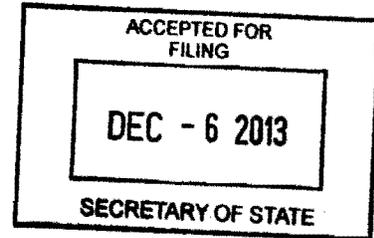
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Sterile Pharmaceuticals

4. Chapter number assigned to the rule: 18
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [x] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.
Signature: [Handwritten Signature]
(Printed Name & Title: Joseph Bruno, Board President)

11. Approved as to form and legality by the Attorney General on 11-18-13
Signature: [Handwritten Signature]
(Printed Name: Lauren LaRochelle)

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 18: STERILE PHARMACEUTICALS**

Summary: This chapter sets forth rules governing the preparation, labeling and distribution of sterile pharmaceuticals.

1. Scope and Purpose

The purpose of this chapter is to provide standards for the preparation, labeling, and distribution of sterile products by drug outlets pursuant to a prescription drug order. These standards apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

A drug outlet that prepares sterile pharmaceutical shall register 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.

2. Policy and Procedure Manual

The drug outlet shall maintain a manual relating to sterile pharmaceuticals that sets forth policies and procedures for the functions listed below. The manual shall be available for inspection at the drug outlet.

1. Clinical services;
2. Cytotoxics handling, storage and disposal;
3. Major and minor spills of cytotoxic agents;
4. Disposal of unused supplies and medications;
5. Drug destruction and returns;
6. Drug dispensing;
7. Drug labeling and relabeling;
8. Drug storage;
9. Duties and qualifications for professional and nonprofessional staff;

- ~~10. Equipment;~~
- ~~11. Handling of infectious wastes;~~
- ~~12. Infusion devices and drug delivery systems;~~
- ~~13. Investigational drugs;~~
- ~~14. Obtaining a protocol on investigational drugs from the principal investigator;~~
- ~~15. Quality assurance procedures as set forth in Section 9 of this chapter;~~
- ~~16. Recordkeeping;~~
- ~~17. Reference materials;~~
- ~~18. Sanitation;~~
- ~~19. Security;~~
- ~~20. Sterile product preparation procedures; and~~
- ~~21. Transportation.~~

~~The manual shall be reviewed and revised as necessary on an annual basis.~~

~~3. Physical Requirements~~

~~1. Space~~

~~The drug outlet shall have a designated area with entry restricted to designated personnel for preparing compounded sterile parenteral products. This area shall be structurally isolated from other areas, with restricted entry or access, and must be designed to avoid unnecessary traffic and airflow disturbances from activity within the controlled facility. This area shall be used only for the preparation of these specialty products, and shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation and security.~~

~~2. Equipment~~

~~A drug outlet preparing sterile parenteral products shall have:~~

- ~~A. For sterile parenteral products which have expiration times of less than 96 hours, appropriate environmental control devices capable of maintaining at least Class 100 conditions in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 conditions during normal activity. Examples of~~

- ~~appropriate devices include laminar airflow hoods and zonal laminar flow of HEPA filtered air;~~
- ~~B. For sterile parenteral products which have expiration times of 96 hours or more, appropriate environmental control devices capable of maintaining the room at Class 1000 conditions with work being done in a Class 100 hood;~~
- ~~C. Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding;~~
- ~~D. Appropriate disposal containers for used needles, syringes, etc., and if applicable, cytotoxic waste from the preparation of chemotherapy agents, and infectious wastes from patients' homes;~~
- ~~E. When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biohazard cabinetry;~~
- ~~F. Refrigerator/freezer with a thermometer;~~
- ~~G. Temperature controlled delivery container; and~~
- ~~H. Infusion devices, if appropriate.~~

~~3. Supplies~~

- ~~A. Disposable needles, syringes, and other supplies needed for aseptic admixture;~~
- ~~B. Disinfectant cleaning solutions;~~
- ~~C. Handwashing agent with bactericidal action;~~
- ~~D. Disposable, lint free towels or wipes;~~
- ~~E. Appropriate filters and filtration equipment;~~
- ~~F. Oncology drug spill kit;~~
- ~~G. Disposable masks, caps, gowns, and sterile disposable gloves~~

~~4. Reference Library~~

- ~~The drug outlet shall have sufficient current reference materials related to sterile products to meet the needs of pharmacy staff.~~

4. Personnel**1. Qualified Pharmacists**

The pharmacist in charge shall ensure that each pharmacist whose responsibilities involve sterile pharmaceuticals is knowledgeable in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. This knowledge may be obtained through: 1) residency training programs; 2) undergraduate studies in college; or 3) experience in an IV admixture facility.

2. 24-Hour Coverage

The drug outlet shall have a pharmacist on site or available by telephone 24 hours per day, 7 days per week to speak with patients and health professionals concerning sterile pharmaceuticals dispensed by the drug outlet. The drug outlet shall include its 24-hour telephone number on the labels of all compounded sterile medications and medication infusion devices.

5. Drug Distribution and Control**1. Patient Profile Record System**

The profile record of patients who have been prescribed sterile pharmaceuticals shall contain, at a minimum:

- A. Patient's full name;
- B. Date of birth or age;
- C. Weight;
- D. Sex;
- E. Sterile products dispensed;
- F. Date dispensed;
- G. Drug content and quantity;
- H. Patient directions;
- I. Identifying number;
- J. Identification of dispensing pharmacist and preparing technician, if applicable;
- K. Other drugs patient is receiving;

~~L. — Known drug sensitivities and allergies to drugs and foods;~~

~~M. — Primary diagnosis, chronic conditions;~~

~~N. — Lot numbers of components.~~

2. — Labeling

~~Each sterile pharmaceutical dispensed to patients shall be labeled with the following:~~

~~A. — Name, address, and telephone number of the drug outlet;~~

~~B. — Date and identifying number;~~

~~C. — Patient's full name;~~

~~D. — Name of each drug, strength, and amount;~~

~~E. — Directions for use, including infusion rate;~~

~~F. — Practitioner's full name;~~

~~G. — Required controlled substances transfer warnings, where applicable;~~

~~H. — Date of compounding;~~

~~I. — Expiration date and time;~~

~~J. — Identity of pharmacist compounding and dispensing, or other authorized individual;~~

~~K. — Storage requirements;~~

~~L. — Auxiliary labels, where applicable;~~

~~M. — Cytotoxic drug auxiliary labels, where applicable.~~

3. — Records and Reports

~~In addition to other records required by the board's rules, the pharmacist in charge shall keep the following records available for inspection at the drug outlet:~~

~~A. — The patient profile record system described in Section 5(1) of this chapter;~~

~~B. — Purchase records;~~

~~C. — Biennial controlled substances inventories;~~

~~D. — The policy and procedure manual required by Section 2 of this chapter;~~

~~E. Training manuals;~~

~~F. Lot number and quantity used of each component in a sterile prescription;~~

~~4. Delivery Service~~

~~The pharmacist in charge shall ensure the environmental control of all products shipped. Any compounded sterile pharmaceutical must be shipped or delivered to a patient in appropriate temperature controlled delivery containers and stored appropriately in the patient's home.~~

~~5. Disposal of Infectious Wastes~~

~~The pharmacist in charge shall ensure that the drug outlet disposes of infectious wastes in accordance with Chapter 900 of the rules of the Department of Environmental Protection, entitled "Biomedical Waste Management Rules." effective January 1, 1991, which the board hereby incorporates this rule into this chapter by reference. A copy of the rule may be obtained from-~~

~~Department of Environmental Protection~~

~~17 State House Station~~

~~Augusta, ME 04333-0017~~

~~6. Emergency Kit~~

~~When sterile pharmaceuticals are provided to home care patients, the dispensing drug outlet may supply the nurse with emergency drugs, if the practitioner has authorized the use of these drugs according to a protocol in an emergency situation, e.g., anaphylactic shock.~~

~~6. Cytotoxic Drugs~~

~~For the protection of personnel, drug outlets that prepare cytotoxic drugs shall comply with the following additional requirements:~~

~~1. All cytotoxic drugs shall be compounded in, a vertical flow, Class II biological safety cabinet. No other products shall be compounded in this cabinet.~~

~~2. Personnel who compound cytotoxic drugs shall wear protective apparel, including gloves, disposable masks and gowns with tight cuffs.~~

~~3. Appropriate safety and containment techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.~~

- ~~4. Prepared doses of cytotoxic drugs must be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.~~

~~7. Clinical Services~~

- ~~1. Systematic processes of drug use review must be designed, followed, and documented to assure that, on an ongoing basis, appropriate patient outcomes occur from drug therapy.~~
- ~~2. The first dose of any new drug therapy must be administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions~~
- ~~3. There must be documentation of ongoing drug therapy monitoring by the pharmacist in the patient's progress notes, including assessment of:~~
- ~~A. The therapeutic appropriateness of the patient's drug regimen;~~
- ~~B. Therapeutic duplication in the patient's drug regimen;~~
- ~~C. The appropriateness of the dose, frequency, and route of administration and whether this regimen is being followed.~~
- ~~D. Potential drug, food or diagnostic test interactions or disease limitations on drug use (or any combination of these);~~
- ~~E. Clinical laboratory or clinical monitoring methods to detect drug effectiveness, side effect, toxicity, or adverse effects, and whether the findings of such methods are consistent with continued use of the drug in its current regimen.~~

~~8. Patient Care Guidelines~~

~~1. Primary Provider~~

- ~~There shall be a designated practitioner primarily responsible for the patient's medical care. The patient's prescription profile shall document a clear understanding between the practitioner, the patient or caregiver, and the drug outlet of the responsibilities of each in the delivery of care and the monitoring of the patient.~~

~~2. Patient Training~~

- ~~The patient, the practitioner, the patient's caregiver or the drug outlet shall demonstrate or document the patient's training and competency in managing this type of therapy in the home environment. The pharmacist shall orally explain to the patient or the patient's caregiver the directions for use and any additional information, in writing if necessary, to assure proper utilization of the medication prescribed. In cases~~

where the patient or the patient's caregiver will be compounding, the pharmacist must be involved in the training process. The pharmacist shall ensure that the patient's competency in the above areas is reassessed on an ongoing basis.

~~3. Pharmacist Patient Relationship~~

~~The patient's prescription profile shall document the establishment and maintenance of an ongoing, interactive professional relationship between the pharmacist and the patient or patient's caregiver throughout the patient's course of therapy.~~

~~4. Patient Monitoring~~

~~The pharmacist shall have access to clinical and laboratory data concerning each patient and shall monitor each patient's response to the drug therapy. The pharmacist shall report any unexpected or untoward response to the prescribing practitioner.~~

~~9. Quality Assurance~~

~~There shall be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. Appropriate samples of finished products shall be examined to assure that the drug outlet is capable of consistently preparing sterile products meeting specifications. Such examination shall include testing for microbial contamination. Quality assurance procedures shall include:~~

~~1. Recall procedures;~~

~~2. Storage and dating;~~

~~3. Educational procedures for professional staff, nonprofessional staff and patients;~~

~~4. Sterile procedures which include a log of the temperature of the refrigerator, routine maintenance, and report of hood certification.~~

~~A. All clean rooms and laminar flow hoods shall be certified by an independent contractor according to Federal Standard 209E or National Sanitation Foundation 49 for operational efficiency at least every 6 months. Appropriate records shall be maintained.~~

~~B. Prefilters for the clean air source shall be replaced on a regular basis and the replacement date documented.~~

~~C. There shall be written justification of the chosen expiration dates for compounded parenteral products.~~

~~D. There shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits. [repealed]~~

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

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 18: STERILE PHARMACEUTICALS

Summary: This chapter sets forth rules governing the preparation, labeling and distribution of sterile pharmaceuticals.

[repealed]

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

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 18
STERILE PHARMACEUTICALS
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter is repealed. The subject matter is now covered in Chapter 13, Section 7 (non-sterile compounding pharmacies) of the board's rules and new Chapter 37, "Licensure of Sterile Compounding Pharmacies."

Response to Comments

No comments were received on the proposed rule.

Rule-Making Cover Sheet

2013-307

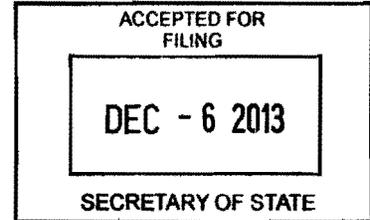
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Receipt and Handling of Prescription Drugs

4. Chapter number assigned to the rule: 19
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE:

DEC 11 2014

Part 4 - Dispensing Prescription Drugs

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 19: RECEIPT AND HANDLING OF PRESCRIPTION DRUG ORDERS

Summary: This chapter sets forth requirements for creating, transmitting, filling and transferring prescription drug orders.

1. General Requirements for Prescription Drug Orders

1. Required Information

Prescription drug orders shall contain, at a minimum, the following information:

- A. Date of issuance by practitioner;
- B. Name and address of the patient [or patient location if an institution];
- C. Name and address of the practitioner [if not a staff physician at an institution];
- D. DEA number of practitioner [in the case of controlled substances];
- E. Name, strength, dosage form and quantity [or stop date, and route of administration] of drug prescribed;
- F. Refills authorized; and
- G. Directions for use by patient.

2. Verification

The pharmacist who receives a prescription drug order shall record the order and verify the identity of the practitioner and, if applicable, the identity and authority of the practitioner's agent.

2. Requirements for Prescription Drug Orders for Controlled Substances

1. Schedule II Drugs

No pharmacist may fill a written prescription drug order from a Maine health care provider for a Schedule II drug that does not comply with Chapter 1 of the rules of the Department of Public Safety, Maine Drug Enforcement Agency, entitled "Requirements for Written Prescriptions of Schedule II Drugs," adopted May 30, 2002 and effective January 1, 2003. The board hereby incorporates Chapter 1 into this chapter by reference. A copy of the rule may be obtained from-

Department of Public Safety
Maine Drug Enforcement Agency
166 State House Station
Augusta, ME 04333-0166

[NOTE: PL 2003, c. 326, amending 32 M.R.S.A. §13786-A(2)-(4), sets forth special requirements for filling a prescription drug order for a Schedule II drug written by an out-of-state practitioner.]

2. All Controlled Substances

- A. A controlled substance may not be pre-printed on a prescription blank.
- B. No pharmacist may fill a prescription drug order for a controlled substance that is presented to the pharmacist more than 90 days after the date of the prescription.

3. Additional Requirements for Specific Forms of Prescription Drug Orders

1. Telephone Prescription Drug Orders

- ~~A. A pharmacist or pharmacy technician may accept a renewal prescription drug order telephoned to a drug outlet by a practitioner or authorized agent of the practitioner.~~
- ~~B. Only a pharmacist may accept an original prescription drug order telephoned to a drug outlet by a practitioner or authorized agent of the practitioner.~~
A pharmacist or pharmacy intern may accept an original or renewal prescription drug order telephoned to a pharmacy by a practitioner or authorized agent of the practitioner. A pharmacy technician may accept an original or renewal prescription drug order telephoned to a pharmacy by a practitioner or authorized agent of the practitioner to the extent authorized by the pharmacist on duty.

2. Facsimile Prescription Drug Orders

- A. A pharmacist, pharmacy intern or pharmacy technician may accept a prescription drug order transmitted by facsimile machine or facsimile

computer software directly to a ~~drug outlet~~pharmacy, ~~except that no prescription drug order may be accepted by facsimile for a Schedule II drug other than a prescription drug order for a resident of a long term care facility or hospice care facility to the extent permitted by 21 CFR §1306.11(f) and (g).~~ Facsimile transmission of prescription drug orders for Schedule II controlled drugs is subject to the requirements of 21 CFR §1306.11(a), (e), (f) and (g).

[NOTE: Title 21 CFR §1306.11(a), (e), (f) and (g) require that the original manually-signed prescription for a Schedule II controlled drug must be presented to the pharmacist before the actual dispensing of the medication, except in the case of certain compounded substances, prescriptions written for a resident of a long term care facility, or prescriptions written for a patient enrolled in a hospice care program. For these prescriptions, the facsimile serves as the original written prescription.]

- B. The prescription must contain the name of the practitioner and the authorized agent of the practitioner, if applicable, the date and time of the transmission, and the name of the ~~drug outlet~~pharmacy intended to receive the transmission.
- C. If the person transmitting a prescription drug order by facsimile is the patient or authorized agent of the patient, the original prescription must be presented by the patient or authorized agent at the time the prescription is dispensed.
- D. A ~~drug outlet~~pharmacy shall use a non-fading or bond paper to ensure the preservation of facsimile prescription drug orders for a period of ~~5~~2 years.

3. ~~Prescription Drug Orders~~Electronic Prescriptions for Noncontrolled Drugs Transmitted Via Email or the World Wide Web

- A. The prescription shall contain the electronic signature of the practitioner or the authorized agent of the practitioner, if applicable.
- B. The prescription shall be electronically protected to prevent access, alteration or use by an unauthorized person.
- C. A pharmacist, pharmacy intern or pharmacy technician who accepts a prescription sent by electronic mail, hypertext transport protocol or other internet protocol shall enter his or her initials into the dispensing record.
- D. Only a pharmacist, pharmacy intern or pharmacy technician shall have access to a computer used to receive or retrieve prescription drug orders sent by electronic mail, hypertext transport protocol or other internet protocol.
- E. A ~~drug outlet~~pharmacy shall implement reasonable data backup, protection and recovery protocols to retrieve electronically-stored prescription drug orders in the event of human error, power failure, computer malfunction,

accident or catastrophe resulting in the loss, destruction or corruption of data. The measures implemented shall be sufficient to provide reasonable continuity of service to the public.

4. Electronic Prescriptions for Controlled Drugs

A. A pharmacist and pharmacy may process and fill an electronic prescription for a controlled drug only if:

- (1) The prescription was issued (i.e., prepared, electronically signed and transmitted) by an authenticated practitioner in conformity with the federal rule provisions identified in paragraph B below; and
- (2) The pharmacist and pharmacy complied in all respects with the federal rule provisions identified in paragraph B below that impose duties and responsibilities on pharmacists and pharmacies:

B. The following DEA rules apply to electronic prescriptions for controlled drugs processed and filled by pharmacists and pharmacies that are subject to the jurisdiction of the board and are incorporated into this chapter by reference:

- (1) 21 CFR Part 1311, "Requirements for Electronic Orders and Prescriptions"(April 1, 2012), and the following provisions of 21 CFR Parts 1300, 1304 and 1306 (April 1, 2012) to the extent such provisions apply to electronic prescriptions:
- (2) Section 1300.03, "Definitions Relating to Electronic Orders for Controlled Substances and Electronic Prescriptions for Controlled Substances;"
- (3) Section 1304.03, "~~Records and Reports of Registrants~~Persons Required to Keep Records and File Reports," paragraphs (c) and (h);
- (4) Section 1304.04, "Maintenance of Records and Inventories," paragraphs (b) and (h);
- (5) Section 1304.06, "Records and Reports for Electronic Prescriptions;"
- (6) Section 1306.05, "Manner of Issuance of Prescriptions," paragraph (e);
- (7) Section 1306.08, "Electronic Prescriptions;"
- (8) Section 1306.11, "Requirement of Prescription," paragraphs (a), (c), (d)(1) and (d)(4);
- (9) Section 1306.13, "Partial Filling of Prescriptions, paragraph (a);

- (10) Section 1306.15, “Provision of Prescription Information Between Retail Pharmacies and Central Fill Pharmacies for Prescriptions of Schedule II Controlled Substances,” paragraph (a)(1);
- (11) Section 1306.21, “Requirement of Prescription,” paragraphs (a) and (c);
- (12) Section 1306.22, “Refilling of Prescriptions,” and
- (13) Section 1306.25, “Transfer Between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances For Refill Purposes;”

C. Copies of the DEA rules identified in paragraph B above may be obtained as follows:

- (1) Original publication in the Federal Register, 75 Fed.Reg. 16236–16319, March 31, 2010, as clarified in 76 Fed.Reg. 64813–64816, October 19, 2011, obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>
- (2) Codification in the Code of Federal Regulations, 21 CFR Parts 1300, 1304, 1306 and 1311 (revised as of April 1, 2012), obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>
- (3) Correction to inadvertent omission of §1300.03 from the April 1, 2012 codification of 21 CFR Part 1300, published in the Federal Register, 77 Fed.Reg. 58767-56769, September 24, 2012, obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>

4. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 M.R.S.A. §2681 *et seq.*, the ~~retail drug outlet~~pharmacy shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3rd party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

5. Life of Prescription Drug Orders for Noncontrolled Drugs

A pharmacist may fill a prescription drug order for a noncontrolled drug for a period no greater than 15 months from the date written.

6. Dispensing Records

A ~~drug outlet~~ pharmacy shall create a dispensing record for each original, refill and transferred prescription drug order that it fills. The dispensing record must include, at a minimum, the following information:

1. The original written or faxed prescription drug order, or record of a telephone or computer prescription drug order;
2. Quantity dispensed, if different than the quantity specified in the prescription drug order;
3. Date of dispensing;
4. Prescription number or its equivalent;
5. ~~Effective June 30, 2006, identifiers~~ Identifiers (e.g., initials) for the individual pharmacists who-
 - A. Performed the drug utilization review; and
 - B. Performed the final check to ensure that the prescription was correct in all respects and ready for dispensing.

The pharmacist is responsible for all work done by others to which the pharmacist has affixed his identifier or permitted another to do so.

6. Documentation of compliance with 32 M.R.S.A. §13781, relating to generic and therapeutically equivalent substitution; and
7. Records of refills to date.

7. Automated Data Processing System

A ~~drug outlet~~ pharmacy may employ an automated data processing system, subject to the following requirements:

1. Sight-Readable Documents vs. Printouts

The system shall be capable of producing sight-readable documents of all dispensing records required by Section 6 of this chapter. In the case of administrative proceedings before the board, records must be provided in paper printout form;

2. **Completeness and Accuracy**

A pharmacist is responsible for the completeness and accuracy of all entries into the system. The system shall be capable of providing a daily printout of the day's prescription drug information. ~~Effective June 30, 2006, the~~ The system or the retail ~~drug outlet~~pharmacy shall also be capable of identifying the individual pharmacists who-

- A. Performed the drug utilization review; and
- B. Performed the final check to ensure that the prescription was correct in all respects and ready for dispensing.

3. **Handwritten Records During Period of Downtime**

If the automated data processing system becomes inoperative and the ~~drug outlet~~pharmacy remains open, the ~~drug outlet~~pharmacy may temporarily revert to handwritten records or other auxiliary recordkeeping system in accordance with the terms of this subsection. The ~~drug outlet~~pharmacy shall ensure that all refills are authorized by the original prescription drug order and that the maximum number of refills is not exceeded. The ~~drug outlet~~pharmacy shall enter into the automatic data processing system all information regarding prescription drug orders that were filled or ~~refilling-refilled~~ during the period of downtime within 96 hours after the automatic data processing system is restored to service. However, nothing in this subsection shall preclude the pharmacist from exercising professional judgment for the benefit of a patient's health or safety.

4. **Data Recovery**

The ~~drug outlet~~pharmacy shall implement reasonable data backup, protection and recovery protocols to retrieve dispensing records created by or stored in the system in the event of human error, power failure, computer malfunction, accident or catastrophe resulting in the loss, destruction or corruption of data. The measures implemented shall be sufficient to provide reasonable continuity of service to the public.

5. **Continuity of Supply**

A ~~drug outlet~~pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the ~~drug outlet~~pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A ~~drug outlet~~pharmacy shall assure continuity in the maintenance of records;

6. **~~Schedule III and IV Controlled Substances~~Drugs**

An automated data processing system used for ~~Schedule III or IV drugs~~controlled drugs must conform to the requirements of 21 CFR §1306.22(b) and (e), as

designated in Chapter 29, §1(6) of the board's rules Parts 1311, 1300, 1304 and 1306 as listed in Section 3(4)(B) of this chapter, as well as all other requirements of this chapter and the board's rules.

8. Transferring Prescriptions for Noncontrolled Drugs

Original prescription drug orders for noncontrolled drugs may be transferred between ~~drug outlets~~ pharmacies for the purpose of refill dispensing provided that the transfer is communicated directly between 2 pharmacists or pharmacy interns, or between a transferring pharmacist or pharmacy intern and a receiving pharmacy technician (~~advanced~~), and the following additional requirements are met:

1. Duties of Transferring Pharmacist

The transferring pharmacist shall:

- A. Enter the following information in the dispensing record of the original prescription drug order created pursuant to Section 6 or 7 of this chapter:
 - (1) A notation that a copy has been issued and that the original prescription is void;
 - (2) The date of the transfer;
 - (3) The name of the transferring pharmacist;
 - (4) The name and address of the ~~drug outlet~~ pharmacy to which the prescription was transferred; and
 - (5) The name of the pharmacist who received the prescription information; and
- B. Not issue further refills once the prescription has been transferred.

2. Duties of Receiving Pharmacist or Pharmacy Technician (~~Advanced~~)

The receiving pharmacist shall:

- A. Enter the word "TRANSFER" in the dispensing record of the transferred prescription drug order created pursuant to Section 5 or 6 of this chapter;
- B. Document the following information in the dispensing record:
 - (1) The name and address of the patient;
 - (2) The name and address of the practitioner;
 - (3) The date of issuance of the original prescription drug order;

- (4) The number of valid refills remaining on the prescription drug order and the date of the most recent refill;
 - (5) The name and address of the transferring ~~drug outlet~~pharmacy and the transferring pharmacist; and
 - (6) The original prescription number from which the prescription information was transferred;
- C. Retain both the original and transferred prescription drug orders as if they were original prescriptions.

3. **Electronic Transfers Between Networked ~~Drug Outlets~~Pharmacies**

~~Drug outlets~~Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among ~~drug outlets~~pharmacies participating in the same common prescription file, provided, however, that any such common file shall contain completed records of each prescription drug order and refill dispensed, and, further, that a hard copy record, or notation on the computer record, of each prescription drug order transferred or accessed for purposes of refilling shall be generated and maintained at the ~~drug outlet~~pharmacy refilling the prescription drug order or to which the prescription drug order is transferred.

4. **Scope of Transfer**

The receiving pharmacist may refill a transferred prescription drug order for up to the number of remaining refills authorized by the transferred prescription drug order or up to 15 months from the date of the original issue, whichever first occurs.

9. **Transferring Prescriptions for Controlled Drugs**

1. **Schedule II Drugs**

A prescription drug order for a Schedule II drug may not be transferred.

2. **Schedule III, IV and V Drugs**

~~The transfer of original prescription information for a controlled substance listed in Schedules III, IV or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only up to the maximum refills permitted by law and the practitioner's authorization. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:~~

- ~~A. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:~~
- ~~(1) Write the word "VOID" on the face of the invalidated prescription.~~
 - ~~(2) Record on the reverse of the invalidated prescription the name, address and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and~~
 - ~~(3) Record the date of the transfer and the name of the pharmacist transferring the information.~~
- ~~B. The pharmacist receiving the transferred prescription information shall reduce to writing the following:~~
- ~~(1) Write the word "transfer" on the face of the transferred prescription;~~
 - ~~(2) Provide all information required to be on a prescription pursuant to 21 CFR §1306.05 and include:~~
 - ~~(a) Date of issuance of original prescription;~~
 - ~~(b) Original number of refills authorized on original prescription;~~
 - ~~(c) Date of original dispensing;~~
 - ~~(d) Number of valid refills remaining and date(s) and locations of previous refill(s);~~
 - ~~(e) Pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;~~
 - ~~(f) Name of pharmacist who transferred the prescription; and~~
 - ~~(g) Pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.~~
- ~~C. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.~~
- The transfer of prescriptions for Schedule III, IV and V drugs for the purpose of refill dispensing is governed by 21 CFR §1306.25, "Transfer Between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances For Refill Purposes" (April 1, 2012) and is incorporated into the board's rules by reference by Section 3(4)(b)(13) of this chapter and Chapter 29, Section 2 of the board's rules.

10. Validity of Prescription Drug Order Upon Unavailability of Practitioner

A pharmacist shall exercise discretion in filling a prescription drug order that was issued by a practitioner who has since become unavailable due to death, disability, retirement, cessation of practice or long-distance relocation. Notwithstanding anything in this chapter to the contrary, a prescription drug order described in this section shall become invalid 6 months after the practitioner first became unavailable.

11. Refusal to Fill

A pharmacist may refuse to fill a prescription or dispense a drug only as permitted by 32 M.R.S.A. §13795(2). A pharmacist not qualified to initiate emergency contraception drug therapy in accordance with 32 M.R.S.A. §§-13821-13825 shall not be deemed to have refused to dispense emergency contraceptives.

[NOTE: 32 M.R.S.A. §13795(2) provides:

2. Refusal to fill prescription or, dispense drug or sell targeted methamphetamine precursor; law enforcement reporting.

A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription or, dispense any drug or sell any targeted methamphetamine precursor if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient, or the intention of the customer to use the drug or targeted methamphetamine precursor according to the instructions for use. A pharmacist or person acting at the direction of a pharmacist may make a report to a law enforcement agency when that person has reasonable cause to suspect that a prescription is not legitimate or appropriate, that a person has presented photographic identification that is not valid or that a customer has the intention to use a drug or targeted methamphetamine precursor in a manner inconsistent with the directions for use.]

12. Security

A drug outlet pharmacy shall ensure the security and confidentiality of prescription drug orders, dispensing records, patient profiles and all other patient records.

STATUTORY AUTHORITY: 22 M.R.S.A. §-2681(6); 32 M.R.S.A. §§-13720, 13721(1), 13722, 13723, 13781, 13785, 13786-A, 13794, 13795

EFFECTIVE DATE:

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Part 4 - Dispensing Prescription Drugs

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 19: RECEIPT AND HANDLING OF PRESCRIPTION DRUG ORDERS

Summary: This chapter sets forth requirements for creating, transmitting, filling and transferring prescription drug orders.

1. General Requirements for Prescription Drug Orders

1. Required Information

Prescription drug orders shall contain, at a minimum, the following information:

- A. Date of issuance by practitioner;
- B. Name and address of the patient [or patient location if an institution];
- C. Name and address of the practitioner [if not a staff physician at an institution];
- D. DEA number of practitioner [in the case of controlled substances];
- E. Name, strength, dosage form and quantity [or stop date, and route of administration] of drug prescribed;
- F. Refills authorized; and
- G. Directions for use by patient.

2. Verification

The pharmacist who receives a prescription drug order shall record the order and verify the identity of the practitioner and, if applicable, the identity and authority of the practitioner's agent.

2. Requirements for Prescription Drug Orders for Controlled Substances

1. Schedule II Drugs

No pharmacist may fill a written prescription drug order from a Maine health care provider for a Schedule II drug that does not comply with Chapter 1 of the rules of the Department of Public Safety, Maine Drug Enforcement Agency, entitled "Requirements for Written Prescriptions of Schedule II Drugs," adopted May 30, 2002 and effective January 1, 2003. The board hereby incorporates Chapter 1 into this chapter by reference. A copy of the rule may be obtained from-

Department of Public Safety
Maine Drug Enforcement Agency
166 State House Station
Augusta, ME 04333-0166

[NOTE: PL 2003, c. 326, amending 32 MRSA §13786-A(2)-(4), sets forth special requirements for filling a prescription drug order for a Schedule II drug written by an out-of-state practitioner.]

2. All Controlled Substances

- A. A controlled substance may not be pre-printed on a prescription blank.
- B. No pharmacist may fill a prescription drug order for a controlled substance that is presented to the pharmacist more than 90 days after the date of the prescription.

3. Additional Requirements for Specific Forms of Prescription Drug Orders

1. Telephone Prescription Drug Orders

A pharmacist or pharmacy intern may accept an original or renewal prescription drug order telephoned to a pharmacy by a practitioner or authorized agent of the practitioner. A pharmacy technician may accept an original or renewal prescription drug order telephoned to a pharmacy by a practitioner or authorized agent of the practitioner to the extent authorized by the pharmacist on duty.

2. Facsimile Prescription Drug Orders

- A. A pharmacist, pharmacy intern or pharmacy technician may accept a prescription drug order transmitted by facsimile machine or facsimile computer software directly to a pharmacy. Facsimile transmission of prescription drug orders for Schedule II controlled drugs is subject to the requirements of 21 CFR §1306.11(a), (e), (f) and (g).

[NOTE: Title 21 CFR §1306.11(a), (e), (f) and (g) require that the original manually-signed prescription for a Schedule II controlled

drug must be presented to the pharmacist before the actual dispensing of the medication, except in the case of certain compounded substances, prescriptions written for a resident of a long term care facility, or prescriptions written for a patient enrolled in a hospice care program. For these prescriptions, the facsimile serves as the original written prescription.]

- B. The prescription must contain the name of the practitioner and the authorized agent of the practitioner, if applicable, the date and time of the transmission, and the name of the pharmacy intended to receive the transmission.
- C. If the person transmitting a prescription drug order by facsimile is the patient or authorized agent of the patient, the original prescription must be presented by the patient or authorized agent at the time the prescription is dispensed.
- D. A pharmacy shall use a non-fading or bond paper to ensure the preservation of facsimile prescription drug orders for a period of 2 years.

3. Electronic Prescriptions for Noncontrolled Drugs

- A. The prescription shall contain the electronic signature of the practitioner or the authorized agent of the practitioner, if applicable.
- B. The prescription shall be electronically protected to prevent access, alteration or use by an unauthorized person.
- C. A pharmacist, pharmacy intern or pharmacy technician who accepts a prescription sent by electronic mail, hypertext transport protocol or other internet protocol shall enter his or her initials into the dispensing record.
- D. Only a pharmacist, pharmacy intern or pharmacy technician shall have access to a computer used to receive or retrieve prescription drug orders sent by electronic mail, hypertext transport protocol or other internet protocol.
- E. A pharmacy shall implement reasonable data backup, protection and recovery protocols to retrieve electronically-stored prescription drug orders in the event of human error, power failure, computer malfunction, accident or catastrophe resulting in the loss, destruction or corruption of data. The measures implemented shall be sufficient to provide reasonable continuity of service to the public.

4. Electronic Prescriptions for Controlled Drugs

- A. A pharmacist and pharmacy may process and fill an electronic prescription for a controlled drug only if:
 - (1) The prescription was issued (i.e., prepared, electronically signed and transmitted) by an authenticated practitioner in conformity with the federal rule provisions identified in paragraph B below; and

- (2) The pharmacist and pharmacy complied in all respects with the federal rule provisions identified in paragraph B below that impose duties and responsibilities on pharmacists and pharmacies:
- B. The following DEA rules apply to electronic prescriptions for controlled drugs processed and filled by pharmacists and pharmacies that are subject to the jurisdiction of the board and are incorporated into this chapter by reference:
- (1) 21 CFR Part 1311, “Requirements for Electronic Orders and Prescriptions”(April 1, 2012), and the following provisions of 21 CFR Parts 1300, 1304 and 1306 (April 1, 2012) to the extent such provisions apply to electronic prescriptions:
 - (2) Section 1300.03, “Definitions Relating to Electronic Orders for Controlled Substances and Electronic Prescriptions for Controlled Substances;”
 - (3) Section 1304.03, “Persons Required to Keep Records and File Reports,” paragraphs (c) and (h);
 - (4) Section 1304.04, “Maintenance of Records and Inventories,” paragraphs (b) and (h);
 - (5) Section 1304.06, “Records and Reports for Electronic Prescriptions;”
 - (6) Section 1306.05, “Manner of Issuance of Prescriptions,” paragraph (e);
 - (7) Section 1306.08, “Electronic Prescriptions;”
 - (8) Section 1306.11, “Requirement of Prescription,” paragraphs (a), (c), (d)(1) and (d)(4);
 - (9) Section 1306.13, “Partial Filling of Prescriptions, paragraph (a);
 - (10) Section 1306.15, “Provision of Prescription Information Between Retail Pharmacies and Central Fill Pharmacies for Prescriptions of Schedule II Controlled Substances,” paragraph (a)(1);
 - (11) Section 1306.21, “Requirement of Prescription,” paragraphs (a) and (c);
 - (12) Section 1306.22, “Refilling of Prescriptions,” and
 - (13) Section 1306.25, “Transfer Between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances For Refill Purposes;”

C. Copies of the DEA rules identified in paragraph B above may be obtained as follows:

- (1) Original publication in the Federal Register, 75 Fed.Reg. 16236–16319, March 31, 2010, as clarified in 76 Fed.Reg. 64813–64816, October 19, 2011, obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>

- (2) Codification in the Code of Federal Regulations, 21 CFR Parts 1300, 1304, 1306 and 1311 (revised as of April 1, 2012), obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>

- (3) Correction to inadvertent omission of §1300.03 from the April 1, 2012 codification of 21 CFR Part 1300, published in the Federal Register, 77 Fed.Reg. 58767-56769, September 24, 2012, obtainable from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>

4. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 MRSA §2681 *et seq.*, the pharmacy shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3rd party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

5. Life of Prescription Drug Orders for Noncontrolled Drugs

A pharmacist may fill a prescription drug order for a noncontrolled drug for a period no greater than 15 months from the date written.

6. Dispensing Records

A pharmacy shall create a dispensing record for each original, refill and transferred prescription drug order that it fills. The dispensing record must include, at a minimum, the following information:

1. The original written or faxed prescription drug order, or record of a telephone or computer prescription drug order;
2. Quantity dispensed, if different than the quantity specified in the prescription drug order;
3. Date of dispensing;
4. Prescription number or its equivalent;
5. Identifiers (e.g., initials) for the individual pharmacists who-
 - A. Performed the drug utilization review; and
 - B. Performed the final check to ensure that the prescription was correct in all respects and ready for dispensing.

The pharmacist is responsible for all work done by others to which the pharmacist has affixed his identifier or permitted another to do so.

6. Documentation of compliance with 32 MRSA §13781, relating to generic and therapeutically equivalent substitution; and
7. Records of refills to date.

7. Automated Data Processing System

A pharmacy may employ an automated data processing system, subject to the following requirements:

1. Sight-Readable Documents vs. Printouts

The system shall be capable of producing sight-readable documents of all dispensing records required by Section 6 of this chapter. In the case of administrative proceedings before the board, records must be provided in paper printout form;

2. Completeness and Accuracy

A pharmacist is responsible for the completeness and accuracy of all entries into the system. The system shall be capable of providing a daily printout of the day's prescription drug information. The system or the retail pharmacy shall also be capable of identifying the individual pharmacists who-

- A. Performed the drug utilization review; and
- B. Performed the final check to ensure that the prescription was correct in all respects and ready for dispensing.

3. Handwritten Records During Period of Downtime

If the automated data processing system becomes inoperative and the pharmacy remains open, the pharmacy may temporarily revert to handwritten records or other auxiliary recordkeeping system in accordance with the terms of this subsection. The pharmacy shall ensure that all refills are authorized by the original prescription drug order and that the maximum number of refills is not exceeded. The pharmacy shall enter into the automatic data processing system all information regarding prescription drug orders that were filled or refilled during the period of downtime within 96 hours after the automatic data processing system is restored to service. However, nothing in this subsection shall preclude the pharmacist from exercising professional judgment for the benefit of a patient's health or safety.

4. Data Recovery

The pharmacy shall implement reasonable data backup, protection and recovery protocols to retrieve dispensing records created by or stored in the system in the event of human error, power failure, computer malfunction, accident or catastrophe resulting in the loss, destruction or corruption of data. The measures implemented shall be sufficient to provide reasonable continuity of service to the public.

5. Continuity of Supply

A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier terminates for any reason. A pharmacy shall assure continuity in the maintenance of records;

6. Controlled Drugs

An automated data processing system used for controlled drugs must conform to the requirements of 21 CFR Parts 1311, 1300, 1304 and 1306 as listed in Section 3(4)(B) of this chapter, as well as all other requirements of this chapter and the board's rules.

8. Transferring Prescriptions for Noncontrolled Drugs

Original prescription drug orders for noncontrolled drugs may be transferred between pharmacies for the purpose of refill dispensing provided that the transfer is communicated directly between 2 pharmacists or pharmacy interns, or between a transferring pharmacist or pharmacy intern and a receiving pharmacy technician, and the following additional requirements are met:

1. Duties of Transferring Pharmacist

The transferring pharmacist shall:

- A. Enter the following information in the dispensing record of the original prescription drug order created pursuant to Section 6 or 7 of this chapter:

- (1) A notation that a copy has been issued and that the original prescription is void;
- (2) The date of the transfer;
- (3) The name of the transferring pharmacist;
- (4) The name and address of the pharmacy to which the prescription was transferred; and
- (5) The name of the pharmacist who received the prescription information; and

B. Not issue further refills once the prescription has been transferred.

2. Duties of Receiving Pharmacist or Pharmacy Technician

The receiving pharmacist shall:

- A. Enter the word "TRANSFER" in the dispensing record of the transferred prescription drug order created pursuant to Section 5 or 6 of this chapter;
- B. Document the following information in the dispensing record:
 - (1) The name and address of the patient;
 - (2) The name and address of the practitioner;
 - (3) The date of issuance of the original prescription drug order;
 - (4) The number of valid refills remaining on the prescription drug order and the date of the most recent refill;
 - (5) The name and address of the transferring pharmacy and the transferring pharmacist; and
 - (6) The original prescription number from which the prescription information was transferred;
- C. Retain both the original and transferred prescription drug orders as if they were original prescriptions.

3. Electronic Transfers Between Networked Pharmacies

Pharmacies accessing a common electronic file or database used to maintain required dispensing information are not required to transfer prescription drug orders or information for dispensing purposes between or among pharmacies participating in the same common prescription file, provided, however, that any such common file

shall contain completed records of each prescription drug order and refill dispensed, and, further, that a hard copy record, or notation on the computer record, of each prescription drug order transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order or to which the prescription drug order is transferred.

4. Scope of Transfer

The receiving pharmacist may refill a transferred prescription drug order for up to the number of remaining refills authorized by the transferred prescription drug order or up to 15 months from the date of the original issue, whichever first occurs.

9. Transferring Prescriptions for Controlled Drugs

1. Schedule II Drugs

A prescription drug order for a Schedule II drug may not be transferred.

2. Schedule III, IV and V Drugs

The transfer of prescriptions for Schedule III, IV and V drugs for the purpose of refill dispensing is governed by 21 CFR §1306.25, “Transfer Between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances For Refill Purposes” (April 1, 2012) and is incorporated into the board’s rules by reference by Section 3(4)(b)(13) of this chapter and Chapter 29, Section 2 of the board’s rules.

10. Validity of Prescription Drug Order Upon Unavailability of Practitioner

A pharmacist shall exercise discretion in filling a prescription drug order that was issued by a practitioner who has since become unavailable due to death, disability, retirement, cessation of practice or long-distance relocation. Notwithstanding anything in this chapter to the contrary, a prescription drug order described in this section shall become invalid 6 months after the practitioner first became unavailable.

11. Refusal to Fill

A pharmacist may refuse to fill a prescription or dispense a drug only as permitted by 32 MRSA §13795(2). A pharmacist not qualified to initiate emergency contraception drug therapy in accordance with 32 MRSA §§13821-13825 shall not be deemed to have refused to dispense emergency contraceptives.

[NOTE: 32 MRSA §13795(2) provides:

2. Refusal to fill prescription, dispense drug or sell targeted methamphetamine precursor; law enforcement reporting.

A pharmacist or person acting at the direction of a pharmacist may exercise discretion and refuse to fill any prescription, dispense any drug or sell any targeted methamphetamine precursor if unsatisfied as to the legitimacy or appropriateness of any prescription presented, the validity of any photographic identification or the identity of any patient presenting a prescription or any person acting on behalf of the patient, or the intention of the customer to use the drug or targeted methamphetamine precursor according to the instructions for use. A pharmacist or person acting at the direction of a pharmacist may make a report to a law enforcement agency when that person has reasonable cause to suspect that a prescription is not legitimate or appropriate, that a person has presented photographic identification that is not valid or that a customer has the intention to use a drug or targeted methamphetamine precursor in a manner inconsistent with the directions for use.]

12. Security

A pharmacy shall ensure the security and confidentiality of prescription drug orders, dispensing records, patient profiles and all other patient records.

STATUTORY AUTHORITY: 22 MRS.A §2681(6); 32 MRSA §§13720, 13721(1), 13722, 13723, 13781, 13785, 13786-A, 13794, 13795

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 19
RECEIPT AND HANDLING OF PRESCRIPTION DRUG ORDERS
ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter sets forth requirements for creating, transmitting, filling and transferring prescription drug orders. In the amendments to this chapter the board made the following changes.

- Authorized pharmacy technicians to accept original prescription drug orders by telephone. (See the discussion in the Basis Statement and Response to Comments to Chapter 7.)
- Referenced DEA rules with respect to the types of prescription drug orders for controlled drugs that may be transmitted by facsimile.
- Incorporated by reference DEA rules authorizing a pharmacist and pharmacy to process and fill electronic prescriptions for a controlled drug.
- Incorporated by reference into this chapter DEA rules governing the transfer of prescriptions for controlled drugs as a substitute for the DEA rule text that is re-stated in the current board rule. The board sees no reason to diverge from the text of the DEA rule.

The predecessor chapter authorized electronic prescriptions for noncontrolled drugs only. Since that time the DEA has promulgated a comprehensive regulatory regime that permits electronic prescriptions for controlled drugs. The board has left its earlier rule (Section 3(3)) in place for noncontrolled drugs and has incorporated by reference into this chapter the DEA rule governing electronic prescriptions for controlled drugs. The board sees no reason to adopt additional, Maine-specific requirements relating to electronic prescriptions for controlled drugs.

Response to Comments

Douglas S. Carr
CARR CONSULTING
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
(oral and written)

- Section 4. The board is commended for recognizing the importance of implementing regulation to facilitate electronic prescribing of controlled drugs. E-prescribing is now in most states. The commenter urged the board to work closely with the Maine Drug Enforcement Agency (MDEA) to overcome any perceived regulatory conflicts that may exist.

Anne Fellows, Regional State Director
National Association of Chain Drug Stores
413 North Lee St., PO Box 1417-D49
Alexandria VA 22313-1480
(oral and written)

- Section 3(4). NACDS supports the rule proposal for electronic prescribing of controlled substances and encourages the board to work with the MDEA on any possible conflicting regulations (*DPS/MDEA Chapter 1, Requirements for Written Prescriptions of Schedule II Drugs*).

Stephen J. Kelleher, JR., FACHE
48 Johnson Heights
Waterville ME 04901
(written)

- The commenter commends the board for “embracing the spirit and intent of the DEA’s IFR which sets out the terms and conditions for Maine providers and pharmacies to use EPCS in their respective practice settings.” The commenter echoed Anne Fellows’ concern about the possibility of regulatory inconsistency and/or ambiguity with DPS/MDEA Chapter 1. The commenter encouraged the board to work with MDEA to resolve any potential problems so as not to discourage pharmacists from using EPCS for Schedule II drugs and setting their sights only on Schedules III – V.
 - ◆ *Board Response to the foregoing comments:* There is no conflict between the Maine Drug Enforcement rule cited by the commenters and this chapter. MDEA Chapter 1 and the statute it implements, 32 MRSA §13786-A(1), clearly apply only to written prescriptions for Schedule II drugs, not to electronic prescriptions. This was confirmed in an email message dated September 4, 2013 from MDEA director Roy McKinney to pharmacy board administrator Geraldine Betts.

Michael Miller
Assistant Attorney General
(written)

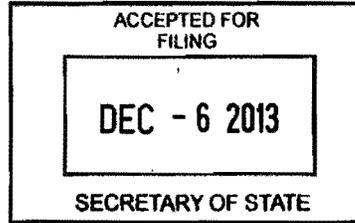
- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-308

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Automated Pharmacy Systems
4. Chapter number assigned to the rule: 20
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13 (date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 20: AUTOMATED PHARMACY SYSTEMS**

Summary: This chapter sets forth requirements for automated pharmacy systems.

**SUBCHAPTER 1
(RETAIL PHARMACIES)****1. Scope**

The provisions of this subchapter apply to automated pharmacy systems that are wholly located in a retail pharmacy.

2. General Use; Control by Pharmacist

An automated pharmacy system may be used for a patient profile dispensing system only if operation of the system is controlled by a pharmacist in all respects. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system.

3. Access to Automated Pharmacy System

Only a pharmacist, pharmacy intern or a pharmacy technician working under the direct supervision of a pharmacist as described in Chapter 1, Section ~~14(A)~~14(1) and ~~Chapter 7, Section 4(3)~~ of the board's rules, or a person legally qualified under a health practice act to administer drugs may stock, remove or label drugs from an automated pharmacy system. No person with access to an automated pharmacy system shall remove more drugs than necessary to fill a prescription.

4. Verification

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and verify appropriate quantity and dosage. The pharmacist shall verify the order prior to dispensation of the drug to the patient or the patient's authorized representative.

5. Responsibilities of Pharmacist on Duty

The pharmacist on duty shall:

1. Directly supervise the stocking of previously packaged and labeled drug units into an automated pharmacy system; and
2. Directly supervise the removal of the drug from an automated pharmacy system and the final labeling of the drug after removal from an automated pharmacy system.

6. Physical Security; Unauthorized Access

A dispensing machine must be kept locked except when unlocking is necessary for loading or servicing. An automated pharmacy system must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

7. Training

All persons given access to an automated pharmacy system must be adequately trained in the operation of the system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

8. Development of Procedures

The pharmacist in charge shall develop, implement, and maintain procedures for the safe and effective use of medications dispensed via an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading and unloading of drugs, and records of the dispensing of drugs, are electronically tracked and recorded by the system and maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. The automated pharmacy system has a documented and ongoing quality assurance program that monitors total system performance;
4. Timely and documented maintenance is performed on the automated pharmacy system in accordance with the manufacturer's recommendations;

5. The purity, potency, and integrity of the drugs contained in the automated pharmacy system shall be preserved;
6. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules; and
7. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
8. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
9. Requirements for controlled substances security are met.

SUBCHAPTER 2

(INSTITUTIONAL PHARMACIES)

1. Scope

The provisions of this subchapter apply to automated pharmacy systems that are located in a rural health center or free clinic; or in a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center (other than a licensed pharmacy), penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board.

2. General Use; Control by Pharmacist

An automated pharmacy system may be used for maintaining patient care unit medication inventories or for a patient profile dispensing system only if the system is under the supervision of a pharmacist in charge and is controlled by a pharmacist at all times. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the dispensing machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system or a dispensing machine at a point of care location.

3. Remote Dispensing

An automated pharmacy system may dispense drugs at one or more point of care locations remote from the pharmacist in charge of the system or the pharmacist on duty. The pharmacist in charge and pharmacist on duty need not be physically present at the point of care location and need not be located within the State. However, such pharmacists must be licensed in Maine and must be in good standing with the board.

4. Access to Automated Pharmacy System

1. Health Care Professionals; Corrections Personnel

Only a pharmacist, allopathic physician, osteopathic physician, certified nurse practitioner, registered nurse, licensed practical nurse, physician's assistant, dentist, podiatrist, or appropriately-trained corrections personnel specifically designated by the warden, superintendent, director or chief administrative officer in charge of a penal institution may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location; and
- D. Perform other functions related to an automated pharmacy system.

Except as set forth in subsection 2 below, none of the foregoing duties may be performed by a medical technician, medical assistant, certified nursing assistant, mental health rehabilitation technician or any other person whose profession or occupation is not listed in this subsection.

2. Pharmacy Technicians ~~(advanced)~~

A pharmacy technician ~~(advanced)~~ or pharmacy intern working under the direct supervision of a pharmacist as defined in Chapter 1, Section ~~14(A), (B) or (C)~~ 14(3) of the board's rules and as referenced in Chapter 7, Section ~~7(1)(B)~~ 5(2) of the board's rules may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location for quality assurance purposes or to carry out a change in formulary; and

- D. Perform other functions related to an automated pharmacy system except for the removal of drugs from a dispensing machine at a point of care location for purposes of administration or dispensing to patients.

No person with access to a dispensing machine may remove more drugs than necessary to fill a prescription or meet the immediate needs of a patient in a hospital or institution.

5. Verification of Prescription Medication to be Dispensed by an Automated Pharmacy System

An automated pharmacy system must use bar code scans or other technology to ensure that the prescription medication to be loaded into a dispensing machine at a point of care location is the intended drug in the intended strength, dosage form and quantity. The pharmacist in charge or pharmacist on duty shall verify that the canisters, pockets or containers to be inserted into the dispensing machine have been properly filled and labeled.

6. Transport and Delivery

Prescription medication to be dispensed by an automated pharmacy system must be transported by courier in locked, tamper-evident carriers to the point of care location for loading into a dispensing machine. The pharmacy or institution receiving the prescription medication shall maintain a delivery log showing the name of the sending pharmacy and pharmacist on duty, the name and employer of the courier, the date and time of delivery, the drugs delivered, and the name of the person accepting delivery on behalf of the pharmacy or institution.

7. Insertion of Canisters, Pockets or Containers into Dispensing Machine

A dispensing machine at a point of care location must use bar code scans or other technology to ensure that the contents of a canister, pocket or container are accurately recognized by the machine.

8. Dispensing of Drugs

A dispensing machine at a point of care location must dispense medications exactly in accordance with the prescriptions entered into the automated pharmacy system. A dispensing machine at a point of care location may only dispense patient-specific drugs to fill an immediate need.

9. Verification of Prescription Drug Order; No Final Check Required**1. Verification**

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and confirm appropriate quantity and dosage. The pharmacist shall verify the order as soon as practicable after administration of the drug to the patient or resident, but in no event more than 28 hours afterwards.

2. No Final Check

No final check on the filled prescription need be performed.

10. Security; Restricted Access

A dispensing machine at a point of care location must be kept locked except when unlocking is necessary for loading or servicing. The dispensing machine must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

11. Video Surveillance; 2-Way Communication; Availability of Pharmacist**1. Video Surveillance**

A dispensing machine at a point of care location must be under video surveillance by the pharmacist in charge or pharmacist on duty 24 hours per day, 7 days per week. Video surveillance consists of separate video cameras trained on the front face of the machine and all other sides of the machine that open for loading. The cameras must be set up so as to facilitate visual identification of persons who service, stock, log on to or remove product from the machine. The video cameras must continually transmit color images at a frame rate no less than 15 frames per second.

The board may grant a waiver from this requirement in whole or in part upon a showing that other security measures in place at the point of care location provide equivalent protection to the requirements of this subsection.

2. 2-Way Communication

There must also be a 2-way, real-time voice and video communication link in operation at all times (24/7) between the pharmacist in charge or pharmacist on duty and any person who services, stocks, logs on to or removes product from the machine.

3. Availability of Pharmacist

A pharmacist must be available by telephone at all times (24/7) to consult with a pharmacy technician (~~advanced~~) or person legally qualified under a health care act to administer drugs regarding any drug dispensed by an automated pharmacy system if a pharmacist is not available at the point of care location where the drug is dispensed.

12. Training

All persons given access to a dispensing machine at a point of care location must be adequately trained in the operation of the automated pharmacy system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

13. Development of Procedures

The pharmacist in charge shall develop, implement, maintain and follow procedures for the safe and effective use of drugs dispensed from an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading, unloading, and returning of canisters, and records of the dispensing of drugs, are electronically tracked and recorded by the system and are maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. Before an automated pharmacy system is deployed at a new point of care location, the pharmacist in charge has tested and validated the system to ensure that the system is releasing drugs properly;
4. The pharmacist in charge monitors an automated pharmacy system for proper use and tests the accuracy of the system at least every 6 months, and whenever any change or upgrade is made to the system;
5. Timely and documented maintenance is performed on the dispensing machine and all other components of an automated pharmacy system in accordance with the manufacturer's recommendations;
6. The purity, potency, and integrity of the drugs contained in the automated pharmacy system is preserved;

7. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules;
8. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
9. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
10. Requirements for controlled substances security are met.

14. Waiver: Hospital Pharmacies

For good cause shown, the board may waive or modify any of the requirements of this Subchapter upon application by a hospital pharmacy. As part of its application, the hospital pharmacy shall demonstrate that alternate means of achieving the goal of the requirement at issue can be implemented.

STATUTORY AUTHORITY: 32 M.R.S.A. §§-13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

EFFECTIVE DATE:

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without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 20: AUTOMATED PHARMACY SYSTEMS**

Summary: This chapter sets forth requirements for automated pharmacy systems.

**SUBCHAPTER 1
(RETAIL PHARMACIES)****1. Scope**

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2. General Use; Control by Pharmacist

An automated pharmacy system may be used for a patient profile dispensing system only if operation of the system is controlled by a pharmacist in all respects. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system.

3. Access to Automated Pharmacy System

Only a pharmacist, pharmacy intern or a pharmacy technician working under the direct supervision of a pharmacist as described in Chapter 1, Section 14(1) of the board's rules, or a person legally qualified under a health practice act to administer drugs may stock, remove or label drugs from an automated pharmacy system. No person with access to an automated pharmacy system shall remove more drugs than necessary to fill a prescription.

4. Verification

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and verify appropriate quantity and dosage. The pharmacist shall verify the order prior to dispensation of the drug to the patient or the patient's authorized representative.

5. Responsibilities of Pharmacist on Duty

The pharmacist on duty shall:

1. Directly supervise the stocking of previously packaged and labeled drug units into an automated pharmacy system; and
2. Directly supervise the removal of the drug from an automated pharmacy system and the final labeling of the drug after removal from an automated pharmacy system.

6. Physical Security; Unauthorized Access

A dispensing machine must be kept locked except when unlocking is necessary for loading or servicing. An automated pharmacy system must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

7. Training

All persons given access to an automated pharmacy system must be adequately trained in the operation of the system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

8. Development of Procedures

The pharmacist in charge shall develop, implement, and maintain procedures for the safe and effective use of medications dispensed via an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading and unloading of drugs, and records of the dispensing of drugs, are electronically tracked and recorded by the system and maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. The automated pharmacy system has a documented and ongoing quality assurance program that monitors total system performance;
4. Timely and documented maintenance is performed on the automated pharmacy system in accordance with the manufacturer's recommendations;

5. The purity, potency, and integrity of the drugs contained in the automated pharmacy system shall be preserved;
6. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules; and
7. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
8. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
9. Requirements for controlled substances security are met.

SUBCHAPTER 2 (INSTITUTIONAL PHARMACIES)

1. **Scope**

The provisions of this subchapter apply to automated pharmacy systems that are located in a rural health center or free clinic; or in a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center (other than a licensed pharmacy), penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board.

2. **General Use; Control by Pharmacist**

An automated pharmacy system may be used for maintaining patient care unit medication inventories or for a patient profile dispensing system only if the system is under the supervision of a pharmacist in charge and is controlled by a pharmacist at all times. For purposes of this chapter, such control includes but is not limited to the ability to fill prescription drug orders; control access to the machine; permit, block and monitor all stocking and dispensing activity; check inventory levels inside the dispensing machine; authenticate users of the system; authorize different levels of user access to the system; and deactivate or shut down the system or a dispensing machine at a point of care location.

3. Remote Dispensing

An automated pharmacy system may dispense drugs at one or more point of care locations remote from the pharmacist in charge of the system or the pharmacist on duty. The pharmacist in charge and pharmacist on duty need not be physically present at the point of care location and need not be located within the State. However, such pharmacists must be licensed in Maine and must be in good standing with the board.

4. Access to Automated Pharmacy System

1. Health Care Professionals; Corrections Personnel

Only a pharmacist, allopathic physician, osteopathic physician, certified nurse practitioner, registered nurse, licensed practical nurse, physician's assistant, dentist, podiatrist, or appropriately-trained corrections personnel specifically designated by the warden, superintendent, director or chief administrative officer in charge of a penal institution may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location; and
- D. Perform other functions related to an automated pharmacy system.

Except as set forth in subsection 2 below, none of the foregoing duties may be performed by a medical technician, medical assistant, certified nursing assistant, mental health rehabilitation technician or any other person whose profession or occupation is not listed in this subsection.

2. Pharmacy Technicians

A pharmacy technician or pharmacy intern working under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(3) of the board's rules and as referenced in Chapter 7, Section 5(2) of the board's rules may:

- A. Accept delivery of prescription medication to be loaded into a dispensing machine at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location for quality assurance purposes or to carry out a change in formulary; and

- D. Perform other functions related to an automated pharmacy system except for the removal of drugs from a dispensing machine at a point of care location for purposes of administration or dispensing to patients.

No person with access to a dispensing machine may remove more drugs than necessary to fill a prescription or meet the immediate needs of a patient in a hospital or institution.

5. Verification of Prescription Medication to be Dispensed by an Automated Pharmacy System

An automated pharmacy system must use bar code scans or other technology to ensure that the prescription medication to be loaded into a dispensing machine at a point of care location is the intended drug in the intended strength, dosage form and quantity. The pharmacist in charge or pharmacist on duty shall verify that the canisters, pockets or containers to be inserted into the dispensing machine have been properly filled and labeled.

6. Transport and Delivery

Prescription medication to be dispensed by an automated pharmacy system must be transported by courier in locked, tamper-evident carriers to the point of care location for loading into a dispensing machine. The pharmacy or institution receiving the prescription medication shall maintain a delivery log showing the name of the sending pharmacy and pharmacist on duty, the name and employer of the courier, the date and time of delivery, the drugs delivered, and the name of the person accepting delivery on behalf of the pharmacy or institution.

7. Insertion of Canisters, Pockets or Containers into Dispensing Machine

A dispensing machine at a point of care location must use bar code scans or other technology to ensure that the contents of a canister, pocket or container are accurately recognized by the machine.

8. Dispensing of Drugs

A dispensing machine at a point of care location must dispense medications exactly in accordance with the prescriptions entered into the automated pharmacy system. A dispensing machine at a point of care location may only dispense patient-specific drugs to fill an immediate need.

9. Verification of Prescription Drug Order; No Final Check Required**1. Verification**

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergies and drug interactions, prevent therapeutic duplication, and confirm appropriate quantity and dosage. The pharmacist shall verify the order as soon as practicable after administration of the drug to the patient or resident, but in no event more than 28 hours afterwards.

2. No Final Check

No final check on the filled prescription need be performed.

10. Security; Restricted Access

A dispensing machine at a point of care location must be kept locked except when unlocking is necessary for loading or servicing. The dispensing machine must be electronically protected against unauthorized access, and must be constructed and installed in such manner as to prevent tampering, break-in and theft of inventory.

11. Video Surveillance; 2-Way Communication; Availability of Pharmacist**1. Video Surveillance**

A dispensing machine at a point of care location must be under video surveillance by the pharmacist in charge or pharmacist on duty 24 hours per day, 7 days per week. Video surveillance consists of separate video cameras trained on the front face of the machine and all other sides of the machine that open for loading. The cameras must be set up so as to facilitate visual identification of persons who service, stock, log on to or remove product from the machine. The video cameras must continually transmit color images at a frame rate no less than 15 frames per second.

The board may grant a waiver from this requirement in whole or in part upon a showing that other security measures in place at the point of care location provide equivalent protection to the requirements of this subsection.

2. 2-Way Communication

There must also be a 2-way, real-time voice and video communication link in operation at all times (24/7) between the pharmacist in charge or pharmacist on duty and any person who services, stocks, logs on to or removes product from the machine.

3. Availability of Pharmacist

A pharmacist must be available by telephone at all times (24/7) to consult with a pharmacy technician or person legally qualified under a health care act to administer drugs regarding any drug dispensed by an automated pharmacy system if a pharmacist is not available at the point of care location where the drug is dispensed.

12. Training

All persons given access to a dispensing machine at a point of care location must be adequately trained in the operation of the automated pharmacy system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

13. Development of Procedures

The pharmacist in charge shall develop, implement, maintain and follow procedures for the safe and effective use of drugs dispensed from an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading, unloading, and returning of canisters, and records of the dispensing of drugs, are electronically tracked and recorded by the system and are maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. Before an automated pharmacy system is deployed at a new point of care location, the pharmacist in charge has tested and validated the system to ensure that the system is releasing drugs properly;
4. The pharmacist in charge monitors an automated pharmacy system for proper use and tests the accuracy of the system at least every 6 months, and whenever any change or upgrade is made to the system;
5. Timely and documented maintenance is performed on the dispensing machine and all other components of an automated pharmacy system in accordance with the manufacturer's recommendations;
6. The purity, potency, and integrity of the drugs contained in the automated pharmacy system is preserved;

7. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules;
8. In the event of a consumer-level recall, the pharmacist in charge can access records of all drugs that have been secured in the automated pharmacy system;
9. The pharmacist in charge develops and maintains a comprehensive backup strategy and disaster recovery plan for use in the event of a technical malfunction resulting from loss of power or internet connectivity or a system malfunction; and
10. Requirements for controlled substances security are met.

14. Waiver: Hospital Pharmacies

For good cause shown, the board may waive or modify any of the requirements of this Subchapter upon application by a hospital pharmacy. As part of its application, the hospital pharmacy shall demonstrate that alternate means of achieving the goal of the requirement at issue can be implemented.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 20
AUTOMATED PHARMACY SYSTEMS
ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter sets forth requirements for automated pharmacy systems. In the amendments to this chapter the board made the following changes:

- Deleted references to the deleted license category of pharmacy technician (advanced). (See the discussion in the Basis Statement and Response to Comments to Chapter 7.)
- Authorized the board to waive requirements of this chapter relating to automated pharmacy systems in hospitals.

On March 12, 2013 LD 993, "Resolve, To Amend Maine Board of Pharmacy Rules Regarding Automated Pharmacy Systems in Hospitals" was introduced. LD 993 provided "[t]hat the Department of Professional and Financial Regulation, Maine Board of Pharmacy shall amend its rules pertaining to automated pharmacy systems to exempt hospital pharmacies from the rules."

LD 993 was reported ought not to pass and went no further. The bill nonetheless prompted the board to examine the suitability of the automated pharmacy systems rule to hospitals.

The current automated pharmacy system rule was substantially revised in 2012. In that rulemaking proceeding and subsequently, hospital pharmacists maintained that many provisions of this chapter were unworkable in a hospital setting. In this rulemaking proceeding the board accordingly adopted new Section 14, which institutes a waiver procedure for hospital pharmacies:

For good cause shown, the board may waive or modify any of the requirements of this Subchapter upon application by a hospital pharmacy. As part of its application, the hospital pharmacy shall demonstrate that alternate means of achieving the goal of the requirement at issue can be implemented.

Response to Comments

Mark Polli, R.Ph., Director, Pharmacy Government & Regulatory Affairs
Delhaize America Shared Services Group, LLC
145 Pleasant Hill Rd.
Scarborough ME 04074
(written)

- Subchapter 1, Section 8(1). The board should add an exception that a password and username beyond the pharmacy software is not needed if the dispensing system is located in a board-licensed facility with adequate enclosures and alarm system. The commenter does not believe that drugs contained in a dispensing system are at any greater risk than inventory of drugs on shelves in a pharmacy.
 - ◆ *Board Response:* The board declines to amend the rule as requested. The addition requested by the commenter was not part of the proposed rule. Also, the board's experience is that the systems themselves allow the bypass requested by the commenter.

Jeffrey Austin
Maine Hospital Association
Representing 39 community-governed hospitals
(written)

- Subchapter 2, Section 11(1) and (2), Section 14. The board regulates pharmacy-related activities and DHHS licenses and regulates hospitals and hospital-based pharmacies. The practice of pharmacy is performed by pharmacists licensed by the board; however, not all hospital-based pharmacies are licensed by the board. The split regulatory authority over hospital-based pharmacies creates complications when attempting to comply with individual regulatory requirements. Hospital-based pharmacies must abide by federally imposed standards known as Medicare "Conditions of Participation" and DHHS standards, which include applied Board of Pharmacy rules. When board rule chapter 20 was adopted (11/8/2004 and amended 3/11/2012), segments of this rule were not attainable by hospital pharmacies and continue to be a compliance issue. In particular, the 24-hour video surveillance of automated pharmacy machines in hospital-based pharmacies is unreasonable and unnecessary as these systems have security provisions to both prevent theft by unauthorized personnel and track misused pharmaceuticals by authorized personnel. The commenter noted that the MHA submitted legislation to exempt hospitals from the Board of Pharmacy rules, which was rejected by the 126th Maine Legislature on the basis of testimony by DPFR that the Board of Pharmacy was revising its rules to allow for a waiver provision of Chapter 20, which is incorporated in this rule proposal. However, the term "good cause" is unclear and the board should further clarify what it considers to be "good cause."

Philip W. Rioux, R.Ph., FASCP
Health System Director of Pharmacy
Central Maine Healthcare
300 Main St
Lewiston ME 04240
(written and oral)

- Sections 11(1) and (2), Section 14. The board does not license hospital pharmacies; they are licensed and regulated by the Department of Health and Human Services. The proposed rule places an undue burden on hospital pharmacists who are licensed by the board. In particular, the requirement to install two way video and audio systems in every location where there is an automated dispensing machine is cost prohibitive. The commenter acknowledges the availability of a waiver for hospital pharmacies in Section 14 and predicts that the vast majority of hospitals will be requesting a waiver. If the rule does not fit the hospital environment, why have it at all?

- ◆ *Board Response to the foregoing two comments:* The board declines to amend the rule as requested. New Section 14, quoted in the Basis Statement, permits the board to waive or modify any of the requirements of this chapter upon a showing of good cause by a hospital pharmacy accompanied by demonstration that alternate means of satisfying the regulatory goal can be implemented. The board intends a flexible application of the good cause standard and will consider all the supporting information offered by the hospital pharmacy.

Only one member of the board is a hospital pharmacist. The board as a whole is unwilling to exempt all hospital pharmacies from portions of this chapter by rule at the present time. The waiver procedure will enable the board to acquire more information about the impact of the video surveillance requirement on hospital pharmacies.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 23: ACCOUNTING FOR PRESCRIPTION DRUGS**

Summary: This chapter sets forth requirements relating to maintenance of a perpetual inventory, disposal of drugs, and reporting the loss of controlled substances.

1. Perpetual Inventory

A ~~drug outlet~~retail pharmacy that dispenses Schedule II controlled substances shall maintain perpetual inventory records. These records shall indicate all receipts and dispersals of Schedule II controlled substances and shall state at any point in time the current inventory quantities of each such drug on hand. The perpetual inventory shall be maintained contemporaneously and shall be made available for inspection by the board at the ~~drug outlet~~pharmacy for a period of 5 years.

2. Disposal of Drugs**1. Controlled Drugs**

In disposing of controlled drugs, a pharmacy shall comply with 21 CFR §1307.21, entitled "Procedure for Disposing of Controlled Substances" and other applicable guidance from DEA. The board incorporates 21 CFR §1307.21 (April 1, 2012) into this chapter by reference. Title 21 CFR §1307.21 may be obtained from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/dfsys/>

[NOTE: On December 21, 2012 DEA proposed new rules for the disposal of controlled substances. 77 Fed.Reg. 75784. The proposed rules would repeal 21 CFR §1307.21.]

12. Compliance With ~~DEP Rules~~Non-controlled Drugs

In disposing of ~~drugs~~non-controlled drugs, a ~~drug outlet~~pharmacy shall follow comply with the Hazardous Waste Management Rules (Chapters 850, 851, 853-857) of the Department of Environmental Protection, to the extent applicable, and other guidance from that department and the U.S. Environmental Protection Agency. The board hereby incorporates these rules into this chapter by reference. The relevant editions of the above rule chapters are:

Chapter 850— as last amended November 3, 2002

~~Chapter 851 — as corrected March 5, 2001~~
~~Chapter 853 — as last amended November 3, 2002~~
~~Chapter 854 — as corrected January 27, 2003~~
~~Chapter 855 — as last amended March 16, 1994~~
~~Chapter 856 — as last amended November 3, 2002~~
~~Chapter 857 — as corrected March 5, 2001~~

~~_____ Copies of the above rules may be obtained from~~

~~_____ Department of Environmental Protection~~
~~_____ 17 State House Station~~
~~_____ Augusta, ME 04333-0017~~

~~_____ **2. Schedule II Drugs Owned by Patients**~~

~~_____ Schedule II controlled substances that are the property of the patient and are no longer in use may be disposed of by any of the following persons:~~

- ~~_____ A. A pharmacist;~~
~~_____ B. A pharmacist member of the board;~~
~~_____ C. A DEA agent; or~~
~~_____ D. An authorized representative of the Department of Human Services in association with a pharmacist or nurse.~~

~~_____ **3. Documentation**~~

~~_____ The disposal of controlled substances shall be recorded on the board's patient controlled substance destruction form or, in the case of nursing facilities and skilled nursing facilities, in a bound book from which no pages shall be removed. The record shall contain the names of all witnesses to the disposal and shall be kept on the premises where disposal occurred.~~

3. Reporting of Theft, Loss and Unresolved Inventory Discrepancies of Prescription Controlled Drugs

~~_____ **1. Theft or Loss**~~

A pharmacist shall report any significant theft, or loss or unresolved inventory discrepancy of prescription-controlled drugs to the board. The pharmacist shall make the report no later than 7 days after discovery of the theft, loss or inventory discrepancy. The report may be made via letter, facsimile transmission or email, must be signed by the pharmacist in charge or other pharmacist with knowledge of the situation, and must list the controlled drugs and quantities of same that were lost or stolen or cannot be accounted for. A pharmacist may satisfy the reporting obligation for controlled substances by filing Form 106 with the DEA and sending a copy to the board.

When determining if a theft, loss or unresolved inventory discrepancy is “significant,” a pharmacist should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

2. Unresolved Inventory Discrepancy

A pharmacist shall report an unresolved inventory discrepancy of prescription drugs to the board as follows:

A. For noncontrolled prescription drugs, unresolved inventory discrepancies that lead to the suspicion of theft must be reported to the board within 7 days after discovery.

B. For controlled substances, the following minimum quantities of unresolved inventory discrepancies must be reported:

(1) Solid dosage forms

(a) Three or more unreported shortages totaling 30 or more dosage units during the previous six months; or

(b) A total of 10 or more doses of the same drug regardless of strength or manufacturer.

(2) Oral liquids

(a) Three or more unreported shortages totaling 360 ml or more during the previous six months; or

(b) A volume greater than 4 oz (120ml) of the same drug regardless of strength or manufacturer.

(3) Injectable medications:

- ~~_____ (a) Three or more unreported shortages of the same drug;~~
- ~~_____ (b) More than one manufacturer original container;~~
- ~~_____ (c) More than 5 dosage units (i.e. ampoule or Tubex); or~~
- ~~_____ (d) For powders, more than 1 gram.~~

~~_____ Nothing in this subsection prevents a pharmacist from reporting any unresolved inventory discrepancy of lesser amount than set forth herein.~~

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

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 23: ACCOUNTING FOR PRESCRIPTION DRUGS**

Summary: This chapter sets forth requirements relating to maintenance of a perpetual inventory, disposal of drugs, and reporting the loss of controlled substances.

1. Perpetual Inventory

A retail pharmacy that dispenses Schedule II controlled substances shall maintain perpetual inventory records. These records shall indicate all receipts and dispersals of Schedule II controlled substances and shall state at any point in time the current inventory quantities of each such drug on hand. The perpetual inventory shall be maintained contemporaneously and shall be made available for inspection by the board at the pharmacy for a period of 5 years.

2. Disposal of Drugs**1. Controlled Drugs**

In disposing of controlled drugs, a pharmacy shall comply with 21 CFR §1307.21, entitled “Procedure for Disposing of Controlled Substances” and other applicable guidance from DEA. The board incorporates 21 CFR §1307.21 (April 1, 2012) into this chapter by reference. Title 21 CFR §1307.21 may be obtained from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/dfs/>

[NOTE: On December 21, 2012 DEA proposed new rules for the disposal of controlled substances. 77 Fed.Reg. 75784. The proposed rules would repeal 21 CFR §1307.21.]

2. Non-controlled Drugs

In disposing of non-controlled drugs, a pharmacy shall comply with the Hazardous Waste Management Rules (Chapters 850, 851, 853-857) of the Department of Environmental Protection, to the extent applicable, and other guidance from that department and the U.S. Environmental Protection Agency.

3. Reporting of Theft, Loss and Unresolved Inventory Discrepancies of Controlled Drugs

A pharmacist shall report any significant theft, loss or unresolved inventory discrepancy of controlled drugs to the board. The pharmacist shall make the report no later than 7 days after discovery of the theft, loss or inventory discrepancy. The report may be made via letter, facsimile transmission or email, must be signed by the pharmacist in charge or other pharmacist with knowledge of the situation, and must list the controlled drugs and quantities of same that were lost or stolen or cannot be accounted for. A pharmacist may satisfy the reporting obligation for controlled substances by filing Form 106 with the DEA and sending a copy to the board.

When determining if a theft, loss or unresolved inventory discrepancy is “significant,” a pharmacist should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances lost;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), 13722, 13723

EFFECTIVE DATE:

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 23
ACCOUNTING FOR PRESCRIPTION DRUGS
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth requirements relating to maintenance of a perpetual inventory, disposal of drugs, and reporting the loss of controlled substances. In the amendments to this chapter the board made the following changes:

- Deleted the incorporation of Maine DEP hazardous waste disposal rules into this chapter by reference, and deleted provisions requiring unused Schedule II drugs owned by patients to be disposed of in the presence of a pharmacist or other named individual. This chapter references instead the current DEA provision governing disposal of controlled substances, and a pending DEA rulemaking proceeding to revamp options for disposing of controlled drugs. Disposal of non-controlled drugs will be principally governed by the Maine DEP hazardous waste disposal rules, to the extent applicable, and other guidance from that Department and the U.S. Environmental Protection Agency.
- Eliminated a pharmacy's obligation to report the theft, loss or unresolved inventory discrepancy of noncontrolled drugs. For the theft, loss or unresolved inventory discrepancy of controlled drugs, the pharmacy's obligation to report will depend on whether the pharmacy determines the theft or loss is "significant" according to standards taken from DEA rules.

...

Section 2(2) of the predecessor chapter required controlled substances that are the property of "the patient" and are no longer in use to be disposed of by a pharmacist, a pharmacist member of the board, a DEA agent, or an authorized representative of Maine DHHS in association with a pharmacist or nurse. A report from a pharmacist in May of 2011 focused attention on the fact that the predominant disposal practice at nursing homes was flushing unused medications down the toilet – a practice not authorized by former Section 2(2).

Disposal by flushing was authorized by DHHS nursing home rules. However, DEP advised that such action is tantamount to an unlicensed discharge of hazardous wastes, whereupon DHHS waived the rules which required flushing of medications.

On the federal level, FDA recommended that unwanted medication be disposed of via medicine take-back programs, or be mixed in an unpalatable substance such as kitty litter or coffee grounds and placed in household trash. For a list of 32 controlled substances that could be harmful if accidentally ingested, FDA recommended disposal by flushing.

The DEA disposal rules for controlled substances in 21 CFR §1307.21 are far more rigid than the FDA guidance. Congress responded to this dilemma by passing the Secure and Responsible Drug Disposal Act of 2010, which authorizes long-term care facilities to dispose of controlled substances on behalf of ultimate users and directs the Attorney General to develop new rules to facilitate disposal of controlled drugs by ultimate users. Implementing rules were proposed on December 21, 2012 at 77 Fed.Reg. 75784 but have not yet been adopted.

For disposal of controlled drugs, the current DEA disposal rules are controlling. Section 2(1) of this chapter accordingly requires pharmacies to comply with 21 CFR §1307.21 until such time as that provision may be superseded by the pending DEA rulemaking proceeding. The board sees no role for itself in regulating disposal of unneeded drugs by nursing homes or other entities other than pharmacies.

Section 2(2) of this chapter governs disposal of noncontrolled drugs by pharmacies and is similar to Section 2(1) of the predecessor rule. New Section 2(2) references DEP hazardous waste rules as well as specific guidance from DEP and the U.S. Environmental Protection Agency. See in particular a January 4, 2012 memo from DEP Commissioner Patricia Aho to John Morris, Public Safety Commissioner, entitled "Medication Disposal Programs," and a September 26, 2012 EPA memo entitled "Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back and Other Collection Programs."

Section 3 of the predecessor chapter was entitled "Theft, Loss and Unresolved Inventory Discrepancies of Prescription Drugs." Subsection 1 required pharmacists to report theft or loss of prescription drugs to the board. Subsection 2 required pharmacists to report unresolved inventory discrepancies to the board. For unresolved inventory discrepancies of controlled drugs, subsection 2 set forth specific reporting thresholds for solid dosage forms, oral liquids and injectable medications.

The board considers the intertwined reporting obligations in Section 3 to be cumbersome at best. First, it is difficult in practice to distinguish a "theft or loss" on one hand from an "unresolved inventory discrepancy" on the other. It is the rare inventory discrepancy that is *not* tied to a theft or loss. Second, the board can no longer justify a time-consuming reporting requirement relating to mysterious disappearance of noncontrolled drugs. Unlike an unexplained loss of controlled drugs, an unexplained loss of noncontrolled drugs does not pose a significant risk of diversion or threat to the public health. Third, the threshold reporting levels for controlled drugs are extremely low.

For these reasons the board has (1) eliminated the reporting requirement in its entirety for noncontrolled drugs, (2) combined the separate reporting requirements of the predecessor rule into one reporting requirement for theft, loss or unresolved inventory discrepancy, and (3) eliminated the former threshold reporting requirements for controlled drugs. In place of the former thresholds, Section 3 now requires a pharmacist to report "any *significant* theft, loss or unresolved inventory disappearance of controlled drugs to the board." The significant loss standard is taken from 21 CFR §1301.74(c), the DEA rule governing reporting of theft or loss of controlled drugs. Section 3 as amended now requires a pharmacist to determine if a loss was significant, so as to trigger the reporting requirement, upon a consideration of the following six factors:

- a. The actual quantity of controlled substances lost in relation to the type of business;
- b. The specific controlled substances lost;
- c. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances
- d. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- e. Whether the specific controlled substances are likely candidates for diversion; and
- f. Local trends and other indicators of the diversion potential of the missing controlled substance.

Response to Comments

Stanley L. Tenenman
55 Rockwood Lane
Poland, ME 04274
(written)

- Section 3. The concept of “significant loss” does not give sufficient guidance as to when a pharmacist must report the theft, loss or unresolved inventory discrepancy of controlled drugs. “...A pharmacist may determine a loss to not be significant but an inspector or the Board may define the same loss as significant. There should be some quantity or percentage of volume written into the regulation. Personally I have made a report on CII drugs even if it is one tablet to make sure I am protected. With this proposed rule, I would continue doing so.”
 - ◆ *Board Response:* The board does not agree with the commenter and declines to amend the rule as requested. The six factors quoted in the Basis Statement offer ample guidance as to whether a loss was significant. The commenter’s practice of reporting the loss of even one tablet of a Schedule II drug exemplifies the unnecessary reporting that the board is trying to move away from. In addition, adopting the federal criteria permits consistency in a pharmacist’s reporting obligations to the DEA and the board.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-310

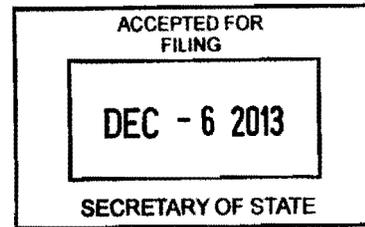
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Retention of Records by Pharmacies

4. Chapter number assigned to the rule: 24
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 1 1 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
392 MAINE BOARD OF PHARMACY

Chapter 24: RETENTION OF RECORDS BY DRUG OUTLETS PHARMACIES

Summary: This chapter sets forth record retention requirements for ~~drug outlets~~pharmacies.

1. Patient Profiles

A ~~drug outlet~~pharmacy shall retain each patient profile, including patient profiles maintained on an automated data processing system pursuant to Chapter 19, Section 7 of the board's rules, for 5 years from the date of last entry.

2. Prescription Drug Orders

1. Controlled Drugs - Written or Faxed Prescriptions

A ~~drug outlet~~pharmacy shall retain each written or faxed prescription drug order for a controlled drug for ~~3-2~~ years. For manually-processed orders, the retention period ~~shall begin~~begins on the date of first fill. For orders processed by an automatic data processing system, the retention period ~~shall begin~~begins on the date of last fill.

2. Noncontrolled Drugs; Manual Recordkeeping

A. A ~~drug outlet~~pharmacy shall retain each written or faxed prescription drug order for a noncontrolled drug that was manually processed for ~~3-2~~ years from the date of first fill.

B. A ~~drug outlet~~pharmacy may retain a scanned or microfiched unadulterated copy of the prescription drug order in place of the original. The scan or microfiche must include any information appearing on the reverse side of the prescription drug order.

3. Noncontrolled Drugs; Automatic Data Processing System

Prescription drug orders for noncontrolled drugs that were processed by an automated data processing system in accordance with Chapter 19, Section 7 of the board's rules need not be retained.

3. Central Fill, Central Processing

A central fill ~~drug outlet~~pharmacy or central processing center shall retain all records relating to the receipt, processing, handling and movement of prescription drug orders and prescription drugs to and from originating ~~drug outlets~~pharmacies and dispensing ~~drug outlets~~pharmacies, including the audit trail required by Chapter 21, Section 5(1) of the board's rules, for ~~3-2~~ years from the date of last fill.

4. All Other Records

Unless otherwise specified in these rules, the retention period for all other records that a pharmacist or ~~drug outlet~~pharmacy is required to create, including records created by an automated pharmacy system in accordance with Chapter 19, Section 7 of the board's rules, is ~~3-2~~ years from the date of creation.

5. Production at Time of Inspection

A pharmacist or ~~drug outlet~~pharmacy shall produce to an inspector of the board, upon request of the inspector, any and all records which the pharmacist or ~~drug outlet~~pharmacy is required to retain. Production of records for the most recent 12-month period must be made immediately at the time of inspection or investigation. The balance of the records requested must be produced within 3 business days of the request.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), ~~13722, 13722(1)(B-1)~~, 13723(7), ~~13784~~13785

EFFECTIVE DATE:

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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 24: RETENTION OF RECORDS BY PHARMACIES**

Summary: This chapter sets forth record retention requirements for pharmacies.

1. Patient Profiles

A pharmacy shall retain each patient profile, including patient profiles maintained on an automated data processing system pursuant to Chapter 19, Section 7 of the board's rules, for 5 years from the date of last entry.

2. Prescription Drug Orders**1. Controlled Drugs - Written or Faxed Prescriptions**

A pharmacy shall retain each written or faxed prescription drug order for a controlled drug for 2 years. For manually-processed orders, the retention period begins on the date of first fill. For orders processed by an automatic data processing system, the retention period begins on the date of last fill.

2. Noncontrolled Drugs; Manual Recordkeeping

A. A pharmacy shall retain each written or faxed prescription drug order for a noncontrolled drug that was manually processed for 2 years from the date of first fill.

B. A pharmacy may retain a scanned or microfiched unadulterated copy of the prescription drug order in place of the original. The scan or microfiche must include any information appearing on the reverse side of the prescription drug order.

3. Noncontrolled Drugs; Automatic Data Processing System

Prescription drug orders for noncontrolled drugs that were processed by an automated data processing system in accordance with Chapter 19, Section 7 of the board's rules need not be retained.

3. Central Fill, Central Processing

A central fill pharmacy or central processing center shall retain all records relating to the receipt, processing, handling and movement of prescription drug orders and prescription drugs to and from originating pharmacies and dispensing pharmacies, including the audit trail required by Chapter 21, Section 5(1) of the board's rules, for 2 years from the date of last fill.

4. All Other Records

Unless otherwise specified in these rules, the retention period for all other records that a pharmacist or pharmacy is required to create, including records created by an automated pharmacy system in accordance with Chapter 19, Section 7 of the board's rules, is 2 years from the date of creation.

5. Production at Time of Inspection

A pharmacist or pharmacy shall produce to an inspector of the board, upon request of the inspector, any and all records which the pharmacist or pharmacy is required to retain. Production of records for the most recent 12-month period must be made immediately at the time of inspection or investigation. The balance of the records requested must be produced within 3 business days of the request.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1), 13722(1)(B-1), 13723(7), 13785

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 24
RETENTION OF RECORDS BY PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter sets forth record retention requirements for pharmacies. In this rulemaking proceeding the board reduced pharmacies' record retention requirement from 3 years to 2 years for all records other than patient profiles.

Retention of patient profiles is governed by 32 MRSA §13785, which provides that a patient profile record must be retained for a period of time not less than the amount of time required by federal Medicare laws. In the 2004 amendments to this chapter, the board determined that the applicable record retention period under the Medicare laws was 5 years. See the Chapter 24 Basis Statement in that rulemaking proceeding. A re-examination of the Medicare rules in this rulemaking proceeding has reached the same conclusion, albeit not without ambiguity.

The general retention period for hospital records set forth in 42 CFR §482.24(b)(1) is 5 years. The Medicare rules contain specialized retention periods as well, some longer and some shorter than 5 years. For Medicare Advantage plans and Part D plans, the retention period is 10 years. CMS has also issued a bulletin noting that HIPAA requires covered entities to retain electronically transmitted documents for 6 years. In short, there is no one single records retention requirement in the federal scheme. The board has chosen to rely on 42 CFR §482.24(b)(1) and has left the 5-year retention period for patient profile records in this chapter unchanged.

Response to Comments

No comments were received on the proposed rule.

Rule-Making Cover Sheet

2013-311

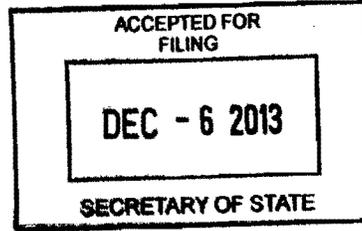
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Patient Counseling

4. Chapter number assigned to the rule: 25
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 25: PATIENT COUNSELING**

Summary: This chapter sets forth the pharmacist's obligation to counsel patients.

1. New Prescription Drug Orders

With each new prescription dispensed, the pharmacist shall:

1. Review

Review the individual's patient profile for the following potential drug therapy problems:

- A. Therapeutic duplication;
- B. Drug disease contraindications when such information has been provided to the pharmacist;
- C. Drug interactions;
- D. Incorrect drug dosage or duration;
- E. Drug allergy interactions; and
- F. Clinical abuse or misuse.

2. Explain

Orally explain to the patient or the authorized agent of the patient the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. Such explanations may include, but are not limited to, the following:

- A. Name and description of the medication;
- B. Dosage form, dosage, route of administration and duration of therapy;
- C. Special directions, precautions for the preparation, administration and use by the patient;
- D. Common significant side effects, adverse effects of interactions, and therapeutic contraindications;

- E. Techniques for self monitoring;
- F. Proper storage;
- G. Refill information; and
- H. Actions in the case of missed dosages.

For prescriptions which are not supplied directly to the patient or to the caregiver responsible for administering the medication or device to the patient, the pharmacist shall make the required counseling available to the patient through access to a telephone service which is toll-free for long distance calls.

2. Refill Prescription Drug Orders

With each refill prescription dispensed, the pharmacist shall offer to counsel the patient on the medication or device being dispensed, or to review with the patient the clinical information provided with the initial dispensing. This offer may be made in the manner determined by the professional judgment of the pharmacist, and may include any one or more of the following:

1. Face-to-face communication with the pharmacist or designee;
2. A notation affixed to or written on the bag in which the prescription is dispensed;
3. A notation contained on the prescription container; or
4. Telephone conversation.

The offer to counsel may be made by a designee of the pharmacist, but only the pharmacist may counsel the patient.

3. Refusal to Accept Counseling

Nothing in this chapter shall be construed as requiring a pharmacist to provide counseling when the patient, the patient's caregiver or the authorized agent of the patient refuses to accept counseling. The pharmacist shall document the refusal.

4. Documentation of Intervention

The pharmacist shall record in the patient profile any significant intervention in the patient's medication utilization that has occurred, in the judgment of the pharmacist, as a result of the counseling required by this chapter.

5. Patients in Hospital or Institution

The obligation to perform or offer counseling set forth in Section 1(2) and Section 2 of this chapter does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

6. Opiate Treatment Programs

The obligation to perform or offer counseling set forth in Section 1(2) and Section 2 of this chapter does not apply to prescriptions for opiate agonist treatment medications dispensed at an opioid treatment program licensed by the board pursuant to Chapter 36 of the board's rules. The dispensing pharmacist shall discharge the pharmacist's statutory obligation to offer counseling in connection with new prescriptions by ensuring that written directions for use and other information relating to proper utilization of the medication prescribed are included with each new prescription delivered by the opioid treatment program. The written information must include a telephone number at which the pharmacist in charge may be contacted by patients.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13784

EFFECTIVE DATE:

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underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 25: PATIENT COUNSELING**

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- E. Drug allergy interactions; and
- F. Clinical abuse or misuse.

2. Explain

Orally explain to the patient or the authorized agent of the patient the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. Such explanations may include, but are not limited to, the following:

- A. Name and description of the medication;
- B. Dosage form, dosage, route of administration and duration of therapy;
- C. Special directions, precautions for the preparation, administration and use by the patient;
- D. Common significant side effects, adverse effects of interactions, and therapeutic contraindications;

- E. Techniques for self monitoring;
- F. Proper storage;
- G. Refill information; and
- H. Actions in the case of missed dosages.

For prescriptions which are not supplied directly to the patient or to the caregiver responsible for administering the medication or device to the patient, the pharmacist shall make the required counseling available to the patient through access to a telephone service which is toll-free for long distance calls.

2. Refill Prescription Drug Orders

With each refill prescription dispensed, the pharmacist shall offer to counsel the patient on the medication or device being dispensed, or to review with the patient the clinical information provided with the initial dispensing. This offer may be made in the manner determined by the professional judgment of the pharmacist, and may include any one or more of the following:

1. Face-to-face communication with the pharmacist or designee;
2. A notation affixed to or written on the bag in which the prescription is dispensed;
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The offer to counsel may be made by a designee of the pharmacist, but only the pharmacist may counsel the patient.

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Nothing in this chapter shall be construed as requiring a pharmacist to provide counseling when the patient, the patient's caregiver or the authorized agent of the patient refuses to accept counseling. The pharmacist shall document the refusal.

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The pharmacist shall record in the patient profile any significant intervention in the patient's medication utilization that has occurred, in the judgment of the pharmacist, as a result of the counseling required by this chapter.

5. Patients in Hospital or Institution

The obligation to perform or offer counseling set forth in Section 1(2) and Section 2 of this chapter does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

6. Opiate Treatment Programs

The obligation to perform or offer counseling set forth in Section 1(2) and Section 2 of this chapter does not apply to prescriptions for opiate agonist treatment medications dispensed at an opioid treatment program licensed by the board pursuant to Chapter 36 of the board's rules. The dispensing pharmacist shall discharge the pharmacist's statutory obligation to offer counseling in connection with new prescriptions by ensuring that written directions for use and other information relating to proper utilization of the medication prescribed are included with each new prescription delivered by the opioid treatment program. The written information must include a telephone number at which the pharmacist in charge may be contacted by patients.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13784

EFFECTIVE DATE:



02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 25
PATIENT COUNSELING
ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter sets forth the pharmacist's obligation to counsel patients. In this rulemaking proceeding the board adopted a modified patient counseling requirement applicable to new prescriptions dispensed at opioid treatment programs licensed pursuant to Chapter 36.

Title 32 MRSA §13784(1) provides:

1. Explanation by pharmacist. With each new prescription dispensed, the pharmacist, in addition to labeling the prescription in accordance with the requirements of the State, must orally explain to the patient or the patient's agent the directions for use and any additional information, in writing if necessary, to assure the proper utilization of the medication or device prescribed. For those prescriptions delivered outside the confines of the pharmacy, the explanation shall be by telephone or in writing. This section does not apply to those prescriptions for patients in hospitals or institutions where the medication is to be administered by a nurse or other individual licensed to administer medications or to those prescriptions for patients who are to be discharged from a hospital or institution.

As part of this rulemaking proceeding the board adopted new Chapter 36, "Licensure of Opioid Treatment Programs." Unlike practice at a retail pharmacy, a pharmacist at an opioid treatment program is typically at the facility for only a brief period of time, typically in the morning. During this time the pharmacist will prepare "doses of opiate agonist treatment medications in properly labeled, patient-specific containers for delivery of such drugs to patients for consumption away from the facility." Chapter 36, Section 4(2); see also Section 4(3). Cups containing a methadone dose will be dispensed to patients by non-pharmacy staff when the patients arrive at the facility later in the day.

Under this practice model a pharmacist at an opioid treatment program cannot comply with §13784(1), which requires the personal availability of the dispensing pharmacist for counseling. Section 13784 was enacted in 1988, prior to the establishment of methadone maintenance clinics in Maine. Such facilities are extensively regulated at both the state and federal levels, and the board does not believe that §13784 should be interpreted as a bar to their operation. The board has accordingly modified the counseling requirement for opioid treatment centers in new Section 6 of this chapter:

6. Opiate Treatment Programs

The obligation to perform or offer counseling set forth in Section 1(2) and Section 2 of this chapter does not apply to prescriptions for opiate agonist treatment medications dispensed at an opioid treatment program licensed by the board pursuant to Chapter 36 of the board's rules. The dispensing pharmacist shall discharge the pharmacist's statutory obligation to offer counseling in connection with new prescriptions by ensuring that written directions for use and other information relating to proper utilization of the medication prescribed are included with each new prescription delivered by the opioid treatment program. The written information must include a telephone number at which the pharmacist in charge may be contacted by patients.

Section 6 follows the counseling requirements for off-premises delivery in §13784(1), which is analogous to the off-premises consumption of the dispensed medication that characterizes opioid treatment programs:

Response to Comments

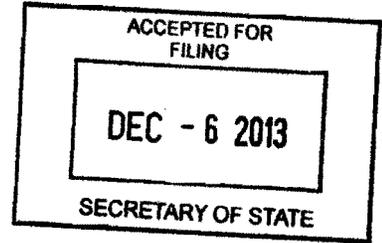
No comments were received on the proposed rule.

Rule-Making Cover Sheet

2013-312

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Violations of State or Federal Law or Rule; Other Standards
4. Chapter number assigned to the rule: 29
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaPachelle

EFFECTIVE DATE: DEC 11 2014

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 and rules and certain chapters of the United States Pharmacopeia as having established standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 M.R.S.A. §~~13742(2)(F)~~13742-A(1)(C).

1. Violations of Federal Law or Rule as Constituting Unprofessional Conduct

The board finds that the federal legislative and regulatory scheme contained in the laws and rules listed in this section have established standards of professional behavior in the practice of pharmacy and the operation of drug outlets licensed or registered by the board. Unprofessional conduct includes, but is not limited to, any violation of the following laws and rules as they relate to prescription drugs and controlled substances:

1. Federal Food, Drug and Cosmetics Act, 21 USCS §301 *et seq.* (~~1997 & 2002 Supp.~~ current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
2. Drug Abuse Prevention and Control law, 21 USCS §801 *et seq.*, including but not limited to the Controlled Substances Act (~~2002~~current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
3. Fair Packaging and Labeling Act, 15 USCS §1451 *et seq.* (~~1993 and 2002 Supp.~~ current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
4. Poison Prevention Packaging Act, 15 USCS §1471 *et seq.* (~~1993 and 2002 Supp.~~ current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
5. The following FDA rules, codified in 21 CFR (April 1, ~~2003~~2012)-

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	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
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 216	Pharmacy 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

*Does not apply to the compounding of sterile or non-sterile drugs by retail pharmacies pursuant to 32 MRSA §13702-A(4) and Chapter 13, Section 7 and Chapter 37 of the board's rules.

6. The following DEA rules, codified in 21 CFR (April 1, 2003~~2012~~)—

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	Order Forms
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
Part 1311	Requirements for Electronic Orders and Prescriptions
Part 1312	Importation and Exportation of Controlled Substances
Part 1313	Importation and Exportation of Precursors and Essential Chemicals
Part 1314	Retail Sale of Scheduled Listed Products

7. The following rules of the Federal Trade Commission, codified in 16 CFR (January 1, ~~2003~~2013)—

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

8. The following rules of the Consumer Product Safety Commission, codified in 16 CFR (January 1, ~~2003~~2013)—

Parts 1700–1702	Poison Prevention Packaging Act of 1970 Regulations
-----------------	---

9. The following law and rules relating to the federal/state Medicaid program (MaineCare), state nursing home licensure, and the following part of the state Medicaid plan—

42 USCS §1396r-8(g)	Grants to States for Medical Assistance Programs (drug use review) (<u>current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com</u>)
42 CFR Part 456	<u>Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims) Utilization Control</u> (Centers for Medicare & Medicaid Services, Dept. of Health and Human Services, October 1, 2003 2012)
10-144 Chapter 101, Section Chapter II, Part Section 80	MaineCare Benefits Manual – Pharmacy Services (Bureau of Medical Services, Dept. of Human Services, July 1, 2003 January 1, 2013)
Pp. 74a–74c	State Medicaid Plan (State Plan Under Title XIX of the Social Security Act (pp. 74a–74c approved May 24, 1993)
Ch. 110, Ch. 17	<u>Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services</u> (DHHS, February 1, 2001 edition, as amended effective October 15, 2004)

10. The following reference standards of the U.S. Pharmacopeia—

<u>USP <795></u>	<u>United States Pharmacopeia USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations, 2013-14 edition, Vol. 1, p. 355</u>
<u>USP <797></u>	<u>United States Pharmacopeia USP 36-NF 31, General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations, 2013-14 edition, Vol. 1, p. 361</u>

2. Incorporation By Reference

The board hereby incorporates by reference into this chapter the rule chapters of the FDA, DEA, Federal Trade Commission and Consumer Product Safety Commission specified in Section 1(5)-(8) of this chapter and the Utilization Control rule chapter of the Centers for Medicare & Medicaid Services, Department of Health and Human Services specified in Section 1(9) of this chapter. Copies of these rules are available at the State Law Library, State House, Augusta, ME 04333, tel. (207 287-1600 and may also be obtained from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>
 Superintendent of Documents
 U.S. Government Printing Office
 Mail Stop SSOP
 Washington, D.C. 20402-0001
 (202 512-1800

~~_____The board hereby incorporates by reference into this chapter pages 74a-74c of the State Medicaid Plan as specified in Section 1(9) of this chapter. The state Medicaid plan may be obtained from-~~

~~Centers for Medicare and Medicaid Services
 7500 Security Boulevard
 Baltimore, MD 21244-1850~~

The board hereby incorporates by reference into this chapter the MaineCare Pharmacy Benefits Manual specified in Section 1(9) of this chapter. The MaineCare Pharmacy Benefits Manual may be obtained from-

~~Bureau of Medical~~Office of MaineCare Services
 Department of Health and Human Services
 11 State House Station
 Augusta, ME 04333

~~_____~~-or-

Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch101.htm>

The board hereby incorporates by reference into this chapter pages 74a-74c of the State Medicaid Plan as specified in Section 1(9) of this chapter. The state Medicaid plan may be obtained from-

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

The board hereby incorporates into this chapter by reference into this chapter the DHHS Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and

Nursing Facilities / Pharmaceutical Services specified in Section 1(9) of this chapter. The rule may be obtained from:

Department of Health and Human Services
Division of Licensing and Regulatory Services
State House Station 11
Augusta, ME 04333

-or-

Maine Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch110.htm>

The board hereby incorporates into this chapter by reference the reference standards of the United States Pharmacopeia specified in Section 1(10) of this chapter. The reference standards may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

STATUTORY AUTHORITY: 32 M.R.S.A. §§-13720, 13721(1)(F), 13722, 13723, 13741,
~~13742(2)(F)~~13742-A(1)(C)

EFFECTIVE DATE:

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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 and rules and certain chapters of the United States Pharmacopeia as having established standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRSA §13742-A(1)(C).

1. Violations of Federal Law or Rule as Constituting Unprofessional Conduct

The board finds that the federal legislative and regulatory scheme contained in the laws and rules listed in this section have established standards of professional behavior in the practice of pharmacy and the operation of drug outlets licensed or registered by the board. Unprofessional conduct includes, but is not limited to, any violation of the following laws and rules as they relate to prescription drugs and controlled substances:

1. Federal Food, Drug and Cosmetics Act, 21 USCS §301 *et seq.* (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
2. Drug Abuse Prevention and Control law, 21 USCS §801 *et seq.*, including but not limited to the Controlled Substances Act (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
3. Fair Packaging and Labeling Act, 15 USCS §1451 *et seq.* (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
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Part 207	Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
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
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Part 226	Current Good Manufacturing Practice for Type A Medicated Articles
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*Does not apply to the compounding of sterile or non-sterile drugs by retail pharmacies pursuant to 32 MRSA §13702-A(4) and Chapter 13, Section 7 and Chapter 37 of the board's rules.

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Part 1304	Records and Reports of Registrants
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Part 1306	Prescriptions
Part 1307	Miscellaneous
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Part 1309	Registration of Manufacturers, Distributors, Importers and Exporters of List I Chemicals
Part 1310	Records and Reports of Listed Chemicals and Certain Machines
Part 1311	Requirements for Electronic Orders and Prescriptions
Part 1312	Importation and Exportation of Controlled Substances
Part 1313	Importation and Exportation of Precursors and Essential Chemicals
Part 1314	Retail Sale of Scheduled Listed Products

7. The following rules of the Federal Trade Commission, codified in 16 CFR (January 1, 2013)—

Parts 500–503	Rules, Regulations, Statement of General Policy or Interpretation and Exemptions Under the Fair Packaging and Labeling Act
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8. The following rules of the Consumer Product Safety Commission, codified in 16 CFR (January 1, 2013)—

Parts 1700–1702	Poison Prevention Packaging Act of 1970 Regulations
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9. The following law and rules relating to the federal/state Medicaid program (MaineCare), state nursing home licensure, and the state Medicaid plan—

42 USCS §1396r-8(g)	Grants to States for Medical Assistance Programs (drug use review) (current through PL 112-263, with a gap of 112-239, approved 1/14/13, www.lexis.com)
42 CFR Part 456	Utilization Control (Centers for Medicare & Medicaid Services, Dept. of Health and Human Services, October 1, 2012)
10-144 Chapter 101, Chapter II, Section 80	MaineCare Benefits Manual – Pharmacy Services (Bureau of Medical Services, Dept. of Human Services, January 1, 2013)
Pp. 74a–74c	State Medicaid Plan (State Plan Under Title XIX of the Social Security Act (pp. 74a–74c approved May 24, 1993)
Ch. 110, Ch. 17	Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services (DHHS, February 1, 2001 edition, as amended effective October 15, 2004)

10. The following reference standards of the U.S. Pharmacopeia—

USP <795>	United States Pharmacopeia USP 36-NF 31, General Chapter <795>, Pharmaceutical Compounding – Nonsterile Preparations, 2013-14 edition, Vol. 1, p. 355
USP <797>	United States Pharmacopeia USP 36-NF 31, General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations, 2013-14 edition, Vol. 1, p. 361

2. Incorporation By Reference

The board hereby incorporates by reference into this chapter the rule chapters of the FDA, DEA, Federal Trade Commission and Consumer Product Safety Commission specified in Section 1(5)-(8) of this chapter and the Utilization Control rule of the Centers for Medicare & Medicaid Services, Department of Health and Human Services specified in Section 1(9) of this chapter. Copies of these rules are available at the State Law Library, State House, Augusta, ME 04333, tel. (207 287-1600 and may also be obtained from the U.S. Government Printing Office, FDsys / Federal Digital System, at the following URL—

<http://www.gpo.gov/fdsys/>

The board hereby incorporates by reference into this chapter the MaineCare Pharmacy Benefits Manual specified in Section 1(9) of this chapter. The MaineCare Pharmacy Benefits Manual may be obtained from-

Office of MaineCare Services
Department of Health and Human Services
11 State House Station
Augusta, ME 04333

-or-

Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch101.htm>

The board hereby incorporates by reference into this chapter pages 74a-74c of the State Medicaid Plan as specified in Section 1(9) of this chapter. The state Medicaid plan may be obtained from-

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

The board hereby incorporates into this chapter by reference into this chapter the DHHS Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services specified in Section 1(9) of this chapter. The rule may be obtained from:

Department of Health and Human Services
Division of Licensing and Regulatory Services
State House Station 11
Augusta, ME 04333

-or-

Maine Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch110.htm>

The board hereby incorporates into this chapter by reference the reference standards of the United States Pharmacopeia specified in Section 1(10) of this chapter. The reference standards may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(F), 13722, 13723, 13742-A(1)(C)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 29
VIOLATIONS OF STATE OR FEDERAL LAW OR RULE; OTHER STANDARDS
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter recognizes certain state and federal statutes and rules as having established standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRSA §13742-A(1)(C). In the amendments to this chapter the board updated the list of federal laws and rules and other external rules and codes that are enforceable by the board, most of which are incorporated into the board's rules by reference. The new additions include:

- DEA and FDA rules relating to prescription drugs and controlled substances that were promulgated subsequent to the board's original adoption of this chapter in 2004. (Sections 5 and 6)
- DHHS rules governing pharmaceutical operations at nursing facilities (Section 9).
- Chapters 795 and 797 of the United States Pharmacopoeia dealing with nonsterile and sterile compounding, respectively. (Section 10)

The board also clarified via footnote that two FDA rules relating to current good manufacturing practice do not apply to the compounding of drugs at retail pharmacies as permitted by state law and rule.

Response to Comments

Christen Roy, PharmD, Director of Pharmacy
and
Stephen Drapeau, RPh, JD, Clinical & Compounding Pharmacist
Briova Specialty Pharmacy
53 Darling Avenue
South Portland, ME 04106

- The board should "eliminate any and all references to Title 21 CFR Good Manufacturing Practices as it relates to compounding and the reference that violates thereof could be regarded as unprofessional conduct in Chapter 29. Remove any and all references and incorporations of Title 21 CFR Good Manufacturing Practices to any all other chapters within the proposed regulations."

Mary Pierskalla, R.Ph. MBA, Director of Pharmacy
New England Life Care
Home Infusion Therapy Services
Portland ME 04103
(written)

- The commenter recommended that the board strike the requirement for compliance with Good Manufacturing Practices as these guidelines are specific to manufacturing and imposing these guidelines on a pharmacy for home infusion patients could put home infusion pharmacies out of business due to the "exorbitant" costs of complying with the guidelines.

Apothecary by Design
84 Marginal Way Suite 100 and
141 Preble St
Portland ME 04101
(oral and written and follow-up written)

- Incorporating Good Manufacturing Practices in Chapter 29 implies that a violation of the rules constitutes unprofessional conduct. The commenter noted that FDA considers Good Manufacturing Practices to be a set of standards developed for large industrial manufacturing settings applicable to compounding and such standards are unattainable for the traditional compounding pharmacy without significant investment. The board should "remove all references to Good Manufacturing Practices as this is not the standard traditional compounding pharmacies are governed by but rather USP 795 and 797." The board should "[eliminate references to Good Manufacturing practices in any part of the Board's regulations of compounding pharmacies (particularly but not exclusively Chapter 29)."

Susan E.D. Doughty, APRN – CNP
100 Brickhill Ave., #304
So. Portland ME 04106

Fredric Shotz, ND
Maine Integrative Wellness
174 Falmouth Rd
Falmouth ME 04105

- "I am concerned that implying that compounding pharmacies may need to conform to Good Manufacturing Practices and FDA oversight versus a clear indication that USP 795 and 797 and the Maine Board of Pharmacy will govern their actions will result in an operating environment for compounding pharmacies that is unsustainable."

Dr. Sean McCloy, Holistic Family Medicine Medical Director
Integrative Health Center of Maine
222 Auburn St., Suite 102
Portland ME 04101
(written)

Keelyn Wu, D.O.
Osteopathic Healthcare of Maine
98 Clearwater Drive
Falmouth ME 04105
(written)

- "...[I]mplying that compounding pharmacies may need to conform to Good Manufacturing Practices and FDA oversight as opposed to the USP 795 and 797 will result in an operating environment for compounding pharmacies that is unsustainable."

Robert A. Morrissette, R.Ph., BPharm
University of New England
Department of Pharmacy Practice
(oral and written)

- The commenter expressed overall support of the rule changes for compounding and adoption of the USP 795 and 797 standards for compounding pharmacies in Maine. However, the board should eliminate the references to Good Manufacturing Practices such as in Chapter 29, Section 5 due to the difficulty in applying these standards.
 - ◆ *Board Response to the foregoing comments:* Section 5 of this chapter incorporates by reference 17 FDA rules. Three of these deal with current good manufacturing practices:

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

Parts 210 and 211 were included in the initial adoption of this chapter in 2004. Part 211, in particular, regulates the industrial production of drugs and includes such topics as building system standards, sampling and testing of drug components, production and process controls, packaging and labeling controls, tamper-evident packaging requirements for over-the-counter drugs, testing of finished product for identity and strength of active ingredients, and stability testing of finished product in order to determine appropriate storage conditions and expiration dates. The board agrees with the commenters that the requirements of Parts 210 and 211 are specific to manufacturing and would be unduly burdensome if applied to the compounding of sterile and non-sterile drugs by a retail pharmacy as regulated by Chapter 13, Section 7 and Chapter 37 of the board's rules.

It is doubtful that Parts 210 and 211 were intended to apply to legitimate retail compounding. Registration of manufacturers at the federal level is governed by 21 USC §360, part of the Federal Food, Drug and Cosmetic Act. Although persons engaged in the compounding of drugs are subject to registration, §360(g)(1) exempts from the registration requirement—

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

The proper remedy is not to remove Parts 210 and 211 from Chapter 29, Section 5, as those Parts do apply to manufacturers licensed under Chapter 12 of the board's rules. Instead, the board has added the following footnote to the incorporation of Parts 210 and 211 by reference:

"Does not apply to the compounding of sterile or non-sterile drugs by retail pharmacies pursuant to 32 MRSA §13702-A(4) and Chapter 13, Section 7 and Chapter 37 of the board's rules."

Section 1(11) and Section 2 of the proposed rule incorporated NABP Appendix B, "Good Compounding Practices Applicable to State Licensed Pharmacies" into the board's rules by reference. In the Response to Comments for Chapter 37, the board decided to remove all provisions of the NABP good compounding practices from Chapter 13, Section 7 and Chapter 37 of the board's rules. The board has accordingly deleted Section 1(11) from this chapter, along with the reference to Section 1(11) in Section 2 of this chapter.

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-313

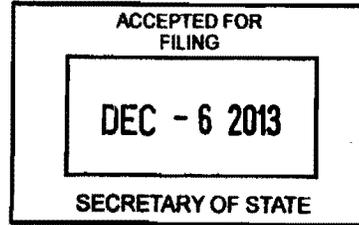
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Unprofessional Conduct

4. Chapter number assigned to the rule: 30
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [x] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 30: UNPROFESSIONAL CONDUCT**

Summary: This chapter establishes standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 M.R.S.A. ~~§13742(2)(F)~~13742-A(1)(C).

1. Examples of Unprofessional Conduct

Unprofessional conduct includes, but is not limited to, the following:

1. Making or entering into an agreement or arrangement with a practitioner, rural health center, boarding home, nursing home or long term care facility under which a part of the selling price to the patient is returned as a rebate to the practitioner or long-term care facility.
2. Making or entering into an agreement or arrangement with a practitioner, rural health center, boarding home, nursing home or long term care facility for the payment or acceptance of compensation in any form for either party using or recommending the services of the other.
3. Making or entering into an agreement or arrangement which in any way tends to limit the free choice of the public in the selection of a pharmacist or a ~~drug outlet~~pharmacy.
4. Providing a practitioner with a facsimile machine, other electronic device or any other gratuity that may induce the practitioner to direct a patient to the pharmacist or ~~drug outlet~~pharmacy or in any way restrict the patient's freedom of choice.
5. Accepting employment as a pharmacist or sharing or receiving compensation in any form arising out of, or incidental to, the pharmacist's professional activities from any practitioners that have a proprietary or beneficial interest sufficient to permit them to exercise supervision or control over the pharmacist in the pharmacist's performance of professional responsibilities and duties.
6. Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
7. Submitting false billings or reports to a third party payor of prescription drugs.
8. Making or filing a report or record which a pharmacist or pharmacy knows to be false; failing to file a report or record required by state or federal law or rule; willfully impeding or obstructing the filing of a report described in this subsection or inducing

another person to do so. Such reports or records include only those which the pharmacist or ~~drug outlet~~pharmacy is required to make or file in the capacity of pharmacist or ~~drug outlet~~pharmacy.

9. Failing to timely submit documentation of continuing professional education pursuant to Chapter 13 of the rules of the Office of ~~Licensing and Registration~~Professional and Occupational Regulation entitled "Uniform Rule for the Substantiation of Continuing Education Requirements."
10. Failing to display or carry proof of licensure or registration while practicing as a pharmacist or pharmacy technician.
11. Except as permitted by Chapter 22 of the board's rules, soliciting, accepting or dispensing prescriptions for drugs at any location other than the ~~drug outlet~~pharmacy at which the prescriptions are filled or compounded, provided, however, that this section shall not be construed to prohibit the collection of a prescription from or the delivery of the filled prescription to the residence, office or place of employment of the person for whom the prescription is issued.
12. Violating, conspiring to violate or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, any provision of the Maine Pharmacy Act, the rules of the board, or the federal or state laws and rules specified in Chapter 29 of the board's rules.
13. Failing to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels.
14. Being unable to practice pharmacy or perform the duties of a pharmacy intern or pharmacy technician with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A ~~pharmacist~~licensee affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the ~~pharmacist~~licensee can resume the competent practice of pharmacy or competent performance of licensed duties with reasonable skill and safety to patients.
15. Failing to establish and maintain effective controls to prevent prescription errors or misfills.
16. Failing to address or attempt to resolve a possible prescription error or situation of potential harm to a patient which was apparent or should have been apparent to the pharmacist, whether or not actual injury to the patient or other person resulted.
17. Theft (including but not limited to, prescription drugs) while licensed to practice pharmacy.
18. Failing to properly preserve, refrigerate, secure or store all drugs in the ~~drug outlet~~pharmacy or pharmacy department.

19. Dispensing or distributing expired or outdated drugs or knowingly distributing substandard drugs or devices or counterfeit drugs or devices to any person or entity that is not licensed or legally authorized to receive such drugs or devices.
20. Purchasing, acquiring or procuring drug samples for the purpose of compounding, dispensing, or in any way reselling the samples.
21. Disclosing health care information in violation of 22 M.R.S.A. §1711-C, entitled "Confidentiality of Health Care Information."

[NOTE: This statute may be viewed on the state's web site at the following URL-

<http://janus.state.me.us/legis/statutes/22/title22sec1711-c.html>

<http://www.mainelegislature.org/legis/statutes/22/title22sec1711-c.html>

This URL is subject to change.]

22. Failing to develop and implement policies, standards and procedures to protect the confidentiality, security and integrity of health care information to ensure that information is not negligently, inappropriately or unlawfully disclosed.
23. Publicly asserting or suggesting material claims of professional superiority in the practice of pharmacy that cannot be substantiated or which convey by implication that the services of similarly qualified pharmacists are unethical or inferior.
24. Refusing to compound or dispense prescriptions that may ordinarily and reasonably be expected to be compounded or dispensed in a pharmacy by a pharmacist.
25. Participating as a consultant in institutional drug distribution without providing pharmaceutical services. .
26. Failure of a ~~drug outlet~~pharmacy to notify the board via letter, fax or email within 7 days of the termination of employment of a pharmacist for any ~~drug-related reason, including but not limited to adulteration, abuse, theft or diversion of drugs of the~~ following reasons, which must be included in the notice:
 - A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
 - B. Theft of non-drug merchandise; or
 - C. Theft of cash or credit/debit card data.
27. Discriminating in the practice of pharmacy on the basis of age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, socioeconomic status, or other basis proscribed by law.

28. Sexual harassment as defined in Chapter 3 of the rules of the Maine Human Rights Commission, entitled "Employment Regulations of the Maine Human Rights Commission," Section 3.06(I), (~~July 17, 1999~~ April 14, 2008). A copy of the rule may be obtained from-

Maine Human Rights Commission
51 State House Station
Augusta, ME 04333-0051

STATUTORY AUTHORITY: 32 M.R.S.A. §§-13720, 13721(1)(F), 13722, 13723, ~~13741,~~
~~13742(2)(F)~~13742-A(1)(C)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 30: UNPROFESSIONAL CONDUCT**

Summary: This chapter establishes standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRSA §13742-A(1)(C).

1. Examples of Unprofessional Conduct

Unprofessional conduct includes, but is not limited to, the following:

1. Making or entering into an agreement or arrangement with a practitioner, rural health center, boarding home, nursing home or long term care facility under which a part of the selling price to the patient is returned as a rebate to the practitioner or long-term care facility.
2. Making or entering into an agreement or arrangement with a practitioner, rural health center, boarding home, nursing home or long term care facility for the payment or acceptance of compensation in any form for either party using or recommending the services of the other.
3. Making or entering into an agreement or arrangement which in any way tends to limit the free choice of the public in the selection of a pharmacist or a pharmacy.
4. Providing a practitioner with a facsimile machine, other electronic device or any other gratuity that may induce the practitioner to direct a patient to the pharmacist or pharmacy or in any way restrict the patient's freedom of choice.
5. Accepting employment as a pharmacist or sharing or receiving compensation in any form arising out of, or incidental to, the pharmacist's professional activities from any practitioners that have a proprietary or beneficial interest sufficient to permit them to exercise supervision or control over the pharmacist in the pharmacist's performance of professional responsibilities and duties.
6. Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
7. Submitting false billings or reports to a third party payor of prescription drugs.
8. Making or filing a report or record which a pharmacist or pharmacy knows to be false; failing to file a report or record required by state or federal law or rule; willfully impeding or obstructing the filing of a report described in this subsection or inducing another person to do so. Such reports or records include only those which the

- pharmacist or pharmacy is required to make or file in the capacity of pharmacist or pharmacy.
9. Failing to timely submit documentation of continuing professional education pursuant to Chapter 13 of the rules of the Office of Professional and Occupational Regulation entitled "Uniform Rule for the Substantiation of Continuing Education Requirements."
 10. Failing to display or carry proof of licensure or registration while practicing as a pharmacist or pharmacy technician.
 11. Except as permitted by Chapter 22 of the board's rules, soliciting, accepting or dispensing prescriptions for drugs at any location other than the pharmacy at which the prescriptions are filled or compounded, provided, however, that this section shall not be construed to prohibit the collection of a prescription from or the delivery of the filled prescription to the residence, office or place of employment of the person for whom the prescription is issued.
 12. Violating, conspiring to violate or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, any provision of the Maine Pharmacy Act , the rules of the board, or the federal or state laws and rules specified in Chapter 29 of the board's rules.
 13. Failing to establish and maintain effective controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels.
 14. Being unable to practice pharmacy or perform the duties of a pharmacy intern or pharmacy technician with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition. A licensee affected under this subsection shall at reasonable intervals be afforded an opportunity to demonstrate that the licensee can resume the competent practice of pharmacy or competent performance of licensed duties with reasonable skill and safety to patients.
 15. Failing to establish and maintain effective controls to prevent prescription errors or misfills.
 16. Failing to address or attempt to resolve a possible prescription error or situation of potential harm to a patient which was apparent or should have been apparent to the pharmacist, whether or not actual injury to the patient or other person resulted.
 17. Theft (including but not limited to, prescription drugs) while licensed to practice pharmacy.
 18. Failing to properly preserve, refrigerate, secure or store all drugs in the pharmacy or pharmacy department.

19. Dispensing or distributing expired or outdated drugs or knowingly distributing substandard drugs or devices or counterfeit drugs or devices to any person or entity that is not licensed or legally authorized to receive such drugs or devices.
20. Purchasing, acquiring or procuring drug samples for the purpose of compounding, dispensing, or in any way reselling the samples.
21. Disclosing health care information in violation of 22 M.R.S.A. §1711-C, entitled "Confidentiality of Health Care Information."

[NOTE: This statute may be viewed on the state's web site at the following URL-

<http://www.mainelegislature.org/legis/statutes/22/title22sec1711-c.html>

This URL is subject to change.]

22. Failing to develop and implement policies, standards and procedures to protect the confidentiality, security and integrity of health care information to ensure that information is not negligently, inappropriately or unlawfully disclosed.
23. Publicly asserting or suggesting material claims of professional superiority in the practice of pharmacy that cannot be substantiated or which convey by implication that the services of similarly qualified pharmacists are unethical or inferior.
24. Refusing to compound or dispense prescriptions that may ordinarily and reasonably be expected to be compounded or dispensed in a pharmacy by a pharmacist.
25. Participating as a consultant in institutional drug distribution without providing pharmaceutical services. .
26. Failure of a pharmacy to notify the board via letter, fax or email within 7 days of the termination of employment of a pharmacist for any of the following reasons, which must be included in the notice:
 - A. Any drug-related reason, including but not limited to adulteration, abuse, theft or diversion;
 - B. Theft of non-drug merchandise; or
 - C. Theft of cash or credit/debit card data.
27. Discriminating in the practice of pharmacy on the basis of age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, socioeconomic status, or other basis proscribed by law.
28. Sexual harassment as defined in Chapter 3 of the rules of the Maine Human Rights Commission, entitled "Employment Regulations of the Maine Human Rights Commission," Section 3.06(I), (April 14, 2008). A copy of the rule may be obtained from-

Maine Human Rights Commission
51 State House Station
Augusta, ME 04333-0051

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(F), 13722, 13723, 13742-A(1)(C)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 30
UNPROFESSIONAL CONDUCT
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter establishes standards of professional behavior, the violation of which constitutes unprofessional conduct pursuant to 32 MRSA §13742-A(1)(C). In the amendments to this chapter the board made the following changes.

- Clarified that the inability to practice with reasonable skill and safety may result in sanctions against a pharmacy technician or pharmacy intern as well as a pharmacist. (Section 1(13))
- Required a pharmacy to notify the board of the termination of a pharmacist due to theft or drug-related misconduct. (Section 1(26))

Response to Comments

Susan E.D. Doughty, APRN – CNP
100 Brickhill Ave., #304
So. Portland ME 04106

Fredric Shotz, ND
Maine Integrative Wellness
174 Falmouth Rd
Falmouth ME 04105

- Section 1, subsections 29 through 36 “would significantly impact my patients’ access to care” if a pharmacy is not permitted to compound medications that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND). The board should allow “the compounding of medication from ingredients that comply with United States Pharmacopoeia (USP) or National Formulary (NF) monographs and that are manufactured by an establishment that is registered with the FDA.”

Christen Roy, PharmD, Director of Pharmacy
and
Stephen Drapeau, RPh, JD, Clinical & Compounding Pharmacist
Briova Specialty Pharmacy
53 Darling Avenue
S. Portland ME 04106

- The board should “remove language from Chapter 30, Section 34 relating to the use of ‘commercial scale manufacturing or testing equipment for compounded drug products,’ as the use of that type of equipment in the process of individual prescription compounding should not, in and of itself, be considered as unprofessional conduct.”

Dr. Sean McCloy, Holistic Family Medicine Medical Director
Integrative Health Center of Maine
222 Auburn St., Suite 102
Portland ME 04101
(written)

Keelyn Wu, D.O.
Osteopathic Healthcare of Maine
98 Clearwater Drive

Falmouth ME 04105
(written)

- Chapter 30, Section 1(29) - (36) will negatively impact patient access to care by reducing or eliminating access to vital compounded medications, such as, prescribed compounded medications for hormone replacement therapy, heavy metal detoxification and chronic illness for patients whose needs are not otherwise met by manufactured products. The commenters support the compounding of medication from ingredients that comply with the United States Pharmacopeia (USP) or National Formulary (NF) monographs. However, the rule proposes that pharmacies “would not be allowed to compound medications that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND). Access to medications used in my practice, such as methylcobalamin, estriol, NADH, DHEA, would be eliminated due to this lengthy, costly, and unrealistic requirement.” The board should establish a definition for anticipatory compounding so that pharmacies can utilize the level of batching necessary to spread the cost of testing to meet acute patient demands.

Mark McAuliffe
Apothecary by Design
84 Marginal Way Suite 100 and
141 Preble St
Portland ME 04101
(oral and written and follow-up written)

- Many of the references to FDA regulations such as, what active bulk ingredients may be used in compounding, and what is considered a new drug, were taken from an FDA opinion document issued in 2002 and has been challenged in the courts as not enforceable (US v Frank Labs, Inc. and Midland case 2004).
- The board should clarify Chapter 30, section 31 “to address a wider range of bulk active ingredients to include additional bulk ingredients beyond just those receiving FDA approval, including but not limited to:
 - a. Applicable USP or National Formulary monographs, homeopathic and herbal remedies
 - b. Products distributed by an FDA approved licensed wholesaler (see Virginia’s rules)
- The board should clarify its authority in regulating compounding facilities in Maine and remove all references to FDA regulations in rule and consider the following statement:

“The Maine Board of Pharmacy is responsible for regulating pharmacies in Maine. The Maine of Pharmacy will work with and support actions by the FDA against a Maine Pharmacy when such actions are taken within the legal authority of the FDA granted by Congress.”
- The board should eliminate Chapter 30, section 34 as a type of equipment used should not dictate unprofessional conduct.
 - ◆ *Board Response to the foregoing comments:* Section 1(29) - (36) of this chapter were copied verbatim from FDA Compliance Policy Guide 460.200, Pharmacy Compounding (reissued May 29, 2002).¹ In CPG 460.200 the FDA

¹ In United States of America v. Frank Labs, Case No. 5:10-cv-147-Oc-32TBS (U.S. District Ct., Middle District FL, 9/12/11), appeal vacated and dismissed as moot 10/22/12, the federal district court denied the FDA’s request for an injunction to bar a state-licensed pharmacist from the bulk compounding of animal

attempts to distinguish traditional retail compounding from large-scale industrial compounding performed under the guise of retail compounding. The eight factors reproduced in Chapter 30, Section 1(29 - 36) (plus one other that was not included in this chapter) were intended as a non-exclusive list of factors to be taken into consideration in determining if a compounding pharmacy had stepped over this line.

The board acknowledges that under Section 1(29 - 36) as drafted, violation of any individual factor (e.g., commercial scale manufacturing or testing equipment; see comment of Roy and Drapeau) constitutes unprofessional conduct. This approach is inconsistent with CPG 460.200, under which the individual factors were not violations in and of themselves, but would inform an enforcement determination as to whether a pharmacy was violating the provisions of the Federal Food, Drug and Cosmetic Act.

The board also acknowledges the legitimacy of the concerns expressed by commenters Doughty, Schotz, McCloy, Wu and McAuliffe. The board is hesitant to adversely affect prevailing pharmacy practice in Maine by importing federal policy guidelines with which it has little familiarity.

For these reasons the board has deleted Section 1(29 - 36) from this chapter as adopted. Cross-references to these provisions have also been deleted from Chapters 13 and 37 as adopted.

Title 32 MRSA §13702-A(28) includes "the compounding...of drugs and devices" in the definition of "practice of pharmacy." "Compounding" is defined in 32 MRSA §13702-A(4) as follows:

4. Compounding. "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device by a pharmacist for the pharmacist's patient either for dispensing as the result of a practitioner's prescription drug order, or for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns.

The board will be guided by 32 MRSA §13702-A(4) in determining whether any violation of the Maine Pharmacy Act related to compounding has occurred.

Mark McAuliffe
Apothecary by Design
84 Marginal Way Suite 100 and
141 Preble St
Portland ME 04101
(oral and written and follow-up written)

drugs pursuant to valid veterinary prescriptions. In the course of its decision the court eschewed reliance on a FDA compliance policy guide relating to the compounding of veterinary drugs. The status of Compliance Policy Guide 460.200 was not at issue in *Frank Labs*, and Compliance Policy Guide 460.200 remains in effect. See FDA Warning Letter 07-09, Civic Center Pharmacy, 12/16/08, cited in Jennifer Staman, "FDA's Authority to Regulate Drug Compounding: A Legal Analysis" (Congressional Research Service, 10/17/12), p. 8, n. 44. The warning letter is accessible at www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048048.htm. The CRS analysis is accessible at <http://docs.house.gov/meetings/IF/IF02/20130416/100668/HHRG-113-IF02-20130416-SD053.pdf>.

- The board should reconsider a compounding pharmacy's ability to provide office supplies (see Virginia's rules).
 - ◆ *Board Response:* The board declines to amend the rule as requested. The definition of compounding in 32 MRSA §13702-A(4) reproduced above permits a pharmacist to compound a drug in connection with a prescription drug order and prohibits compounding for sale or dispensing in the absence of a prescription. In a memorandum dated April 5, 2013, Assistant Attorney General Carrie Carney interpreted §13702-A(4) as not permitting compounding for "office use," i.e., a pharmacy "[compounding] drugs without a prescription to give to a practitioner to keep in his or her office for patient use." The board is following the advice of counsel.

Mark McAuliffe
 Apothecary by Design
 84 Marginal Way Suite 100 and
 141 Preble St
 Portland ME 04101
 (oral and written and follow-up written)

- Under Chapter 30, section 29, the board should recognize the right of a compounding pharmacy to "compound in anticipation of receiving prescriptions...be allowed to compound 30-90 days' supply of recent prescription volume per drug (limited by beyond use dating) with no more than an additional 10% above that based on credible expected additional volume."
 - ◆ *Board Response:* The board declines to amend the rule as requested. The definition of "compounding" in 32 MRSA §13702-A(4) quoted above includes "the preparation of drugs or devices in anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns." This may well vary by pharmacy, drug and refill frequency. At this point in time the board has no experience from which to draw a bright line regarding the volume of permissible anticipatory compounding.

Michael Miller
 Assistant Attorney General
 (written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-314

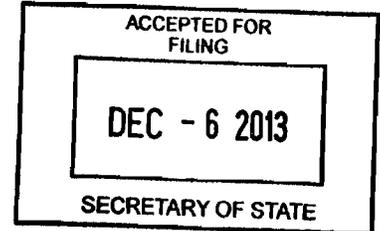
TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

2. Agency umbrella and unit number: 02-392
(2 digit umbrella # and 3 digit unit #)

3. Title of rule: Licensure of Retail Suppliers of Medical Oxygen

4. Chapter number assigned to the rule: 34
(must be 3 digits or less)



5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.

6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME

7-A. Type: [] new rule [X] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

[] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-18-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRoche

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 34: LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN**

Summary: This chapter provides for the licensure of retail suppliers of medical oxygen and oxygen devices

1. Definition [deleted]

As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

- ~~1. **Medical oxygen.** “Medical oxygen” means oxygen in liquid or gaseous form intended for therapeutic use.~~
- ~~2. **Retail supplier of medical oxygen.** “Retail supplier of medical oxygen” means a person who sells or dispenses medical oxygen to a consumer —~~
 - ~~D. Pursuant to a prescription from a practitioner; or~~
 - ~~E. In circumstances where a prescription is required by federal law.~~

1-A. Authority

A retail supplier of medical oxygen is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required**1. General Requirement**

Medical oxygen for use by a specific person may be sold at retail only pursuant to a prescription from a practitioner. A retail supplier of medical oxygen located within or outside Maine who sells or dispenses medical oxygen to consumers who reside in Maine shall obtain a retail supplier of medical oxygen license from the board. A retail supplier of medical oxygen need not have a pharmacist in charge or a pharmacist.

2. Exception for Licensed Pharmacies

A pharmacy licensed by the board may sell medical oxygen at retail without need of a license under this chapter.

3. Sales for Emergency Medical Use – Dual Licensure Not Required

A retail supplier of medical oxygen licensed under this chapter who sells oxygen for emergency medical use to a licensed practitioner or licensed health care facility need not, by virtue of those sales alone, be licensed as a wholesaler pursuant to Chapter 12 of the board's rules.

3. Temporary Licensure

1. Timeline

The board may issue a temporary license as a retail supplier of medical oxygen upon receipt of an application for licensure submitted pursuant to Section 4 of this chapter. The application must demonstrate the applicant's prima facie eligibility for licensure. The temporary license expires 90 days from the date of issuance. Within the first 60 days of temporary licensure, a temporary licensee shall complete the application to the satisfaction of the board. The board will act on timely-completed applications for licensure within the 90-day period of the temporary license.

2. Limitation

A temporary license may not be extended or renewed. A person may not receive a temporary license more than once.

4. Licensure

1. Application; Fees

An application for licensure as a retail supplier of medical oxygen must be filed on forms provided by the board ~~along with such other information as the board may require.~~ The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of ~~Licensing and Registration~~ Professional and Occupational Regulation, entitled "Establishment of License Fees." Except as described in Section 3 of this chapter, incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, physical address, contact address, telephone number, email address and world wide web address of the retail supplier of medical oxygen;
- B. All trade or business names used by the retail supplier of medical oxygen;
- C. The names of the owner of the retail supplier of medical oxygen, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;

- (2) If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
- (3) If the applicant is a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
- (4) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;

~~A-D.~~ The job title, name, address, telephone number, email address and emergency contact information of the person responsible for operation of the retail supplier of medical oxygen;

~~D-E.~~ The days and hours of operation of the retail supplier of medical oxygen; and

F. A scaled drawing of the facility demonstrating sufficient space for the proper carrying on of the business of a retail supplier of medical oxygen. The drawing must identify the use of all space within the facility;

~~E-G.~~ Such other information as the board may require.

2. Processing of Application

A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail supplier of medical oxygen will be in the best interest of the public health and welfare.

B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the

information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

2.4. Separate License for Each Facility

The owner of a retail supplier of medical oxygen must file a separate application for each facility that sells or dispenses medical oxygen.

3.5. License Term; Renewal

All retail supplier of medical oxygen licenses other than the temporary license expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of ~~Licensing and Registration~~ Professional and Occupational Regulation, entitled “Establishment of License Fees.”

4.6. Change of Ownership, Location or Application Information

Upon a change of ownership, a retail supplier of medical oxygen shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a retail supplier of medical oxygen shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

5. Prescription Drug Order

Each retail sale of medical oxygen must be authorized by a prescription from a practitioner. A retail supplier of medical oxygen may fill a prescription for the length of medical need authorized by the prescribing practitioner. If the length of medical need is not specified, the prescription drug order is valid for 15 months.

6. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 M.R.S.A. §2681 *et seq.*, the retail supplier of medical oxygen shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3d party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

7. Patient Records

A retail supplier of medical oxygen shall keep in written or any electronic format prescriptions, invoices and delivery records for each patient served. Records must be retained for 3 years from the date of last delivery to a patient and must be produced to an inspector or representative of the board upon request.

8. Compliance with Current Good Manufacturing Practices; Incorporation by Reference

1. Current Good Manufacturing Practices

A retail supplier of medical oxygen that manufactures, processes, packages or holds oxygen as defined in the Federal Food, Drug, and Cosmetic Act and its implementing rules shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Parts 210 and 211 (April 1, ~~2010~~2012 edition).

~~5.2.~~ Incorporation by Reference

The board hereby incorporates the following documents by reference into this chapter:

~~B.A.~~ Title 21 CFR Part 210, "Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General" promulgated by the U.S. Food and Drug Administration (April 1, ~~2010~~2012 edition). This document is available from the FDA on line at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

- B. Title 21 CFR Part 211, “Current Good Manufacturing Practice for Finished Pharmaceuticals” promulgated by the U.S. Food and Drug Administration (April 1, ~~2010~~2012 edition). This document is available from the FDA on line at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

9. Packaging, Storage and Labeling

A retail supplier of medical oxygen shall store, package and label oxygen in accordance with the requirements of the U.S. Pharmacopoeia ~~Pharmacopoeia~~Pharmacopeia.

STATUTORY AUTHORITY: 22 MRSA §2681(6); 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 34: LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN**

Summary: This chapter provides for the licensure of retail suppliers of medical oxygen and oxygen devices

1. [deleted]**1-A. Authority**

A retail supplier of medical oxygen is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required**1. General Requirement**

Medical oxygen for use by a specific person may be sold at retail only pursuant to a prescription from a practitioner. A retail supplier of medical oxygen located within or outside Maine who sells or dispenses medical oxygen to consumers who reside in Maine shall obtain a retail supplier of medical oxygen license from the board. A retail supplier of medical oxygen need not have a pharmacist in charge or a pharmacist.

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3. Sales for Emergency Medical Use – Dual Licensure Not Required

A retail supplier of medical oxygen licensed under this chapter who sells oxygen for emergency medical use to a licensed practitioner or licensed health care facility need not, by virtue of those sales alone, be licensed as a wholesaler pursuant to Chapter 12 of the board's rules.

3. Temporary Licensure**1. Timeline**

The board may issue a temporary license as a retail supplier of medical oxygen upon receipt of an application for licensure submitted pursuant to Section 4 of this chapter.

The application must demonstrate the applicant's prima facie eligibility for licensure. The temporary license expires 90 days from the date of issuance. Within the first 60 days of temporary licensure, a temporary licensee shall complete the application to the satisfaction of the board. The board will act on timely-completed applications for licensure within the 90-day period of the temporary license.

2. Limitation

A temporary license may not be extended or renewed. A person may not receive a temporary license more than once.

4. Licensure

1. Application; Fees

An application for licensure as a retail supplier of medical oxygen must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Except as described in Section 3 of this chapter, incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, physical address, contact address, telephone number, email address and world wide web address of the retail supplier of medical oxygen;
- B. All trade or business names used by the retail supplier of medical oxygen;
- C. The names of the owner of the retail supplier of medical oxygen, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If the applicant is a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names

and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.

- (4) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- D. The job title, name, address, telephone number, email address and emergency contact information of the person responsible for operation of the retail supplier of medical oxygen;
- E. The days and hours of operation of the retail supplier of medical oxygen;
- F. A scaled drawing of the facility demonstrating sufficient space for the proper carrying on of the business of a retail supplier of medical oxygen. The drawing must identify the use of all space within the facility;
- G. Such other information as the board may require.

2. Processing of Application

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the retail supplier of medical oxygen will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;

- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

4. Separate License for Each Facility

The owner of a retail supplier of medical oxygen must file a separate application for each facility that sells or dispenses medical oxygen.

5. License Term; Renewal

All retail supplier of medical oxygen licenses other than the temporary license expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10 of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

6. Change of Ownership, Location or Application Information

Upon a change of ownership, a retail supplier of medical oxygen shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a retail supplier of medical oxygen shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

5. Prescription Drug Order

Each retail sale of medical oxygen must be authorized by a prescription from a practitioner. A retail supplier of medical oxygen may fill a prescription for the length of medical need authorized by the prescribing practitioner. If the length of medical need is not specified, the prescription drug order is valid for 15 months.

6. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 MRSA §2681 *et seq.*, the retail supplier of medical oxygen shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3d party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

7. Patient Records

A retail supplier of medical oxygen shall keep in written or any electronic format prescriptions, invoices and delivery records for each patient served. Records must be retained for 3 years from the date of last delivery to a patient and must be produced to an inspector or representative of the board upon request.

8. Compliance with Current Good Manufacturing Practices; Incorporation by Reference**1. Current Good Manufacturing Practices**

A retail supplier of medical oxygen that manufactures, processes, packages or holds oxygen as defined in the Federal Food, Drug, and Cosmetic Act and its implementing rules shall comply with the current good manufacturing practices promulgated by the Food and Drug Administration in 21 CFR Parts 210 and 211 (April 1, 2012 edition).

2. Incorporation by Reference

The board hereby incorporates the following documents by reference into this chapter:

- A. Title 21 CFR Part 210, “Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General” promulgated by the U.S. Food and Drug Administration (April 1, 2012 edition). This document is available from the FDA on line at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

- B. Title 21 CFR Part 211, “Current Good Manufacturing Practice for Finished Pharmaceuticals” promulgated by the U.S. Food and Drug Administration (April 1, 2012 edition). This document is available from the FDA on line at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

This document may also be obtained from the State Law Library, State House, Augusta, Maine, tel. (207) 287-1600.

9. Packaging, Storage and Labeling

A retail supplier of medical oxygen shall store, package and label oxygen in accordance with the requirements of the U.S. Pharmacopeia.

STATUTORY AUTHORITY: 22 MRSA §2681(6); 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 34
LICENSURE OF RETAIL SUPPLIERS OF MEDICAL OXYGEN
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter provides for the licensure of retail suppliers of medical oxygen devices. In the amendments to this chapter the board made the following changes:

- Relocated the definitions of “medical oxygen” and “retail supplier of medical oxygen” to Chapter 1.
- Stated the legal basis for licensing retail suppliers of medical oxygen as a classification of retail pharmacy. A similar statement of legal authority is included in new Chapter 35, “Licensure of Extended Hospital Pharmacies, new Chapter 36, “Licensure of Opioid Treatment Programs,” new Chapter 37, “Licensure of Sterile Compounding Pharmacies,” and new Chapter 38, “Licensure of Closed-Shop Pharmacies.”
- Standardized license application and processing language for consistency among retail pharmacies, retail suppliers of medical oxygen, extended hospital pharmacies, opioid treatment programs, sterile compounding pharmacies and closed-shop pharmacies, to the extent practicable.

Response to Comments

Michael Miller
Assistant Attorney General
(written)

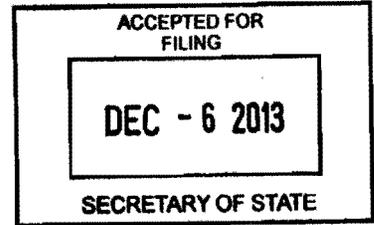
- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-315

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Licensure of Extended Hospital Pharmacies
4. Chapter number assigned to the rule: 35
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [X] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.
Signature: [Handwritten Signature]
Printed Name & Title: Joseph Bruno, Board President
11. Approved as to form and legality by the Attorney General on 11-18-13
Signature: [Handwritten Signature]
Printed Name: Lauren LaRochelle

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 35: LICENSURE OF EXTENDED HOSPITAL PHARMACIES**

Summary: This chapter provides for the licensure of extended hospital pharmacies.

1. Authority

An extended hospital pharmacy is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3). An extended hospital pharmacy must be licensed pursuant to this chapter.

2. Coordination With Hospital Licensure by DHHS

Licensure of an extended hospital pharmacy under this chapter is intended to authorize activities that are deemed by DHHS as being outside the scope of the pharmaceutical services encompassed by its licensure of the hospital in which the extended hospital pharmacy is located.

3. Scope of License

An extended hospital pharmacy may dispense, deliver and distribute prescription drugs only to the following persons:

1. Nursing Home Residents

Residents of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital pharmacy is located.

2. Employees, Students, Medical Staff and Dependents

Employees, students and medical staff of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital pharmacy is located, and their dependents, for their personal use.

4. Applicability of DHHS Rules

An extended hospital pharmacy that dispenses to residents of an affiliated nursing home must comply with Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services"(February 1, 2001 edition, as amended effective October 15, 2004.)

The pharmacist in charge of the extended hospital pharmacy has the responsibilities of the pharmacist consultant described in Chapter 110, Chapter 17.

The board incorporates Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services" (February 1, 2001 edition, as amended effective October 15, 2004) into this chapter by reference. A copy of Chapter 110, Chapter 17 may be obtained from:

Department of Health and Human Services
Division of Licensing and Regulatory Services
State House Station 11
Augusta, ME 04333

-or-

Maine Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch110.htm>

5. Licensure

1. Application; Fees

An application for licensure as an extended hospital pharmacy must be filed by the hospital in which the extended hospital pharmacy is located on forms provided by the board. The application must be accompanied by the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the hospital;
- C. All trade or business names used or to be used by the extended hospital pharmacy or the hospital in which it is located;
- D. The names of the owner of the hospital, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and

title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;

(3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;

(4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.

(5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;

E. The hours of operation of the extended hospital pharmacy during which a pharmacist will be on duty;

F. The DEA number of the hospital pharmacy;

G. The name and license number of the pharmacist in charge of the hospital pharmacy;

H. The name and license number of the pharmacist in charge of the extended hospital pharmacy (if different than the above);

I. A copy of the hospital's current license from DHHS;

J. Survey or Inspection Report—

(1) If the hospital is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, the portion of the

most recent survey conducted by the accrediting organization that relates to pharmacy services;

(2) If the hospital is not accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, the portion of the most recent report of an inspection of the hospital conducted by DHHS that relates to pharmacy services;

(3) All adverse findings, responses, remediation plans, and follow-up surveys or follow-up inspection reports related to the survey or inspection report provided pursuant to subparagraph 1 or 2 above;

K. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;

L. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body;

M. A text summary of any complaints filed or generated against the hospital relating to pharmacy services during the ten years preceding application that includes, for each such complaint, the allegations of the complaint, the complaint investigation, and the findings, resolution, and any remediation or penalties ordered against or agreed to by the hospital; and

N. Such other information as the board may require.

2. Processing of Application

A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the extended hospital pharmacy will be in the best interest of the public health and welfare.

B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

A. Submit an application with modifications requested by the board;

B. Furnish additional information requested by the board;

- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

4. License Term; Renewal

All extended hospital pharmacy licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

5. Change of Ownership, Location or Application Information

Upon a change of ownership, the hospital in which the extended hospital pharmacy is located shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, the hospital in which the extended hospital pharmacy is located shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

6. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

An extended hospital pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

6. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 MRSA §2681 *et seq.*, the extended hospital pharmacy shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3d party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

STATUTORY AUTHORITY: 22 MRSA §2681(6); 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 35: LICENSURE OF EXTENDED HOSPITAL PHARMACIES**

Summary: This chapter provides for the licensure of extended hospital pharmacies.

1. Authority

An extended hospital pharmacy is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3). An extended hospital pharmacy must be licensed pursuant to this chapter.

2. Coordination With Hospital Licensure by DHHS

Licensure of an extended hospital pharmacy under this chapter is intended to authorize activities that are deemed by DHHS as being outside the scope of the pharmaceutical services encompassed by its licensure of the hospital in which the extended hospital pharmacy is located.

3. Scope of License

An extended hospital pharmacy may dispense, deliver and distribute prescription drugs only to the following persons:

1. Nursing Home Residents

Residents of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital pharmacy is located.

2. Employees, Students, Medical Staff and Dependents

Employees, students and medical staff of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital pharmacy is located, and their dependents, for their personal use.

4. Applicability of DHHS Rules

An extended hospital pharmacy that dispenses to residents of an affiliated nursing home must comply with Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services"(February 1, 2001 edition, as amended effective October 15, 2004.)

The pharmacist in charge of the extended hospital pharmacy has the responsibilities of the pharmacist consultant described in Chapter 110, Chapter 17.

The board incorporates Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services"(February 1, 2001 edition, as amended effective October 15, 2004) into this chapter by reference. A copy of Chapter 110, Chapter 17 may be obtained from:

Department of Health and Human Services
Division of Licensing and Regulatory Services
State House Station 11
Augusta, ME 04333

-or-

Maine Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch110.htm>

5. Licensure

1. Application; Fees

An application for licensure as an extended hospital pharmacy must be filed by the hospital in which the extended hospital pharmacy is located on forms provided by the board. The application must be accompanied by the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the hospital;
- C. All trade or business names used or to be used by the extended hospital pharmacy or the hospital in which it is located;
- D. The names of the owner of the hospital, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and

title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;

- (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- E. The hours of operation of the extended hospital pharmacy during which a pharmacist will be on duty;
- F. The DEA number of the hospital pharmacy;
- G. The name and license number of the pharmacist in charge of the hospital pharmacy;
- H. The name and license number of the pharmacist in charge of the extended hospital pharmacy (if different than the above);
- I. A copy of the hospital's current license from DHHS;
- J. Survey or Inspection Report—
- (1) If the hospital is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, the portion of the

most recent survey conducted by the accrediting organization that relates to pharmacy services;

- (2) If the hospital is not accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, the portion of the most recent report of an inspection of the hospital conducted by DHHS that relates to pharmacy services;
 - (3) All adverse findings, responses, remediation plans, and follow-up surveys or follow-up inspection reports related to the survey or inspection report provided pursuant to subparagraph 1 or 2 above;
- K. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
 - L. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body;
 - M. A text summary of any complaints filed or generated against the hospital relating to pharmacy services during the ten years preceding application that includes, for each such complaint, the allegations of the complaint, the complaint investigation, and the findings, resolution, and any remediation or penalties ordered against or agreed to by the hospital; and
 - N. Such other information as the board may require.

2, Processing of Application

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the extended hospital pharmacy will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

3. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;

- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

4. License Term; Renewal

All extended hospital pharmacy licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

5. Change of Ownership, Location or Application Information

Upon a change of ownership, the hospital in which the extended hospital pharmacy is located shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, the hospital in which the extended hospital pharmacy is located shall file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

6. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

An extended hospital pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

6. Maine Rx Plus Prescriptions

With each prescription dispensed to a participant in the Maine Rx Plus Program, 22 MRSA §2681 *et seq.*, the extended hospital pharmacy shall disclose to the purchaser in writing the usual and customary price of the prescription to a purchaser not covered by or enrolled in any type of health insurance, prescription drug benefit or 3d party payor plan, public or private, and the amount of savings provided to the purchaser as a result of the Maine Rx Plus Program. No proprietary information need be disclosed pursuant to this subsection.

STATUTORY AUTHORITY: 22 MRSA §2681(6); 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 35
LICENSURE OF EXTENDED HOSPITAL PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter creates a new classification of retail pharmacy license for extended hospital pharmacies. The new license will cover hospital pharmacy operations that according to DHHS are not included within the scope of the hospital license issued by DHHS. These consist of prescriptions filled for:

- Residents of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital pharmacy is located, and
- Employees, students and medical staff of a nursing facility or skilled nursing facility that is affiliated with the hospital in which the extended hospital is located and their dependents, for their personal use.

“Affiliated” is defined in Chapter 1, Section 1-A(1) to mean, “...a relationship in which one entity owns 100% of the ownership of both a hospital and a nursing facility or skilled nursing facility.”

...

In notices dated April 15 and 16, 2010, PenBay Medical Center (PenBay) notified the board that it intended to start providing pharmacy services to residents at two affiliated nursing homes operated by PenBay, and that it would be taking such action under authority of its hospital license issued by DHHS. The board referred this notice to DHHS for consideration as to whether the proposed activity lay within the scope of the DHHS license, as represented by PenBay.

On August 27, 2010 DHHS responded in the negative, stating that the DHHS hospital license (which includes the hospital pharmacy) is limited to inpatient beds and outpatient services only. In the spring of 2011 the Legislature considered LD 1406, “An Act Regarding the Scope of Services That May Be Provided by Pharmacies Owned by Hospitals.” LD 1406, as amended in committee, would have expanded the scope of the DHHS hospital license to explicitly permit a hospital pharmacy to prescribe to a nursing facility affiliated with the hospital. LD 1406 received a divided report and was not enacted, on the belief that the Board of Pharmacy had the legal authority to issue a license for the requested activity. Such authority resides in 32 MRSA §13751(2)(A) and §13751(3), which authorize the board to issue “various types of licenses with various restrictions to [retail pharmacies] when the board determines it necessary by reason of the type of pharmacy requesting a license.”

On November 16, 2012 board staff commenced discussions with DHHS to clarify the scope of DHHS’ licensing authority with respect to hospital pharmacies. At this time, DHHS interpreted its license as authorizing a hospital pharmacy to fill a prescription only in the following situations:

1. Inpatients, ER patients and outpatients for treatment at the hospital;
2. Former patients upon their discharge, as take home prescriptions necessary for a limited and reasonable time as a continuation of hospital treatment (but not refills);

3. Staff physicians and dependents for personal use; and
4. Employees, students and their dependents for personal use.

These are the types of prescription determined to be for a hospital's "own use" in *Abbott Laboratories v. Portland Retail Druggists Ass'n*, 425 U.S. 1 (1976). In DHHS' view, the *Abbott* criteria represent the limits of DHHS' license authority. The purpose of new Chapter 35 is to authorize dispensing by a hospital pharmacy to a patient population—chiefly residents of affiliated nursing homes—that are outside the scope of the DHHS license.

The board recognizes, of course, that hospital pharmacies and nursing facilities are heavily regulated by DHHS and CMS. For this reason, Chapter 35 does not add any new layer of substantive regulation to the hospital pharmacy other than to confirm, in Section 4, that an extended hospital pharmacy must abide by the DHHS rules governing pharmaceutical services at nursing facilities.

Section 5(1)(J) also requires an extended hospital pharmacy to provide to the board copies of its most recent survey or inspection report as part of the initial application for licensure. The board needs assurance that the hospital pharmacy is meeting pertinent performance standards relating to the pharmacy's existing operations before it confers the additional dispensing authority authorized by this chapter.

Response to Comments

Jeffrey Austin
Maine Hospital Association
Representing 39 community-governed hospitals
(Written comment)

- This rule proposes to resolve the issue to allow hospital-based pharmacies to dispense prescription medication to legally-related nursing facilities by providing an alternative licensure pathway. However, the MHA believes that the proposed rule is requiring "far too much information than is reasonably" required of a hospital-based pharmacy that is licensed by DHHS and heavily regulated and suggest the following modest revisions:
 1. Section 4. Maine hospitals must comply with the Centers for Medicaid and Medicare Services (CMS) Conditions of Participation (CoP) that may be conflict with pharmacy rules. Also, DHHS nursing home rules (Chapter 17) include provisions that do not exist in hospitals, such as, "professional policy group." MHA has not thoroughly reviewed all of chapter 17 it identify other problems, but believer there are other conflicting issues. The board should amend Chapter 35, Section 4 as follows:

~~"An extended hospital pharmacy that dispenses to residents of an affiliated nursing home must comply with the Conditions of Participation promulgated by the Centers for Medicare and Medicaid Services. Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing Facilities and Nursing Facilities / Pharmaceutical Services"(February 1, 2001 edition, as amended effective October 15, 2004. The pharmacist in charge of the extended hospital pharmacy has the responsibilities of the pharmacist consultant described in Chapter 110, Chapter 17.~~

~~The board incorporates Chapter 110, Chapter 17, of DHHS' rules, "Regulations Governing the Licensing and Functioning of Skilled Nursing~~

~~Facilities and Nursing Facilities / Pharmaceutical Services~~ (February 1, 2001 edition, as amended effective October 15, 2004) into this chapter by reference. A copy of Chapter 110, Chapter 17 may be obtained from:

Department of Health and Human Services
Division of Licensing and Regulatory Services
State House Station 11
Augusta, ME 04333

— or —

Maine Secretary of State
<http://www.maine.gov/sos/cec/rules/10/ch110.htm>

- ◆ *Board Response:* The board declines to amend the rule as requested. The Conditions of Participation referenced by the commenter are principally found at 42 CFR Part 482.² Title 42 CFR §482.25 contains a brief condition of participation relating to pharmaceutical services. The condition establishes standards of pharmacy administration and management, security, reporting of drug administration errors and adverse drug reactions, and other requirements of a general nature. None of this specifically addresses pharmaceutical services for patients in nursing homes. The DHHS nursing home rule, by contrast, comprehensively addresses issues relating to drug storage, drug administration, patient safety, drug handling, drug security and recordkeeping requirements that are specific to nursing homes.

The commenter misreads the reference to “Professional Policy Committee” in DHHS Chapter 17, Section (C)(2)(i). The committee is part of the nursing home, not the hospital.

2. Section 5(1)(D)(3). MHA does not see the need for the board to request the name and contact number of each hospital trustee and should be removed.

“If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; ~~the name, contact address and title of each corporate officer and director; the name and contact address of each voting member;~~ a certificate of existence from the corporation’s state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;”

- ◆ *Board Response:* The board declines to amend the rule as requested. The text at issue is part of the board’s standardized application provisions and also appears in Chapter 8 (retail pharmacies), Chapter 36 (opioid treatment centers), Chapter 37 (sterile compounding pharmacies) and Chapter 38 (closed-shop pharmacies) of the board’s rules. The board needs to know who its licensees are. This application requirement does not strike the board as particularly onerous.

3. Section 5(1)(J). MHA does not find it necessary for the board to receive the actual information identified in Sections 5(1)(J)(1 and 2) and considers it sufficient for the board to receive a summary letter in light of information it will obtain pursuant to #3 of the same section. The board should amend the rule as follows:

² Conditions of participation for critical access hospitals are found at 42 CFR Part 485, Subpart F.

J. Survey or Inspection Report—

- (1) If the hospital is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, a copy of the most recent accreditation letter ~~the portion of the most recent survey conducted by the accrediting organization that relates to pharmacy services;~~
- (2) If the hospital is not accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services, ~~the portion of the most recent report of an inspection of the hospital conducted by DHHS that relates to pharmacy services;~~ Maine Department of Health and Human Services, Division of Licensing and Regulatory Services' letter to the hospital following most recent full licensing survey.
- (3) All adverse findings, responses, remediation plans, and follow-up surveys or follow-up inspection reports related to the survey or inspection of pharmacy services ~~report~~ provided pursuant to subparagraph 1 or 2 above;

◆ *Board Response:* The board declines to amend the rule as requested. The board needs the underlying survey or inspection documentation in order to make a responsible licensing decision.

4. Sections 5(1)(K) and (L). The board should include a time period for each provision and recommends a period of five years back and believe this is a sufficient period of time to review prior events. The rule should be amended as follows:

- K. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant during the previous five years;
- L. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body during the previous five years;

◆ *Board Response:* The board declines to amend the rule as requested. All other OPOR programs require an applicant to report past disciplinary violations without any time limitation. The board needs an applicant's complete disciplinary history in order to make a responsible decision on the application before it.

5. Section 5(1)(M). Similar to above, change the reporting time period from ten years preceding application to five years and the board should limit the request to only complaints that resulted in some action taken. The following change is recommended:

- M. A text summary of any complaints filed or generated against the hospital relating to pharmacy services during the ~~ten~~ five years preceding application that resulted in any remediation or penalties and ~~that includes;~~ for each such complaint, the allegations of the complaint, the complaint investigation, and the findings, resolution,

and ~~any~~the remediation or penalties ordered against or agreed to by the hospital; and

- ◆ *Board Response:* The board declines to amend the rule as requested. The 10 year lookback period for the complaint summary is reasonable. Obtaining information about all complaints filed during this period regardless of disposition may alert the board to issues that may warrant investigation prior to issuance of a license.
6. Section 5(1)(N). This section is “too open-ended” and the board should specifically identify any other information that it may require. The board should amend the rule as follows:

N. Such other information, related to subsections A through M above, as the board may require.

- ◆ *Board Response:* The board declines to amend the rule as requested. The text at issue is part of the board’s standardized application provisions and also appears in Chapter 8 (retail pharmacies), Chapter 36 (opioid treatment centers), Chapter 37 (sterile compounding pharmacies) and Chapter 38 (closed-shop pharmacies) of the board’s rules. The board needs the flexibility to request additional information as part of the application process in response to the materials submitted by the applicant. The board cannot predict what issues may arise during the application process that may affect the applicant’s qualifications or eligibility for licensure. The board needs the discretion to obtain all necessary information regarding the applicant’s qualifications and eligibility for licensure.

Douglas S. Carr
CARR CONSULTING
45 Melville St., Suite 1
Augusta ME 04330
Representing 79 Maine retail community pharmacies
Oral and written

- Section 3. Hospital pharmacies should not be permitted to sell at retail those prescription drugs products purchases under GPO (Group Purchasing Organization) pricing. The board should make it clear that extended hospital pharmacies “must not enable the sale of prescription drugs to outpatients in a retail pharmacy setting utilizing their GPO pricing.” The commenter recommends that the board add to the definition of “extended hospital pharmacy” in Chapter 1, Section 18-A this chapter and to Section 3 of this chapter the following language:

“Hospital extended pharmacy shall not utilize GPA pricing or otherwise dispense, deliver or distribute prescription drugs to any other person.” Hospitals under this new Chapter should not be allowed to utilize its better pricing arrangements to sell at retail those products purchased under its hospital agreements.”

- ◆ *Board Response:* The board declines to amend the rule as requested. Section 3 of this chapter clearly states that an extended hospital pharmacy may only dispense prescription drugs to residents of an affiliated nursing home, and to employees, students and medical staff of an affiliated nursing home and their dependents, for their personal use. No further prohibitory language is necessary.

Michael Miller
Assistant Attorney General
(written)

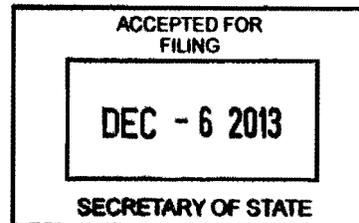
- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-316

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Licensure of Opioid Treatment Programs
4. Chapter number assigned to the rule: 36
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013;
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [X] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following

- [] Provisional adoption (prior to Legislative review) [] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: [Handwritten Signature]
(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. Approved as to form and legality by the Attorney General on 11-19-13
(date)

Signature: [Handwritten Signature]
(original signature, personally signed by an Assistant Attorney General)

Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 36: LICENSURE OF OPIOID TREATMENT PROGRAMS**

Summary: This chapter provides for the licensure of opioid treatment programs.

1. Authority

An opioid treatment program is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required; Coordination With State and Federal Regulatory Requirements

An opioid treatment program must obtain a license from the board. This chapter applies to opioid treatment programs that are—

- Certified or provisionally certified by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration pursuant to 42 CFR Part 8; and
- Licensed by the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services pursuant to 14-118 CMR Chapter 5, Section 19.8.

An opioid treatment program licensed by the board pursuant to this chapter must furnish copies of its federal DHHS certification, DEA number and state DHHS license to the board prior to opening for operation.

Maintenance of federal DHHS certification and state DHHS licensure as set forth above is an ongoing requirement of licensure by the board. Any loss or lapse of federal DHHS certification or state DHHS licensure may result in disciplinary action by the board.

3. Licensure**1. Application; Fees**

An application for licensure as an opioid treatment program must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will

not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the opioid treatment program;
- C. All trade or business names used or to be used by the opioid treatment program;
- D. The names of the owner of the opioid treatment program, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.

- (5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- E. A scaled drawing and floor plan of the opioid treatment program which details the usage of each area, including the waiting area, consultation area, dispensing area and drug storage area;
- F. Confirmation that the following equipment is available on site:
- (1) An automated data processing system;
- (2) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
- (3) Prescription labels imprinted or computer-generated with the name, address, and telephone number of the opioid treatment program that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
- (4) Auxiliary labels;
- (5) Sufficient equipment to maintain the scope of practice;
- G. Demonstration of compliance with the barrier, alarm and security camera requirements of Chapter 13, Section 6 of the board's rules;
- H. The name and license number of the pharmacist in charge of the opioid treatment program;
- I. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
- J. Such other information as the board may require.

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as an opioid treatment program:

- A. The applicant's past experience in the dispensing or compounding of prescription drugs;
- B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing or compounding of prescription drugs;

- C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
- D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
- E. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by pharmacies.

3. Processing of Application

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the opioid treatment program will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

4. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.

Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

5. Separate License for Each Facility

The owner of an opiate treatment program must file a separate application for each facility that dispenses or administers opioids.

6. License Term; Renewal

All opioid treatment program licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

7. Change of Ownership, Location or Application Information

Upon a change of ownership, the opioid treatment program must file a new application with the board no less than 7 days prior to the change. Upon a change of location, the opioid treatment program must file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

8. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

An opioid treatment program shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

9. Alteration of Dispensing Area

An opiate treatment program may not alter the physical dimensions of the dispensing area or add or change the doors, windows or other means of access to the dispensing area prior to receiving approval from the board. The opiate treatment program must provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

4. Pharmacist in Charge**1. Generally**

Dispensing of opioids and other prescription drugs must be conducted under the indirect supervision of a licensed pharmacist who has registered with the board as the pharmacist in charge of the opioid treatment program. No opioid treatment program may operate without a pharmacist in charge.

2. Responsibilities

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the opioid treatment program for which the licensee is registered as pharmacist in charge, and for the opioid treatment program's

compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules specified in Chapter 29, Section 1 of the board's rules.

The pharmacist in charge is responsible for preparing doses of opiate agonist treatment medications in properly labeled, patient-specific containers for delivery of such drugs to patients for consumption away from the facility. The responsibilities of the pharmacist in charge also include, but are not limited to:

- A. The opioid treatment program's procedures for the procurement, storage, compounding and dispensing of drugs;
- B. The recordkeeping systems required in the practice of pharmacy for the purchase, possession, storage and repackaging of drugs; and
- C. Ensuring that the dispensing area is operating in conformance with good pharmaceutical practices.

3. Presence at Opioid Treatment Center

The pharmacist in charge of an opioid treatment program shall be physically present at the facility to prepare drugs for delivery as described in subsection 2 above. The pharmacist in charge need not be present when drugs are delivered to patients. As set forth in Chapter 13, Section 3(4) of the board's rules, a pharmacist's application to serve as pharmacist in charge of an opioid treatment program and one other type of non-opioid pharmacy, or two opioid treatment programs and no other non-opioid pharmacy, will be approved automatically, subject to disciplinary review.

4. Patient Counseling

A pharmacist in charge may comply with the requirement of patient counseling set forth in 32 MRSA §13784 by ensuring that written directions for use and other information relating to proper utilization of the medication prescribed are included with each new prescription delivered by the opioid treatment program. The written information must include a telephone number at which the pharmacist in charge may be contacted by patients.

5. Operational Requirements

1. Security

The opioid treatment program must comply at all times with the alarm and security camera requirements of Chapter 13, Section 6 of the board's rules.

2. Cleanliness and Sanitation

- A. The opioid treatment program must at all times be operated in a clean and sanitary manner in compliance with all federal, state and local health laws. The program must:

- (1) Keep walls, ceilings, windows and floors clean and in good repair;
 - (2) Have a sufficient number of waste receptacles in the dispensing and drug storage areas;
 - (3) Keep equipment clean and stored in an orderly manner; and
 - (4) Have adequate restroom facilities for employees and patients.
- B. All areas where drugs are dispensed or stored must be well-lighted, dry, and well-ventilated. The drug storage area must be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP or the manufacturer's or distributor's labeling unless otherwise indicated by the board.
- C. Animals may not be kept or allowed in the dispensing or drug storage area. This provision does not apply to service animals accompanying disabled persons.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 36: LICENSURE OF OPIOID TREATMENT PROGRAMS**

Summary: This chapter provides for the licensure of opioid treatment programs.

1. Authority

An opioid treatment program is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3).

2. License Required; Coordination With State and Federal Regulatory Requirements

An opioid treatment program must obtain a license from the board. This chapter applies to opioid treatment programs that are—

- Certified or provisionally certified by the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration pursuant to 42 CFR Part 8; and
- Licensed by the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services pursuant to 14-118 CMR Chapter 5, Section 19.8.

An opioid treatment program licensed by the board pursuant to this chapter must furnish copies of its federal DHHS certification, DEA number and state DHHS license to the board prior to opening for operation.

Maintenance of federal DHHS certification and state DHHS licensure as set forth above is an ongoing requirement of licensure by the board. Any loss or lapse of federal DHHS certification or state DHHS licensure may result in disciplinary action by the board.

3. Licensure**1. Application; Fees**

An application for licensure as an opioid treatment program must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled “Establishment of License Fees.” Incomplete applications will

not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the opioid treatment program;
- C. All trade or business names used or to be used by the opioid treatment program;
- D. The names of the owner of the opioid treatment program, including:
 - (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.

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 - (1) An automated data processing system;
 - (2) Containers which meet official compendia standards, available with closures that meet Federal Poison Prevention Packaging Act of 1970 requirements, as well as regular closures;
 - (3) Prescription labels imprinted or computer-generated with the name, address, and telephone number of the opioid treatment program that do not contain any symbol or background logo that interferes with the reading and interpretation of any information written by the pharmacist on the label;
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- G. Demonstration of compliance with the barrier, alarm and security camera requirements of Chapter 13, Section 6 of the board's rules;
- H. The name and license number of the pharmacist in charge of the opioid treatment program;
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- C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
- D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
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- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the opioid treatment program will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

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[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

4. Pharmacist in Charge**1. Generally**

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compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules specified in Chapter 29, Section 1 of the board's rules.

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- B. The recordkeeping systems required in the practice of pharmacy for the purchase, possession, storage and repackaging of drugs; and
- C. Ensuring that the dispensing area is operating in conformance with good pharmaceutical practices.

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5. Operational Requirements

1. Security

The opioid treatment program must comply at all times with the alarm and security camera requirements of Chapter 13, Section 6 of the board's rules.

2. Cleanliness and Sanitation

- A. The opioid treatment program must at all times be operated in a clean and sanitary manner in compliance with all federal, state and local health laws. The program must:

- (1) Keep walls, ceilings, windows and floors clean and in good repair;
 - (2) Have a sufficient number of waste receptacles in the dispensing and drug storage areas;
 - (3) Keep equipment clean and stored in an orderly manner; and
 - (4) Have adequate restroom facilities for employees and patients.
- B. All areas where drugs are dispensed or stored must be well-lighted, dry, and well-ventilated. The drug storage area must be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the USP or the manufacturer's or distributor's labeling unless otherwise indicated by the board.
- C. Animals may not be kept or allowed in the dispensing or drug storage area. This provision does not apply to service animals accompanying disabled persons.
-

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 36
LICENSURE OF OPIOID TREATMENT PROGRAMS
ADOPTED OCTOBER 3, 2013

Basis Statement

This chapter creates a new classification of retail pharmacy license for opioid treatment programs. Opioid treatment programs are currently licensed as ordinary retail pharmacies, but various requirements of Chapters 8 and 13 (e.g., full-time pharmacist in charge, equipment requirements, minimum pharmacy hours, posting of hours, general prescription obligations, signage) are inapplicable to such facilities. This chapter also coordinates licensure by the board with certification by the federal DHHS and licensure by Maine DHHS.

Response to Comments

Mark W. Parrino, President
American Association for the Treatment of Opioid Dependence, Inc. (AATOD)
225 Varick St, 4th floor
New York, NY 10014
(written comment as presented by Timothy McBrady at public hearing)

- AATOD represents more than 900 opioid treatment programs in the U.S. and Mexico. OTPs are extensively regulated by the Substance Abuse and Mental Health Services Administration (SAMHSA) within the federal DHHS, by DEA, and by the Maine Office of Substance Abuse. SAMHSA regulation takes the form of a certification requirement, accreditation oversight through federally approved accrediting agencies, and a treatment improvement protocol. The SAMSHA rules “provides guidance on initial dosage induction, in addition to criteria to determine take home medication for patients who are stable enough to receive such medication.” The treatment improvement protocol “provides extremely detailed information on the pharmacology of medications used to treat opioid addiction, as well as initial screening, admission procedures, and clinical techniques. It also provides specific guidance with regard to the induction of the patient with the federally approved medications and phases of care. In effect, these guidance documents and regulations provide a clear direction of how such medications should be used in the treatment of opioid addiction at the program setting.” The commenter provided further detail concerning initial dosage for new clients, avoidance of overdosing during the first days of treatment, and the transition of clients to unsupervised or “take-home” medication.

“We understand that Maine is proposing to reduce pharmacy oversight of OTPs, which is appropriate. However, we would suggest that the Board take the additional step of removing OTPs from pharmacy regulation given the existing layers of oversight” summarized above. The administration of methadone is not the same as the practice of retail pharmacy. “Rather, the vast majority of OTPs in the United States have nurses administering and dispensing take home doses of medication to patients. These clinics are supervised by medical directors under federal regulation.”

“Finally, AATOD and SAMHSA do not view OTPs as retail pharmacy operations. OTPs offer comprehensive rehabilitative care to patients who are treated for chronic opioid addiction. Three federally approved medications to treat chronic opioid addiction are

administered and dispensed to patients through these OTPs. Comprehensive counseling and other clinical/medical services are provided to patients as part of treatment. In summary, OTPs are not pharmacies nor should they be regulated as pharmacies through Boards of Pharmacy.”

Christopher P. Joseph, R.Ph.
and
Frieda L. Joseph, R.Ph.
(written)

- “[Pharmacists’] role at the clinics is to prepare doses for patients to take home with them after they have met certain criteria of the programs. We confirm inventory and that ordering is carried out in accordance to the DEA regulations. We are also available for drug effect and interaction questions of the staff.” The commenters agree with the June 14, 2013 letter from Mark Parrino of the American Association for the Treatment of Opioid Dependence presented at the public hearing. “We feel that with the oversight in place throughout the government, the OTPs are well regulated and the Board of Pharmacy rules are not necessary for the safe and effective treatment of patients in the OTP setting. We would suggest that OTPs should be considered clinics and that the patients are treated under the supervision of physicians, nurses and counselors. The take away doses would be more effectively prepared at the time of dosing by the nurse who prepares the dose at the window... OTPs do not fit into the framework of a pharmacy and do not need to be regulated by the Board of Pharmacy.”
 - ◆ *Board Response to the foregoing comments:* The board declines to abandon regulation of opioid treatment centers. Common sense dictates that the board have jurisdiction over a facility in which prescription drugs are dispensed. The board’s rules and regulatory enforcement reach areas of pharmacy practice and center operation that combat diversion of drugs and ensure that pharmaceutical operations are under the supervision of a pharmacist in charge. The board actively investigates possible violations of its rules. See, e.g., the consent agreements in Discovery House of Central Maine, Complaint No. 2011-PHA-7586 (December 21, 2011) (installation of third dispensing window without seeking board approval); Turning Tide, Inc., Complaint No. 2009-PHA-5648 (February 2, 2010) (registered PIC was never present at the facility); Metro Treatment of Maine, LP, Complaint No. 2008-PHA-4813 (July 30, 2009) (violation of security camera requirements).

Opioid treatment centers are currently treated as retail pharmacies in the rulemaking scheme. The board proposed adoption of this chapter to remove unnecessary regulatory requirements that currently apply to opioid treatment centers. Total deregulation of opioid treatment centers was not part of the proposed rules and for this reason may not be considered in this rulemaking proceeding.

Michael Miller
Assistant Attorney General
(written)

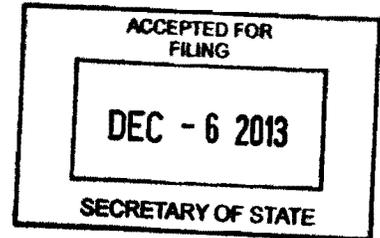
- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-317

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

- 1. Agency: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. Agency umbrella and unit number: 02-392
3. Title of rule: Licensure of Sterile Compounding Pharmacies
4. Chapter number assigned to the rule: 37
5. Date(s)/method(s) of notice: Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. Date(s)/place(s) of hearing(s): June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. Type: [X] new rule [] partial amendment(s) of existing rule
[] suspension of existing rule [] repeal of rule [] emergency rule
[] repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.

8. Name/phone of agency contact person: Geraldine Betts, Board Administrator, (207) 624-8625

- 9. If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following
[] Provisional adoption (prior to Legislative review)
[] Final adoption
[] Emergency adoption of major-substantive rule

10. Certification Statement: I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.
Signature: [Handwritten Signature]
Printed Name & Title: Joseph Bruno, Board President
11. Approved as to form and legality by the Attorney General on 11-19-13
Signature: [Handwritten Signature]
Printed Name: Lauren LaRochelle

EFFECTIVE DATE: DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 37: LICENSURE OF STERILE COMPOUNDING PHARMACIES**

Summary: This chapter provides for the licensure of sterile compounding pharmacies.

1. Authority

A sterile compounding pharmacy is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3). A sterile compounding pharmacy must be licensed by the board pursuant to this chapter. For pharmacies that hold or apply for a general retail pharmacy license or closed-shop pharmacy license, the sterile compounding pharmacy license may be issued in the form of an endorsement to the general retail or closed-shop pharmacy license.

2. Scope of License Requirement

A sterile compounding pharmacy must be licensed by the board pursuant to this chapter. A non-sterile compounding pharmacy must be licensed as a general retail pharmacy pursuant to Chapter 8 of the board's rules or a closed-shop pharmacy pursuant to Chapter 38 of the board's rules.

3. Licensure**1. Application; Fees**

An application for licensure as a sterile compounding pharmacy must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the sterile compounding pharmacy;
- C. All trade or business names used or to be used by the sterile compounding pharmacy;

D. The names of the owner of the sterile compounding pharmacy, including:

- (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
- (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
- (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
- (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
- (5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;

E. A scaled drawing and floor plan of the sterile compounding pharmacy which details the usage of each area;

F. The name and license number of the pharmacist in charge of the sterile compounding pharmacy;

G. Demonstration of compliance with the barrier, alarm and security camera requirements of Section 5, 6 and 7 of this chapter;

H. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and

I. Such other information as the board may require.

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as a sterile compounding pharmacy:

A. The applicant's past experience in the dispensing or compounding of prescription drugs;

B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing or compounding of prescription drugs;

C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;

D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and

E. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by pharmacies.

3. Processing of Application

A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the sterile compounding pharmacy will be in the best interest of the public health and welfare.

B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

4. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

A. Submit an application with modifications requested by the board;

- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

5. Separate License for Each Facility

The owner of a sterile compounding pharmacy must file a separate application for each facility engaged in the compounding of sterile pharmaceuticals.

6. License Term; Renewal

All sterile compounding pharmacy licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

7. Change of Ownership, Location or Application Information

Upon a change of ownership, the sterile compounding pharmacy must file a new application with the board no less than 7 days prior to the change. Upon a change of location, the sterile compounding pharmacy must file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

8. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A sterile compounding pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

4. Pharmacist in Charge

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the sterile compounding pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules and other codes specified in Chapter 29, Section 1 of the board's rules. Unless waived by the

board for good cause shown, the pharmacist in charge shall practice at the sterile compounding pharmacy for a minimum of 30 hours per week or 50% of the hours the pharmacy is open, whichever is less. However, a waiver from the 30 hour/50% requirement will be automatically approved upon request by a pharmacist to the extent authorized by Chapter 13, Section 43(4) of the board's rules.

[NOTE: Chapter 13, Section 43(4) provides in pertinent part that “[a] request to serve as pharmacist in charge of a retail pharmacy, closed pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically subject to disciplinary review.”]

The responsibilities of the pharmacist in charge include, but are not limited to:

1. The pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;
2. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
3. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination;
4. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
5. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

5. Deployment of Barrier

1. Applicability

This section applies to a self-standing sterile compounding pharmacy or a sterile compounding pharmacy at the same location as a general retail pharmacy. This section does not apply to a sterile compounding pharmacy at the same location as a closed-shop pharmacy.

2. Barrier

During the absence of a pharmacist or pharmacy technician from the prescription filling area, the prescription filling area shall be secured with a barrier that extends from the floor or counter to the ceiling. The barrier must be constructed of a material of sufficient strength so that the barrier cannot be readily removed, penetrated or bent. If the barrier is constructed of non-solid material, any openings or interstices must be small enough to prevent the removal, by any means, of items from the prescription filling area. If, in addition, there is no authorized person in the prescription filling area, the barrier shall also be locked. The retail pharmacy and

pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the lock.

As an alternative to the barrier described in the preceding paragraph, the sterile compounding pharmacy may be protected by a restricted admission protocol such as a locked, secured door which is only opened for customers and visitors on an individual basis.

6. Alarm

The gowning room, clean room, prescription filling area, drug storage areas and shipping area must be protected by an electronic security system. The sterile compounding pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

7. Security Cameras

A sterile compounding pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy, including, at a minimum, the gowning room, clean room, prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, controlled drug storage areas, shipping area and checkout area. The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A sterile compounding pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the gowning room, clean room, controlled drug storage areas and shipping area goes into effect on July 1, 2014.

8. Alteration of Prescription Filling Area

A sterile compounding pharmacy may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

9. Deliveries; Closing Procedures

A sterile compounding pharmacy shall comply with the following rules of the board applicable to retail pharmacies:

1. Chapter 13, Section 6(9), Deliveries and Delivery Logs; and
2. Chapter 13, Section 9, Permanent Closing of a Retail Pharmacy.

10. Operational Requirements

A sterile compounding pharmacy shall comply in all respects with United States Pharmacopeia USP 36-NF 31, General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations, 2013-14 edition, Vol. 1, p. 361 (“Chapter 797”). The board incorporates Chapter 797 into this chapter by reference. Chapter 797 may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

11. Activity Records

At the request of the board, a sterile compounding pharmacy shall generate within 3 business days a report showing the number and type of prescriptions dispensed during the period of time specified by the board. The contents and format of the report shall be determined by the board. The reporting period is subject to the record retention requirements contained in Chapter 24 of the board’s rules.

12. Notice of Potential Contamination

Upon discovery of potential contamination, the pharmacist in charge or pharmacist on duty shall immediately notify the board and any patients to whom a potentially contaminated sterile pharmaceutical was dispensed or administered. Positive sterility test results shall prompt a rapid and systematic investigation of aseptic techniques, environmental controls, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 37: LICENSURE OF STERILE COMPOUNDING PHARMACIES**

Summary: This chapter provides for the licensure of sterile compounding pharmacies.

1. Authority

A sterile compounding pharmacy is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3). A sterile compounding pharmacy must be licensed by the board pursuant to this chapter. For pharmacies that hold or apply for a general retail pharmacy license or closed-shop pharmacy license, the sterile compounding pharmacy license may be issued in the form of an endorsement to the general retail or closed-shop pharmacy license.

2. Scope of License Requirement

A sterile compounding pharmacy must be licensed by the board pursuant to this chapter. A non-sterile compounding pharmacy must be licensed as a general retail pharmacy pursuant to Chapter 8 of the board's rules or a closed-shop pharmacy pursuant to Chapter 38 of the board's rules.

3. Licensure**1. Application; Fees**

An application for licensure as a sterile compounding pharmacy must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the sterile compounding pharmacy;
- C. All trade or business names used or to be used by the sterile compounding pharmacy;

- D. The names of the owner of the sterile compounding pharmacy, including:
- (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- E. A scaled drawing and floor plan of the sterile compounding pharmacy which details the usage of each area;
- F. The name and license number of the pharmacist in charge of the sterile compounding pharmacy;
- G. Demonstration of compliance with the barrier, alarm and security camera requirements of Section 5, 6 and 7 of this chapter;

- H. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
- I. Such other information as the board may require.

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as a sterile compounding pharmacy:

- A. The applicant's past experience in the dispensing or compounding of prescription drugs;
- B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing or compounding of prescription drugs;
- C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
- D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
- E. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by pharmacies.

3. Processing of Application

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the sterile compounding pharmacy will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

4. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;

- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

5. Separate License for Each Facility

The owner of a sterile compounding pharmacy must file a separate application for each facility engaged in the compounding of sterile pharmaceuticals.

6. License Term; Renewal

All sterile compounding pharmacy licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

7. Change of Ownership, Location or Application Information

Upon a change of ownership, the sterile compounding pharmacy must file a new application with the board no less than 7 days prior to the change. Upon a change of location, the sterile compounding pharmacy must file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

8. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A sterile compounding pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

4. Pharmacist in Charge

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the sterile compounding pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules and other codes specified in Chapter 29, Section 1 of the board's rules. Unless waived by the

board for good cause shown, the pharmacist in charge shall practice at the sterile compounding pharmacy for a minimum of 30 hours per week or 50% of the hours the pharmacy is open, whichever is less. However, a waiver from the 30 hour/50% requirement will be automatically approved upon request by a pharmacist to the extent authorized by Chapter 13, Section 3(4) of the board's rules.

[NOTE: Chapter 13, Section 3(4) provides in pertinent part that “[a] request to serve as pharmacist in charge of a retail pharmacy, closed pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically subject to disciplinary review.”]

The responsibilities of the pharmacist in charge include, but are not limited to:

1. The pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;
2. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
3. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination;
4. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
5. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

5. Deployment of Barrier

1. Applicability

This section applies to a self-standing sterile compounding pharmacy or a sterile compounding pharmacy at the same location as a general retail pharmacy. This section does not apply to a sterile compounding pharmacy at the same location as a closed-shop pharmacy.

2. Barrier

During the absence of a pharmacist or pharmacy technician from the prescription filling area, the prescription filling area shall be secured with a barrier that extends from the floor or counter to the ceiling. The barrier must be constructed of a material of sufficient strength so that the barrier cannot be readily removed, penetrated or bent. If the barrier is constructed of non-solid material, any openings or interstices must be small enough to prevent the removal, by any means, of items from the prescription filling area. If, in addition, there is no authorized person in the prescription filling area, the barrier shall also be locked. The retail pharmacy and

pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the lock.

As an alternative to the barrier described in the preceding paragraph, the sterile compounding pharmacy may be protected by a restricted admission protocol such as a locked, secured door which is only opened for customers and visitors on an individual basis.

6. Alarm

The gowning room, clean room, prescription filling area, drug storage areas and shipping area must be protected by an electronic security system. The sterile compounding pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

7. Security Cameras

A sterile compounding pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy, including, at a minimum, the gowning room, clean room, prescription filling area, self-service customer kiosks, dispensing machines that are part of an automated pharmacy system, controlled drug storage areas, shipping area and checkout area. The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A sterile compounding pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the gowning room, clean room, controlled drug storage areas and shipping area goes into effect on July 1, 2014.

8. Alteration of Prescription Filling Area

A sterile compounding pharmacy may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

9. Deliveries; Closing Procedures

A sterile compounding pharmacy shall comply with the following rules of the board applicable to retail pharmacies:

1. Chapter 13, Section 6(9), Deliveries and Delivery Logs; and
2. Chapter 13, Section 9, Permanent Closing of a Retail Pharmacy.

10. Operational Requirements

A sterile compounding pharmacy shall comply in all respects with United States Pharmacopeia USP 36-NF 31, General Chapter <797>, Pharmaceutical Compounding – Sterile Preparations, 2013-14 edition, Vol. 1, p. 361 (“Chapter 797”). The board incorporates Chapter 797 into this chapter by reference. Chapter 797 may be obtained from:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
(703) 605-6400

-or-

U.S. Pharmacopeial Convention
www.usp.org

11. Activity Records

At the request of the board, a sterile compounding pharmacy shall generate within 3 business days a report showing the number and type of prescriptions dispensed during the period of time specified by the board. The contents and format of the report shall be determined by the board. The reporting period is subject to the record retention requirements contained in Chapter 24 of the board’s rules.

12. Notice of Potential Contamination

Upon discovery of potential contamination, the pharmacist in charge or pharmacist on duty shall immediately notify the board and any patients to whom a potentially contaminated sterile pharmaceutical was dispensed or administered. Positive sterility test results shall prompt a rapid and systematic investigation of aseptic techniques, environmental controls, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 37
LICENSURE OF STERILE COMPOUNDING PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter creates a new classification of retail pharmacy license for sterile compounding pharmacies. The release of contaminated product by Massachusetts-based New England Compounding Center in 2012 and the ensuing patient deaths and illnesses caused the board to re-evaluate existing Chapter 18, Sterile Pharmaceuticals. In this rulemaking proceeding the board repealed Chapter 18 and replaced it with this chapter.

Chapter 797 of the U.S. Pharmacopeia, "Pharmaceutical Compounding – Sterile Preparations" is a recognized industry standard for the compounding of sterile pharmaceuticals. This chapter incorporates USP 797 by reference as the regulatory standard for the compounding of sterile pharmaceuticals in Maine. The board sees no need to gild the lily by writing additional rules in this area.

The board considered but ultimately rejected other operational requirements that were under consideration in Massachusetts during the board's rule development process. These included sterility testing requirements that exceed the sterility testing requirements in USP 797, and a requirement that sterile compounding pharmacies be accredited by a third-party accrediting body such as the Pharmacy Compounding Accreditation Board.

Records of compounding activity must be produced upon request of the board. Such a request could arise in the context of a complaint or other investigation, or as a follow-up to an inspection.

This chapter requires the pharmacist in charge or pharmacist on duty to give immediate notice of potential contamination to the board and any patients to whom a potentially contaminated sterile pharmaceutical was dispensed or administered. This notice requirement, if complied with, may help limit the scope of potential death or injury in the event that contaminated product is shipped.

Response to Comments

Mark McAuliffe
Apothecary by Design
84 Marginal Way Suite 100 and
141 Preble St
Portland ME 04101
(oral and written and follow-up written)

- The commenter supports the overall efforts of the board and offered two recommendations in the area of compounding and pharmacy technician ratios and roles (Chapter 7CK). The commenter recognized the recent compounding tragedies in Massachusetts and Tennessee that shocked and saddened the compounding community and "...supports additional controls and licensing for sterile compounding facilities" and that it is "...critical that the regulatory process not only discipline compounding pharmacies when needed but also ensure that the regulations under which the pharmacies work are clear and that the inspection process focuses on improving processes. The commenter applauds the board for making it clear that it adopts USP 795 and 797 guidelines as the

standards for compounding pharmacies in Maine. The board should consider five changes:

1. "Incorporate a clearer statement about the traditional right of pharmacies to compound within the rules promulgated by the (board) and that such pharmacies are subject to USP 797 and 795 and not Good Manufacturing Practices."
2. Reiterate that pharmacies that compound in accordance with Maine rules and regulations are subject to the (board's) authority.
3. Require that the (board) be responsible to inspect compounding pharmacies...and must either have trained staff to inspect compounding facilities or contract to independent, nonfederal third parties (like NABP)
4. Eliminate references to Good Manufacturing practices in any part of the Board's regulations of compounding pharmacies (particularly but not exclusively Chapter 29)
5. Ensure that hospitals that do compounding are not excluded from meeting USP 795 and 797 guidelines.

Robert A. Morrissette, R.Ph., BSPHarm
University of New England
Department of Pharmacy Practice
(oral and written)

- The commenter expressed overall support of the rule changes for compounding and adoption of the USP 795 and 797 standards for compounding pharmacies in Maine. However, the board should eliminate the references to Good Manufacturing Practices such as in Chapter 29, 5 due to the difficulty in applying these standards.

Christen Roy, PharmD, Director of Pharmacy
and
Stephen Drapeau, RPh, JD, Clinical & Compounding Pharmacist
Briova Specialty Pharmacy
53 Darling Avenue
S. Portland ME 04106
(written)

- The commenters support the board's proposal naming USP chapters 795 and 797 as the standards for pharmacies to follow when compounding drugs, with the following recommended change. The board should:
 1. "Include a statement requiring traditional sterile and non-sterile compounding by Maine Licensed pharmacies to be conducted in accordance with the standards set forth in USP chapters 795 and 797."

Mary Pierskalla, R.Ph. MBA, Director of Pharmacy
New England Life Care
Home Infusion Therapy Services
Portland ME 04103
(written)

- The commenter commended the board on its comprehensive rulemaking initiative. The commenter raised concerns that apply to her unique circumstance as a home infusion pharmacist.
- The commenter supports the adoption of the USP chapter 797 guidelines that will elevate the overall quality of sterile compounding services.

- ◆ *Board Response to the foregoing four comments:* This chapter proposed that compounding of sterile pharmaceuticals be conducted in accordance with:
 - USP 797 (Section 11(1))
 - Records maintenance requirements taken from the NABP "Good Compounding Practices Applicable to State Licensed Pharmacies" (Section 10(1))
 - Quality assurance standards taken from Section 11 of the 2012 NABP Model Rules for Sterile Pharmaceuticals (Section 11(2))

Chapter 13, Section 7 proposed that compounding of non-sterile pharmaceuticals be conducted in accordance with:

- USP 795 (Section 7(4)(A))
- Records maintenance requirements taken from the NABP "Good Compounding Practices Applicable to State Licensed Pharmacies" (Section 7(2))
- Operational requirements taken from the NABP "Good Compounding Practices Applicable to State Licensed Pharmacies" (Section 7(4)(B))

The above comments support the board's reliance on USP 795 and 797, but oppose the board's use of good manufacturing practices as a basis for regulation. See also the Response to Comments for Chapter 29. The opposition to reliance on good manufacturing practices with respect to compounding is primarily focused on the FDA Current Good Manufacturing Practice for Finished Pharmaceuticals discussed in the Response to Comments for Chapter 29. However, the board interprets these comments as also applying to the board's reliance on the NABP good compounding practices as described immediately above.

USP 795 and 797 are comprehensive industry standards in the area of compounding. Upon consideration of the comments, the board now concludes that inclusion of the NABP good compounding practices both in this chapter and Chapter 13, Section 7 poses the risk of overlapping, conflicting or duplicative regulation. The board has accordingly deleted all regulatory requirements based on the NABP good compounding practices in the adopted rules. The provisions deleted from the proposed rules are:

- Chapter 13, Section 7(2)
- Chapter 13, Section 7(4)(B)
- Chapter 37, Section 10(1)
- Chapter 37, Section 11(2)

The board has reordered the surviving provisions of Chapter 13, Section 7 as adopted. The board has reordered and renumbered the surviving provisions of Chapter 37, Sections 10 and 11 as proposed into Chapter 37, Sections 10, 11 and 12 of the adopted rule.

Chapter 29, Section 1(11) and Section 2 of the proposed rules incorporated the NABP good compounding practices into the board's rules by reference. Due to the removal of the NABP good compounding practices from Chapters 13 and 37, this is no longer necessary. The board has accordingly deleted Section 1(11) from Chapter 29 as adopted, along with the reference to Section 1(11) in Section 2 of Chapter 29.

This chapter as proposed contained a Note relating to Chapter 30, Section 1(29) - (36). For the reason discussed in the response to comments for Chapter 30, the board has deleted Chapter 30, Section 1(29) - (36) of the proposed rules from Chapter 30 as adopted. The board has accordingly deleted the Note from this chapter as adopted. Similar action was taken with respect to Chapter 13, Section 7.

Mary Pierskalla, R.Ph. MBA, Director of Pharmacy
New England Life Care
Home Infusion Therapy Services
Portland ME 04103
(written)

- The USP 797 guidelines are confusing and difficult to interpret; the Board should consider further defining expectations of pharmacies to meet the USP 797 requirements delineating between "shall" and "should" and how the board may assess compliance. The board should also consider New Hampshire's edge with petitioning infusion pharmacists from hospitals and home infusion companies to organize a task force to meet and develop clinically specific and pharmacy practice relevant verbiage for the board to consider and incorporate into rules.
- Lastly, the board should adopt a specific checklist for inspectors to use when conducting inspections of compounding facilities that would also assist pharmacists on inspection expectations.
 - ◆ *Board Response:* The board acknowledges that implementation of USP 797 isn't always clear. Where USP 797 is ambiguous or lends itself to different interpretations, the board will allow pharmacies ample leeway in complying consistent with the text of USP 797, the purpose of the requirement at issue, and protection of the public health and safety.

Establishment of a task force relating to home infusion pharmacies and development of an inspection checklist are outside the scope of this rulemaking proceeding.

Christen Roy, PharmD, Director of Pharmacy
and
Stephen Drapeau, RPh, JD, Clinical & Compounding Pharmacist
Briova Specialty Pharmacy
53 Darling Avenue
S. Portland ME 04106
(written)

- The board should:
 2. "Include language stating that the Maine Board of Pharmacy reserves the exclusive right to inspect compounding pharmacies within the State of Maine or can delegate their inspection authority to a non-federal organization such as NABP to undertake such an inspection."
 - ◆ *Board Response:* The board declines to amend the rule as requested. The board cannot bar the FDA or DEA from inspecting a compounding pharmacy if either entity believes that a violation of federal law or rule may have occurred.

Susan E.D. Doughty, APRN – CNP
100 Brickhill Ave., #304
So. Portland ME 04106
(written)

Fredric Shotz, ND
Maine Integrative Wellness
174 Falmouth Rd
Falmouth ME 04105
(written)

- “Also, without a clear definition of anticipatory compounding, pharmacies are unable to utilize the level of batching that is necessary to spread the cost of testing and to meet acute patient demands.”
 - ◆ *Board Response:* The board declines to amend the rule as requested. As discussed in the response to the Mark McAuliffe comment on Chapter 30, at this point in time the board has no experience from which to draw a bright line regarding the volume of permissible anticipatory compounding.

Representative Sharon Anglin Treat
Maine House District 79
(written)

- During the 126th Maine Legislature, 1st Regular Session, Rep. Treat introduced LD 1315, which was vetoed by Governor LePage, who stated that the issues raised in the bill around compounding “could be better addressed through rulemaking.” Rep. Treat commented that the proposed rules are a major step in the right direction, but fall short in some areas.
 1. The “proposed rules do not assure the safety of compounding drugs subject to the new Maine sterile compounding license requirement, when the facility sending these drugs into Maine are inspected (or not) in another state.”
 2. The board should address potential conflicts of interest among members of the board by requiring each member to disclose potential conflicts and to recuse from participating in board actions.
 3. The board should better coordinate information and responses between other state government agencies, including the Maine CDC and “provisions to insure that other states notify Maine when a problem is identified in that other state.”
 4. The board should increase staffing to carry out the responsibilities of the board under the rules being proposed as the current level of inspection and enforcement staff is insufficient and require sterile compounding-specific training of its enforcement staff.
 5. The board should require sterile compounding facilities to report on volumes/quantities of compounded drugs produced and used in Maine and compounded drugs shipped out of state.
 6. The board should institute a method of tracking sterile compounded drugs used in Maine that are imported from other states, including the facility performing the compounding.
 7. The board should require, by rule, notification to the “sending pharmacy board or public health authority if a problem is detected in a drug shipped from another state.”
 8. The board should require in conjunction with the licensing process an “assessment of the adequacy of the licensing and inspection in the sending state before those drugs are used in Maine.”
 9. The board should clarify its authority to conduct inspections of out-of-state facilities as may be determined necessary and refuse licensure if the facility is deemed to not be compliance with Maine requirements. Rep. Treat cited the undertaking by the Iowa Board to inspect out-of-state facilities with allegations of a facility shipping medications to hospitals without the required individual prescription and engaging in manufacturing.
 10. The board or the Maine CDC should have authority to act immediately to halt shipments of potentially harmful compounded drugs.

11. The board should publish in readily searchable format information on pharmacy violations involving compounded drugs.

- ◆ *Board Response:* The board declines to amend the rule as requested. The new rules adopted by the board significantly increase state oversight of compounded drugs. New protections include a specific license requirement for sterile compounding pharmacies, incorporation by reference of USP 795 and 797 as standards for the preparation of compounded drugs, a notification requirement upon discovery of potential contamination, and the obligation to provide compounding records to the board upon request.

Many of the commenter's recommendations focus on the importation of compounded drugs from other states into Maine. The commenter suggests that the board license compounding pharmacies in other states that ship into Maine and exercise regulatory authority over such pharmacies in connection with licensure by conducting inspections and by tracking shipments of compounded drugs into the state.

The board currently licenses out-of-state manufacturers and distributors of drugs as well as mail order prescription pharmacies and mail order contact lens suppliers. Specific statutory authority allows the board to license such operations located outside the state.³ The board has no statutory authority to license compounding pharmacies (other than manufacturers) located in other states. Even if the board did have extra-territorial licensing authority, direct inspection of compounding pharmacies in other states would not be feasible for the board. The board's current practice is to rely on inspections performed by the home state licensing authority when licensing manufacturers, distributors, mail order prescription pharmacies and mail order contact lens suppliers located in other states. The board simply does not have the budget or the staff to inspect its licensees that are not located in Maine.

The board recognizes the need for additional inspectors, and recently obtained authorization to fill a vacant inspector position. The position has been upgraded to require a pharmacy or related degree, and the successful applicant will receive training related to the inspection of compounding pharmacies.

The board declines to routinely collect "volumes/quantities of compounded drugs produced and used in Maine and compounded drugs shipped out of state." Chapter 13, Section 7(3) and Chapter 37, Section 11 permit the board to request this information from compounding pharmacies on an as-needed basis.

The board currently has the authority to halt shipments of potentially harmful compounded drugs. See the embargo provisions in 32 MRSA §13723(8).

The board does not disagree with the importance of coordination with other state agencies. Agreements of this nature are typically memorialized in memoranda of understanding rather than agency rule.

Potential conflicts of interest by board members are addressed at the beginning of every disciplinary hearing conducted by the board. The hearing

³ For manufacturers and distributors, see 32 MRSA §§13702-A(24)(B) and 13758. For mail order prescription pharmacies, see 32 MRSA §§13702-A(17) and 13702-A(24)(B). For mail order contact lens suppliers, see 32 MRSA §§13702-A(16) and §13751(3-A).

officer polls the board members for any bias or personal or financial interest that may require disqualification pursuant to 5 MRSA §9063.

The board publishes on its web site in readily searchable format copies of all disciplinary actions issued by the board. Any violations involving compounding drugs would be automatically added to the web site.

Finally, none of the commenter's suggestions were included in the proposed rule and for this reason may not be considered in this rulemaking proceeding.

Michael Miller
Assistant Attorney General
(written)

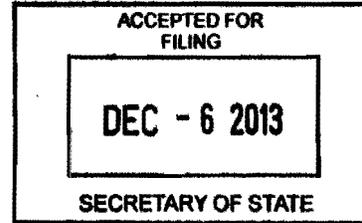
- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.

Rule-Making Cover Sheet

2013-318

TO: Secretary of State
ATTN: Administrative Procedure Officer,
State House Station 101, Augusta, Maine 04333

1. **Agency:** Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy
2. **Agency umbrella and unit number:** 02-392
(2 digit umbrella # and 3 digit unit #)
3. **Title of rule:** Licensure of Closed-Shop Pharmacies
4. **Chapter number assigned to the rule:** 38
(must be 3 digits or less)
5. **Date(s)/method(s) of notice:** Newspaper advertisement by Secretary of State, May 29, 2013; mailing to interested parties, May 23, 2013; posting on OPOR's web site, May 21, 2013.
6. **Date(s)/place(s) of hearing(s):** June 20, 2013, Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, ME



- 7-A. **Type:** new rule partial amendment(s) of existing rule
 suspension of existing rule repeal of rule emergency rule
 repeal and replace: complete replacement of existing chapter, with former version simultaneously repealed.
8. **Name/phone of agency contact person:** Geraldine Betts, Board Administrator, (207) 624-8625
9. **If a major substantive rule under Title 5, c. 375, sub-CII-A, check one of the following**
 Provisional adoption (prior to Legislative review) Final adoption
 Emergency adoption of major-substantive rule

10. **Certification Statement:** I, Joseph Bruno, hereby certify that the attached is a true copy of the rule(s) described above and lawfully adopted by the Maine Board of Pharmacy on October 3, 2013.

Signature: _____

(original signature, personally signed by the head of agency)

Printed Name & Title: Joseph Bruno, Board President

11. **Approved as to form and legality by the Attorney General on** _____

11-19-13

(date)

Signature: _____

(original signature, personally signed by an Assistant Attorney General)

Printed Name: _____

Lauren LaRoche

EFFECTIVE DATE:

DEC 11 2014

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**392 MAINE BOARD OF PHARMACY****Chapter 38: LICENSURE OF CLOSED-SHOP PHARMACIES**

Summary: This chapter provides for the licensure of closed-shop pharmacies.

1. Authority

A closed-shop pharmacy is a classification of retail pharmacy regulated by the board pursuant to 32 MRSA §13751(2)(A) and §13751(3). A closed-shop pharmacy must be licensed by the board pursuant to this chapter. For pharmacies that hold or apply for a general retail pharmacy license, the closed-shop pharmacy license may be issued in the form of an endorsement to the general retail pharmacy license.

2. Scope of License

A closed-shop pharmacy may only serve a limited, institutional patient population such as residents of a long term care facility, assisted living program, residential care facility, residential child care facility, intermediate care facility for persons with mental retardation, or residential mental health facility. A closed-shop pharmacy may not dispense to or be open to the general patient population.

3. Licensure**1. Application; Fees**

An application for licensure as a closed-shop pharmacy must be filed on forms provided by the board. The application must be accompanied by the application and license fees required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees." Incomplete applications will not be accepted and will be returned to the applicant. The applicant shall provide the following information:

- A. The name, address, telephone number and email address of the person responsible for submission of the application;
- B. The name, physical address, contact address, telephone number, email address and world wide web address of the closed-shop pharmacy;
- C. All trade or business names used or to be used by the closed-shop pharmacy;
- D. The names of the owner of the closed-shop pharmacy, including:

- (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
 - (5) If a sole proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;
- E. A scaled drawing and floor plan of the closed-shop pharmacy which details the usage of each area;
- F. The name and license number of the pharmacist in charge of the closed-shop pharmacy;
- G. Verification of the following facilities, apparatus and equipment:
- Adequate lighting
 - Sink with hot and cold running water
 - Rest room facilities

- Refrigerator
- Rx weights (if required by type of Rx balance used)
- Rx balance
- Spatula, non-metal (1)
- Spatula, metal (2)
- Mortar and pestle (2)
- Graduates assorted (4)
- Safety cap Rx containers, if applicable
- Appropriate Rx labels
- Professional reference library, including drug interactions (in any format)
- Current Maine pharmacy laws and rules (in any format);

- H. Demonstration of compliance with the alarm and security camera requirements of Sections 6 and 7 of this chapter;
- I. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
- J. Such other information as the board may require.

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for licensure as a closed-shop pharmacy:

- A. The applicant's past experience in the dispensing or compounding of prescription drugs;
- B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensing or compounding of prescription drugs;
- C. Suspension, revocation or other disciplinary action taken by a federal, state or local governmental body with respect to any type of pharmacy license currently or previously held by the applicant;
- D. Issuance of a citation, warning letter or untitled letter to the applicant by the FDA, or similar action taken by another governmental body; and
- E. Compliance with the requirements to maintain and/or to make available to the board or to federal, state or local law enforcement officials those records required to be maintained by pharmacies.

3. Processing of Application

- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the closed-shop pharmacy will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

4. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

- A. Submit an application with modifications requested by the board;
- B. Furnish additional information requested by the board;
- C. Make site modifications requested by the board;
- D. Request a hearing to contest a preliminary denial; or
- E. Request a hearing to contest a condition imposed by the board.
- F. Failure of the applicant to act within the applicable time period shall result in the automatic denial of the application without need of further action by the board or, in the case of applications conditionally approved, finality of the conditions.

5. Separate License for Each Facility

The owner of a closed-shop pharmacy must file a separate application for each facility.

6. License Term; Renewal

All closed-shop pharmacy licenses expire annually on December 31. A licensee may renew the license by completing the renewal application form provided by the board and remitting the license fee required by Chapter 10, Section 5(27) of the rules of the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, entitled "Establishment of License Fees."

7. Change of Ownership, Location or Application Information

Upon a change of ownership, the closed-shop pharmacy must file a new application with the board no less than 7 days prior to the change. Upon a change of location, the

closed-shop pharmacy must file a new application with the board no less than 7 days prior to the change. The licensee shall notify the board of any other change in the information provided on its application within 10 days after the change.

8. Notice of Termination of Employment of Pharmacist For Drug-Related Reasons or Theft

A closed-shop pharmacy shall notify the board of the termination of employment of a pharmacist for drug-related reasons or theft as required by Chapter 30, Section 1(26) of the board's rules.

4. Pharmacist in Charge

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the closed-shop pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal and state laws and rules and other codes specified in Chapter 29, Section 1 of the board's rules. Unless waived by the board for good cause shown, the pharmacist in charge shall practice at the closed-shop pharmacy for a minimum of 30 hours per week or 50% of the hours the pharmacy is open, whichever is less. However, a waiver from the 30 hour/50% requirement will be automatically approved upon request by a pharmacist to the extent authorized by Chapter 13, Section 3(4) of the board's rules.

[NOTE: Chapter 13, Section 43(4) provides in pertinent part that “[a] request to serve as pharmacist in charge of a retail pharmacy, closed-shop pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically subject to disciplinary review.”]

The responsibilities of the pharmacist in charge include, but are not limited to:

1. The pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;
2. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
3. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination;
4. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
5. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

5. Shared Facilities

A closed-shop pharmacy may share a physical location with another pharmacy. However, the closed-shop pharmacy may not be accessible to the public; inventory of the closed-shop pharmacy must be physically separated from inventory of the other pharmacy; and all records required by the board's rules must be separately maintained.

6. Alarm

The prescription filling area, drug storage areas, compounding area (if applicable) and shipping area shall be protected by an electronic security system. The pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The closed-shop pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

7. Security Cameras

A closed-shop pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy, including, at a minimum, the prescription filling area, dispensing machines that are part of an automated pharmacy system, compounding area (if applicable), controlled drug storage areas and shipping area. The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A closed-shop pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the compounding area (if applicable), controlled drug storage areas and shipping area goes into effect on July 1, 2014.

8. Alteration of Prescription Filling Area

A closed-shop pharmacy may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

9. Compounding

A closed-shop pharmacy that is also a non-sterile compounding pharmacy must comply with Chapter 13, Section 7 of the board's rules. A closed-shop pharmacy that is also a sterile compounding pharmacy must be licensed as a sterile compounding pharmacy pursuant to Chapter 37 of the board's rules.

10. Deliveries; Closing Procedures

A closed-shop pharmacy shall comply with the following rules of the board applicable to retail pharmacies:

1. Chapter 13, Section 6(9), Deliveries and Delivery Logs; and
2. Chapter 13, Section 9, Permanent Closing of a Retail Pharmacy.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

Clean
version
without
strikeouts or
underlines

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- B. The name, physical address, contact address, telephone number, email address and world wide web address of the closed-shop pharmacy;
- C. All trade or business names used or to be used by the closed-shop pharmacy;
- D. The names of the owner of the closed-shop pharmacy, including:

- (1) If a partnership, the name, contact address, telephone number and employer identification number of the partnership, and the name and contact address of each partner;
 - (2) If a business corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock, unless the company is traded on a major stock exchange and not over-the-counter; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (3) If a nonprofit corporation, the name, contact address, telephone number and employer identification number of the corporation; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; the name and contact address of each voting member; a certificate of existence from the corporation's state of organization and, for corporations not organized under Maine law, a certificate of authority from the Maine Secretary of State;
 - (4) If a limited liability company, the name, contact address, employer identification number, telephone number, fax number and email address of the limited liability company; the names and mailing addresses of each member and manager; a certificate of existence from the Maine Secretary of State or, for limited liability companies not organized under Maine law, a certificate of authority or certificate of qualification from the Maine Secretary of State; and the name of the member or manager who will be representing the applicant in matters before the board.
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- E. A scaled drawing and floor plan of the closed-shop pharmacy which details the usage of each area;
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- G. Verification of the following facilities, apparatus and equipment:
- Adequate lighting
 - Sink with hot and cold running water
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- Refrigerator
 - Rx weights (if required by type of Rx balance used)
 - Rx balance
 - Spatula, non-metal (1)
 - Spatula, metal (2)
 - Mortar and pestle (2)
 - Graduates assorted (4)
 - Safety cap Rx containers, if applicable
 - Appropriate Rx labels
 - Professional reference library, including drug interactions (in any format)
 - Current Maine pharmacy laws and rules (in any format);
- H. Demonstration of compliance with the alarm and security camera requirements of Sections 6 and 7 of this chapter;
- I. Upon request of the board, all plumbing permits, electrical permits, certificates of occupancy and other documents necessary to show full compliance with all federal, state and local laws and rules; and
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2. Additional Qualifications

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- A. The board shall review the application for compliance with the pharmacy law and rules and shall issue a license upon a determination that operation of the closed-shop pharmacy will be in the best interest of the public health and welfare.
- B. Following review of the application the board may approve the application, preliminarily deny the application, approve the application with conditions, direct the applicant to resubmit the application with specific modifications, request further information from the applicant, or investigate any of the information contained in the application. A denial shall identify the specific deficiencies in the application that resulted in the denial.

4. Response by Applicant to Adverse Board Action

No later than 30 days following receipt of written notice from the board, or within such longer or shorter time as the board may specify, an applicant may, as the case may be-

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4. Pharmacist in Charge

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[NOTE: Chapter 13, Section 3(4) provides in pertinent part that “[a] request to serve as pharmacist in charge of a retail pharmacy, closed-shop pharmacy and/or sterile compounding pharmacy at the same location will be approved automatically subject to disciplinary review.”]

The responsibilities of the pharmacist in charge include, but are not limited to:

1. The pharmacy's procedures for the procurement, storage, compounding and dispensing of drugs;
2. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;
3. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination;
4. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and
5. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

5. Shared Facilities

A closed-shop pharmacy may share a physical location with another pharmacy. However, the closed-shop pharmacy may not be accessible to the public; inventory of the closed-shop pharmacy must be physically separated from inventory of the other pharmacy; and all records required by the board's rules must be separately maintained.

6. Alarm

The prescription filling area, drug storage areas, compounding area (if applicable) and shipping area shall be protected by an electronic security system. The pharmacy shall activate the electronic security system during the absence of a pharmacist, pharmacy technician or authorized person from the prescription filling area. The closed-shop pharmacy and pharmacist in charge shall ensure that only a pharmacist or authorized person possesses or has access to the key, combination or activation code to the electronic security system.

7. Security Cameras

A closed-shop pharmacy shall deploy security cameras sufficient in number to monitor the critical areas of the pharmacy, including, at a minimum, the prescription filling area, dispensing machines that are part of an automated pharmacy system, compounding area (if applicable), controlled drug storage areas and shipping area. The cameras shall operate continuously, without interruption, 24 hours per day each day of the year. The cameras shall continuously record and store images of the monitored area at a frequency of no less than 15 frames per second. A closed-shop pharmacy shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

The requirement of security camera coverage of the compounding area (if applicable), controlled drug storage areas and shipping area goes into effect on July 1, 2014.

8. Alteration of Prescription Filling Area

A closed-shop pharmacy may not alter the physical dimensions of the prescription filling area or add or change the doors, windows or other means of access to the prescription filling area prior to receiving approval from the board. The pharmacy shall provide a scaled drawing of the proposed alteration at the time it requests approval.

[NOTE: Cosmetic changes (e.g., carpet replacement) and changes that are non-structural in nature (e.g., relocation of shelving) do not require board approval.]

9. Compounding

A closed-shop pharmacy that is also a non-sterile compounding pharmacy must comply with Chapter 13, Section 7 of the board's rules. A closed-shop pharmacy that is also a sterile compounding pharmacy must be licensed as a sterile compounding pharmacy pursuant to Chapter 37 of the board's rules.

10. Deliveries; Closing Procedures

A closed-shop pharmacy shall comply with the following rules of the board applicable to retail pharmacies:

1. Chapter 13, Section 6(9), Deliveries and Delivery Logs; and
 2. Chapter 13, Section 9, Permanent Closing of a Retail Pharmacy.
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STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

**BASIS STATEMENT AND RESPONSE TO COMMENTS
CHAPTER 38
LICENSURE OF CLOSED-SHOP PHARMACIES
ADOPTED OCTOBER 3, 2013**

Basis Statement

This chapter creates a new classification of retail pharmacy license for closed-shop pharmacies. A closed-shop pharmacy serves a limited, institutional patient population, such as residents of a long-term care facility, and is not open to the general public. The impetus for this chapter came from pharmacies that encountered difficulties in participating in discount group purchasing programs offered by manufacturers unless the pharmacy was a licensed entity separate and apart from an ordinary retail pharmacy. The new chapter permits a closed-shop pharmacy to share a pharmacist in charge with a retail pharmacy at the same location as the retail pharmacy, but requires that inventory and records of the two pharmacies be separately maintained.

Response to Comments

Michael Miller
Assistant Attorney General
(written)

- Ms. Miller identified a number of clerical errors, incorrect cross-references, and items in need of minor clarification in this and other chapters. Almost all of her suggestions have been incorporated into the adopted rules.