02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

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Part 1-General Information

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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(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.

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. [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 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 opthalmics) 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).

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

EFFECTIVE DATE:
November 8, 2004 - filing 2004-503

AMENDED:
February 9, 2009 – Section 8-A added, filing 2009-48
October 1, 2009 – Section 14-A, filing 2009-510 (EMERGENCY)
November 25, 2009 – Section 14-A, filing 2009-610
March 11, 2012 – filing 2012-60
December 11, 2013 – filing 2013-298

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Chapter 2: ADVISORY RULINGS

Summary: This chapter provides for the discretionary issuance of advisory rulings by the board.

1. Request and Consideration

Upon written request of any interested person, the board may issue an advisory ruling pursuant to 5 M.R.S.A. §9001 with respect to the applicability of any statute or rule it administers. Requests for advisory rulings must set forth in detail all facts pertinent to the question. The board may decline to issue an advisory ruling if the question is hypothetical, if there is insufficient information upon which to base a ruling, or for any other reason the board deems proper.

2. Response

The board shall acknowledge receipt of a request for an advisory ruling within 15 days after receipt. The board shall respond to every written request for an advisory ruling within 90 days of its receipt of the request, indicating whether or not a ruling will be issued by the board.

STATUTORY AUTHORITY: 5 M.R.S.A. §§ 8051, 9001(4)

EFFECTIVE DATE:
November 8, 2004 - filing 2004-504

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Chapter 3: APPLICABILITY OF RULES TO UNREGISTERED FACILITIES

Summary: This chapter provides for the applicability of the board's rules to the facilities identified in 32 M.R.S.A. §13721(1)(D).

1. Facilities Not Registered or Licensed by the Board

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 shall comply with and be bound by Chapters 1 - 7 and 14-32 of the board's rules.

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

EFFECTIVE DATE:
November 8, 2004 - filing 2004-505

Part 2 - Licenses and Registrations

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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:
November 8, 2004 - filing 2004-506

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December 11, 2013 – filing 2013-299

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Chapter 4-A: ADMINISTRATION OF DRUGS AND VACCINES AND OPERATION OF A DRUG OR VACCINE ADMINISTRATION CLINIC INSIDE, OUTSIDE OR OFF THE PREMISES OF A LICENSED RETAIL PHARMACY, RURAL HEALTH CLINIC OR FREE CLINIC

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

1. Minimum Requirements for Treatment Protocol Issued Pursuant to 32 M.R.S. §13833

For purposes of this section, a treatment protocol is a written collaborative agreement between a practitioner as described in 32 M.R.S. §13833 and a pharmacist who holds a certificate of administration or pharmacy as described in this section. A treatment protocol authorizes the administration and injection of drugs and vaccines by a pharmacist who holds a certificate of administration pursuant to 32 M.R.S. §§ 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 and injection 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.

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 drug or 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 M.R.S. §13831(2) which authorized administration to the patient or to the patient population of which the patient is a member.

B. Where the Maine Immunization Information System (ImmPact) or a successor system allows for entry of administration of a vaccine, reporting the administration of a vaccine through that system satisfies the requirements of this section.

C. 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 Prevention and the Food and 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.]

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 M.R.S. §13831(2); and

- The applicable treatment protocol issued pursuant to 32 M.R.S. §13833 and Section 1 of this chapter.

1. **Verification**

A. For the administration of all drugs and vaccines pursuant to a prescription or treatment protocol or standing written order, the pharmacist who holds a certificate of administration shall verify:

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

(2) 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.

B. In addition, for the administration of vaccines, the pharmacist who holds a certificate of administration shall verify:

(1) For administration of a COVID-19 vaccine pursuant to 32 M.R.S. §13831(2-A), that the patient is 3 years of age or older;

(2) For administration of influenza vaccines, that the patient is 7 years of age or older; or

(3) For the administration of all other vaccines pursuant to a prescription or treatment protocol or standing written order, 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. **Drug or Vaccine Information**

A pharmacist who holds a certificate of administration, prior to administration, shall give each patient or the patient's legal representative the appropriate drug or vaccine information for the drug or vaccine to be administered. The pharmacist shall 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 drug or vaccine information, 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 vaccine shall issue a certificate of vaccination to the patient or patient's representative at the time the 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 vaccine was administered.

6. **Record of Individual Administration**

A pharmacist who holds a certificate of administration shall record the administration of a drug or 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 drugs and 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 M.R.S. §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 drugs and non-influenza vaccines**

(1) For drugs and vaccinations authorized by prescription, the prescription; and

(2) For drugs and 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.

3. Operation of Drug or Vaccine Administration Clinics; One-Time Approval by Board for a Drug Administration Clinic

1. **Site Suitability**

A drug or 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 or 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 drug administration 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 drug or vaccine information 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 drug or 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 drug or 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 drug or 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 drugs or 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

(5) *Drug or Vaccine Preparation*. Proper drug or vaccine handling and preparation is critical in maintaining the integrity of the drug or 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 or vaccine 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 for a Drug Administration Clinic**

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 drug 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. This section does not apply to a vaccine administration clinic.

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 M.R.S. §13832(3) may administer drugs and vaccines.

5. Scope of this Chapter

The provisions of this chapter apply to drugs and vaccines that may be administered pursuant to 32 M.R.S. §13831.

The provisions of this chapter do not apply to prescribing, administering, or dispensing HIV prevention drugs pursuant to 32 M.R.S. §13786-E.

STATUTORY AUTHORITY:
32 M.R.S. §§ 13720, 13723, 13831, 13832, 13833, 13834(1), 13835

EFFECTIVE DATE:
October 1, 2009 – filing 2009-511 (EMERGENCY)
November 25, 2009 – filing 2009-611

AMENDED:
December 11, 2013 – filing 2013-300
May 15, 2023 – filing 2023-068

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 5: CONTINUING PHARMACY EDUCATION

Summary: This chapter implements the requirement in 32 M.R.S.A. §13735 that each pharmacist complete 15 hours of continuing pharmacy education annually as a condition of license renewal.

[NOTE: Title 32 M.R.S.A. §13735 does not permit the carryover of excess hours from one year to the next.]

1. Continuing Education Requirement

All pharmacists other than newly-licensed pharmacists shall complete 15 contact hours of continuing pharmacy education annually as set forth in this chapter.

2. Newly-Licensed Pharmacists

All pharmacists who obtain an initial license to practice pharmacy in Maine by examination or by reciprocity shall complete 1.25 hours of continuing pharmacy education for each month following initial licensure through December 31 of the calendar year in which they were initially licensed.

3. Processing of Requests For Exceptions

Requests for exceptions to the requirement of 15 hours of continuing pharmacy education made pursuant to 32 M.R.S.A. §13735 (active licensees) or 32 M.R.S.A. §13734(2) (nonactive licensees) shall be decided by the continuing education committee established pursuant to 32 M.R.S.A. §13735.

4. Approved Programs and Activities

Continuing pharmacy education credit may be earned only through attendance or participation in programs and activities that meet the content criteria of 32 M.R.S.A. §13735 and one of the approval criteria set forth in this section. No credit will be given for business meetings of professional associations.

1. Maine Board of Pharmacy

The program or activity is offered or sponsored by the board.

2. Approved Provider

The program or activity is offered by a provider approved by the American Council on Pharmaceutical Education.

3. Approved by Other Jurisdiction

The program or activity is offered outside Maine in a state or province with a requirement of continuing pharmacy education and has been approved by the pharmacy regulatory body for that jurisdiction for continuing pharmacy education credit.

4. Approved by Maine Board of Licensure in Medicine

The program or activity is recognized for continuing medical education credit by the Maine Board of Licensure of Medicine or the Accreditation Council for Continuing Medical Education.

5. Approved Pharmacy Course

A pharmacist who seeks continuing pharmacy education credit for an academic course has obtained advance approval from the continuing education committee prior to the start of classes. The course must be offered by an institution of higher education that has been accredited by an accrediting agency recognized by the U.S. Department of Education. Continuing education credit for approved courses will be recognized at the rate of 15 hours per college credit, but not to exceed 15 hours for any 1 calendar year. A pharmacist who claims continuing pharmacy education credit for an approved academic course will be required to produce proof of successful completion in the event of audit.

6. Approved Lecture

A pharmacist who seeks continuing pharmacy education credit for a lecture delivered by the pharmacist, including reasonable preparation time, has obtained advance approval from the continuing education committee prior to delivering the lecture as set forth in Section 4(7) of this chapter, Section 4(7)(B)(4) and (5) excepted. Credit may only be requested once for the same or substantially the same lecture or presentation.

7. Approved by the Board's Continuing Education Committee

A. The sponsor of the program or activity has obtained advance approval from the continuing education committee established pursuant to 32 M.R.S.A. §13735. The request for approval shall be made within a time designated by the committee and on forms supplied by the committee.

B. In acting on requests for approval, the committee shall consider the following criteria:

(1) The program or activity meets the subject matter requirements of 32 M.R.S.A. §13735;

(2) The program or activity has a demonstrable basis in data, theory or research; offers content that is accurate, objective and timely; is presented in an organized manner conducive to the learning process; and does not overemphasize the commercial views of the provider or sponsor or of anyone giving financial assistance to the provider or sponsor;

(3) The instructor is a pharmacist or other professional who has recognized expertise in the specific subject area of the activity;

(4) The announcement materials for the activity clearly state the name of the sponsor and provider, the name of the individual(s) delivering instruction, the number of contact hours for which the activity has been approved by the board, and the learning objectives of the activity; and

(5) The sponsor has given assurance that-

(a) The program will distribute its articulated learning goals to participants at the beginning of the activity;

(b) The program will solicit the participants' view of the presenter's success at achieving the articulated learning goals of the program; and

(c) Attendees or participants will be given a certificate of completion at the conclusion of the activity stating the clock hours of continuing education credit authorized by the board.

C. The continuing education committee will review the request and will notify the instructor or sponsor, as the case may be, as to whether the activity has been approved for continuing pharmacy education credit and the number of clock hours for which the activity has been approved. In the event of denial, the sponsor or instructor may appeal to the full board.

D. A request for approval of a continuing pharmacy education activity is ordinarily made by the sponsor or instructor. Alternatively, approval may be requested by a prospective attendee or participant.

5. Reinstatement

No license will be issued to a pharmacist applying for reinstatement within 2 years of expiration unless the applicant has completed 15 hours of continuing pharmacy education in the 12 months prior to application.

6. Appeal

A pharmacist may appeal a final decision of the continuing education committee to the board by filing a request for hearing with the board within 30 days of the pharmacist's receipt of the

committee decision from which appeal is taken. An adjudicatory hearing will be scheduled upon receipt of a timely appeal. Non-timely appeals will be denied without hearing.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13723, 13735

EFFECTIVE DATE:
November 8, 2004 - filing 2004-507

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

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

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:
November 8, 2004 - filing 2004-508
March 11, 2012 – filing 2012-61

REPEALED:
December 11, 2013 – filing 2013-301

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:
March 11, 2012 – filing 2012-62

AMENDED:
December 11, 2013 – filing 2013-302

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:
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March 11, 2012 – filing 2012-63

AMENDED:
December 11, 2013 – filing 2013-303

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:
November 8, 2004 - filing 2004-510

AMENDED:
December 11, 2013 – filing 2013-304

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 9: REGISTRATION OF RURAL HEALTH CENTERS

Summary: This chapter sets forth registration requirements for rural health centers.

1. Application for Registration

The rural health center 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.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the rural health center, including the name, contact address, telephone number and employer identification number of the private nonprofit corporation that owns and/or operates the rural health center; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; 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;

2. A copy of the contract between the rural health center and consulting pharmacist required by Chapter 14, Section 1 of the board's rules;

3. The hours of operation of the rural health center;

4. A scaled drawing and floor plan of the rural health center which details the usage of each area;

5. Demonstration of compliance with the storage and security requirements of Chapter 14, Section 4 of the board's rules.

6. 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."

2. Waiver Requests

For good cause shown, the board may waive the storage and security requirements of Chapter 14, Section 4 of the board's rules.

3. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for registration as a rural health center:

1. The applicant's past experience in the dispensation of prescription drugs;

2. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensation of prescription drugs;

3. Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the dispensation of prescription drugs;

4. Compliance with previously granted licenses of any kind; and

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 rural health centers.

4. Change of Owner, Operator, Location or Consulting Pharmacist; Change in Other Registration Information

Upon a change of ownership or operator, a rural health center 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 rural health center 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 consulting pharmacist, the rural health center 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 rural health center in its most recent application, the rural health center shall notify the board via letter, fax or email within 7 days after the change.

5. Alteration of Prescription Filling or Storage Area

No rural health center shall alter the physical dimensions of the prescription filling or storage area or add or change the doors, windows or other means of access to the prescription filling or storage area prior to receiving approval from the board. The rural health center shall provide a scaled drawing of the proposed alteration at the time it requests approval.

6. Operation of Rural Health Center

A rural health center shall comply with the rules of operation contained in Chapter 14 of the board's rules.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(E), 13723, 13751, 13762, 13763, 13764

EFFECTIVE DATE:
November 8, 2004 - filing 2004-511

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 10: REGISTRATION OF FREE CLINICS

Summary: This chapter sets forth registration requirements for free clinics.

1. Application for Registration

The free clinic 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.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the free clinic, including the name contact address, telephone number and employer identification number of the private nonprofit corporation that owns and/or operates the free clinic; the name of the parent company, if any; the name, contact address and title of each corporate officer and director; 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.

2. The hours of operation of the free clinic;

3. The DEA number, if required;

4. The name and license number of the pharmacist in charge of the free clinic;

5. A scaled drawing and floor plan of the free clinic which details the usage of each area;

6. Demonstration of compliance with the storage and security requirements of Chapter 15, Section 5 of the board's rules; and

7. 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."

2. Waiver Requests

For good cause shown, the board may waive the storage and security requirements of Chapter 15, Section 5 of the board's rules.

3. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for registration as a free clinic:

1. The applicant's past experience in the dispensation of prescription drugs;

2. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensation of prescription drugs;

3. Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the dispensation of prescription drugs;

4. Compliance with previously granted licenses of any kind; and

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 free clinics.

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

Upon a change of ownership or operator, a free clinic 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 free clinic 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 free clinic 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 free clinic in its most recent application, the free clinic shall notify the board via letter, fax or email within 7 days after the change.

5. Alteration of Prescription Filling or Storage Area

No free clinic shall alter the physical dimensions of the prescription filling or storage area or add or change the doors, windows or other means of access to the prescription filling or storage area prior to receiving approval from the board. The free clinic shall provide a scaled drawing of the proposed alteration at the time it requests approval.

6. Operation of Free clinic

A free clinic shall comply with the rules of operation contained in Chapter 15, "Operation of Free clinics" of the board's rules.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(E), 13723, 13751, 13752, 13752-A, 13753

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November 8, 2004 - filing 2004-512

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 11: REGISTRATION OF MAIL ORDER PRESCRIPTION PHARMACIES AND LICENSURE OF MAIL ORDER CONTACT LENS SUPPLIERS

Summary: This chapter sets forth registration requirements for mail order prescription pharmacies and license requirements for mail order contact lens suppliers. This chapter also contains enforcement provisions unique to these two types of drug outlet.

1. Mail Order Prescription Pharmacy

1. Registration

A mail order prescription pharmacy that dispenses prescription drugs or devices by mail or carrier from a facility not located in this State for a patient who resides in this State 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.

A. The name, physical address, contact address, telephone number, email address and world wide web address of the mail order prescription pharmacy;

B. All trade or business names used by the mail order prescription pharmacy;

C. Type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

D. The name(s) of the owner and/or operator of the mail order prescription 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 each partner;

(2) If a corporation, the name, physical address, 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 if such certificate is required by 13-C M.R.S.A. §1501;

(3) If a sole proprietorship, the name, contact address and social security number of the sole proprietor and the name of the business entity.

E. The DEA number;

F. Verification of licensure for all jurisdictions in which the mail order prescription pharmacy has at any time been licensed;

G. The name, contact address, telephone number and email address of the pharmacist in charge of the mail order prescription pharmacy;

H. A copy of the most recent inspection report from the state in which the drug outlet is located; and

I. 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."

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for registration as a mail order prescription pharmacy:

A. The applicant's past experience in the dispensation of prescription drugs;

B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensation of prescription drugs;

C. Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the dispensation of prescription drugs;

D. Compliance with previously granted licenses of any kind; 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 mail order prescription pharmacies.

3. Separate Applications for Separate Facilities

The owner must file a separate application for each facility that dispenses prescription drugs to Maine residents.

4. Toll-Free Telephone Access to Pharmacist

The mail order prescription pharmacy shall provide a toll-free telephone number to enable communication between a Maine patient and a pharmacist at the drug outlet who has access to the patient's records. The toll-free telephone number must appear on all prescription labels. Toll-free telephone access to a pharmacist must be available for a minimum of 40 hours per week.

2. Mail Order Contact Lens Supplier

1. Licensure

A mail order contact lens supplier that fills contact lens prescriptions by mail or carrier for a patient who resides in this State 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.

A. The name, physical address, contact address, telephone number, email address and world wide web address of the mail order contact lens supplier;

B. All trade or business names used by the mail order contact lens supplier;

C. Type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

D. The name(s) of the owner and/or operator of the mail order contact lens supplier, 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 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 if such certificate is required by 13-C M.R.S.A. §1501;

(3) 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 DEA number; if applicable;

F. Verification of licensure for all jurisdictions in which the mail order contact lens supplier has at any time been licensed;

G. The name, contact address, telephone number and email address of the person responsible for licensure of the mail order contact lens supplier; and

H. A copy of the most recent inspection report from the state in which the mail order contact lens supplier is located, if an inspection requirement exists; and

I. 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."

2. Additional Qualifications

The board will consider the following additional factors in determining the applicant's eligibility for registration as a mail order contact lens supplier:

A. The applicant's past experience in the dispensation of contact lenses or prescription drugs;

B. The furnishing by the applicant of false or fraudulent material in any application made in connection with the dispensation of contact lenses or prescription drugs;

C. Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the dispensation of contact lenses or prescription drugs;

D. Compliance with previously granted licenses of any kind; 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 mail order contact lens suppliers or mail order prescription pharmacies.

3. Separate Applications for Separate Facilities

The owner must file a separate application for each facility that dispenses contact lens to Maine residents.

4. Toll-Free Telephone Access to Qualified Representative

The mail order contact lens supplier shall provide a toll-free telephone number to enable communication between a Maine patient and a qualified representative of the contact lens supplier who has access to the patient's records. The toll-free telephone number must appear on all product packaging. Toll-free telephone access to a qualified representative must be available for a minimum of 40 hours per week.

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

Upon a change of ownership, a mail order prescription pharmacy or mail order contact lens supplier 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 mail order prescription pharmacy or mail order contact lens supplier 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 (mail order prescription pharmacy) or person responsible for licensure (mail order contact lens supplier), the mail order prescription pharmacy or mail order contact lens supplier 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 mail order prescription pharmacy or mail order contact lens supplier in its most recent application, the entity shall notify the board via letter, fax or email within 7 days after the change.

4. Disciplinary Action

The Board may initiate disciplinary action against a mail order prescription pharmacy or mail order contact lens supplier when:

1. Violation Affecting Individual Maine Citizen

A violation of the *Maine Pharmacy Act* or board rules affecting a Maine citizen has occurred and the state in which the mail order prescription pharmacy or mail order contact lens supplier is located has taken no action or insufficient action; or

2. Violation Affecting Maine Citizens Generally

A violation of the *Maine Pharmacy Act* or board rules affecting Maine citizens generally has occurred.

A mail order prescription pharmacy and mail order contact lens supplier shall provide the board, upon request, with all information needed by the board to carry out its responsibilities under the laws and rules pertaining to mail order prescription pharmacies and mail order contact lens suppliers.

5. Notice to Consumers

A mail order prescription pharmacy and mail order contact lens supplier shall include with each prescription filled prominent notice that complaints against the mail order prescription pharmacy or mail order contact lens supplier may be filed with the Complaint Coordinator, Office of Licensing and Registration, 35 State House Station, Augusta, ME 04333, tel. (207) 624-8660, or on the worldwide web at www.MaineProfessionalReg.org.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(E), 13721(2), 13723, 13751, 13752, 13752-A, 13753

EFFECTIVE DATE:

November 8, 2004 - filing 2004-513

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 12: LICENSURE OF MANUFACTURERS AND WHOLESALERS

Summary: This chapter sets forth license requirements for wholesalers, also known as wholesale pharmacies or wholesale drug distributors, and manufacturers.

1. Scope

This chapter applies to manufacturers and wholesalers.

2. Application for Licensure

The manufacturer or wholesaler 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.

1. The name, physical address, contact address, telephone number, email address and world wide web address of the wholesaler or manufacturer;

2. All trade or business names used by the wholesaler or manufacturer;

3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the wholesaler or manufacturer for storing, handling and distributing prescription drugs.

4. Type of ownership or operation (i.e., partnership, corporation, limited liability company or sole proprietorship); and

5. The name(s) of the owner and/or operator of the wholesaler or manufacturer, 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 if such certificate is required by 13-C M.R.S.A. §1501;

   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 proprietorship, the name, contact address, telephone number and social security number of the sole proprietor and the name of the business entity;

6. The DEA number;

6-A. If the applicant is accredited by VAWD, proof of current accreditation.

7. A list of all jurisdictions in which the manufacturer or wholesaler licensed as of the date of application to the board, along with the license number and license expiration date for each such jurisdiction;

7-A. Disclosure of, and the final disposition document pertaining to, any disciplinary action taken against the manufacturer or wholesaler by a licensing or regulatory authority in any jurisdiction. If the applicant is accredited by VAWD, such disclosure and documentation need only pertain to the period of time subsequent to the wholesaler's initial accreditation or most recent annual renewal of accreditation.

8. A copy of the most recent inspection report from the state in which the manufacturer or wholesaler is located. If a wholesaler is accredited by VAWD, this information need not be provided; and

9. 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."

3. Separate Applications for Separate Facilities

The owner must file a separate application for each facility that manufactures or distributes wholesale prescription drugs. Applications need not be filed for business locations at which no manufacturing or distribution occurs.

4. Minimum Qualifications

The board will consider the following factors in determining the eligibility for licensure of persons who engage in the manufacture or wholesale distribution of drugs:

1. Subject to 5 M.R.S.A. §5301 *et seq*., any findings by the board that the applicant has violated any federal, state or local laws relating to drug manufacturing or distribution;

2. Subject to 5 M.R.S.A. §5301 *et seq*., any felony convictions of the applicant under federal, state or local laws;

3. The applicant's past experience in the manufacture or distribution of drugs;

4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

5. Disciplinary action taken by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of drugs;

6. Compliance with previously granted licenses of any kind;

7. Compliance with the requirements to maintain and/or make available to the board or to federal, state or local law enforcement officials those records required to be maintained by manufacturers or wholesale drug distributors; and

8. Accreditation by VAWD.

5. Change of Owner or Location; Change in Other Registration Information

Upon a change of ownership, a manufacturer or wholesaler shall file a new application with the board no less than 7 days prior to the change. Upon a change of location, a manufacturer or wholesaler 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. Operation of Manufacturer or Wholesaler

A manufacturer or wholesaler shall comply with the rules of operation contained in Chapter 16, "Operation of Wholesalers and Manufacturers" of the board's rules.

7. Exception to Prohibition Against Gifts to Practitioners

The following definitions apply to terms contained in 32 M.R.S. §13759, which constitute exceptions to the general prohibition against manufacturers and wholesalers making gifts to practitioners.

1. For purposes of 32 M.R.S. §13759(2)(A)(3), "modest meals and refreshments" means food and beverage of minimal value provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states, or other scientific information as long as the meeting or presentation occurs in a venue and manner conducive to informational communication. Such food and beverage must be of the type and quantity typically provided for attendees at the venue where the meeting or presentation occurs. For purposes of this section, minimal value means the cost of which is similar to that which a practitioner would pay when dining at his or her own expense as judged by local standards where the event is held.

2. For purposes of 32 M.R.S. §13759(2)(C), "reasonable honoraria" means cash, gratuity and/or a gift given to a practitioner in recognition for the Maine licensed practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler. The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of $500 in retail value. Reasonable honoraria does not include or apply to:

   A. The fee for service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred; or

   B. Where the manufacturer or wholesaler sponsoring the event does not participate or have influence over the selection of the practitioner chosen for the speaking engagement or payment for the services rendered by the practitioner.

   The term "practitioner" does not include pharmacists.

3. For purposes of 32 M.R.S. §13759(2)(C), "reasonable expenses" means the reasonable and actual expenses for travel, lodging, and meals incurred by a practitioner and that are necessary in order for the practitioner to speak at a professional or educational conference sponsored by a manufacturer or wholesaler.

STATUTORY AUTHORITY:
32 M.R.S. §§ 13720, 13721(1)(E), 13723, 13751, 13758, 13759

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AMENDED:
March 11, 2012 – filing 2012-64
June 6, 2020 – added Section 7, filing 2020-114 *(Final adoption, major substantive)*

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

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November 8, 2004 - filing 2004-515

AMENDED:
March 11, 2012 – filing 2012-65
December 11, 2013 – filing 2013-305

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 14: PHARMACY SERVICES AT RURAL HEALTH CENTERS

Summary: This chapter sets forth requirements for the pharmacy services provided by rural health centers licensed by the board.

1. Consulting Pharmacist; Monthly Inspection

Each rural health center must have a consulting pharmacist who inspects the rural health center on a monthly basis pursuant to a written contract between the pharmacist and the rural health center. The consulting pharmacist shall send a report of each inspection to the medical director and the administrator of the rural health center within 10 days after the inspection.

2. Limitation on Prescription Authority

No rural health center may dispense Schedule II controlled substances.

3. Recordkeeping

1. Prescription Drug Orders Filled From Inventory

A practitioner shall write all prescription drug orders in duplicate. The original shall be given to the drug outlet provider daily. The copy shall be kept at the rural health center.

2. Daily Reports

A rural health center shall provide the provider drug outlet with a daily report of each medication dispensed from inventory, the patient name, and all other information needed for the patient profile.

3. Patient Profiles and Medication Records

Patient profiles shall be maintained at the provider drug outlet. Medication records shall be kept at the rural health center.

4. Labels and Containers

A. Each rural health center shall use its own label for prescription drugs. The consulting pharmacist shall ensure that the labels used by the rural health

center contain complete and accurate directions for use. The rural health center shall provide the patient with verbal directions as to proper medication usage.

B. The consulting pharmacist shall ensure that each prescription container provided by the provider drug outlet lists the lot number, manufacturer and expiration date of the medication.

C. The consulting pharmacist shall ensure that the provider drug outlet supplies the rural health center with the latest package inserts of all medications in the formulary.

4. Storage and Security

A rural health center shall ensure the security of drugs at all times. A rural health center shall keep drugs in a locked storage area during non-business hours. A rural health center that provides pharmacy services must be protected by an alarm system.

5. Freedom of Choice

A rural health center shall advise its patients of their right to choose a source of pharmaceutical services.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13762, 13763, 13764

EFFECTIVE DATE:
November 8, 2004 - filing 2004-516

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 15: OPERATION OF FREE CLINICS

Summary: This chapter sets forth requirements for the operation of free clinics licensed by the board.

1. Pharmacist in Charge

1. Generally

The activities of a free clinic shall be conducted under the direct supervision of a licensed pharmacist who has registered as the pharmacist in charge of that drug outlet with the board. No free clinic 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 free clinic for which the licensee is registered as pharmacist in charge, and for the drug outlet'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 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; and

E. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination.

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

A free health clinic 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.

3. Security of Prescription Filling Area

1. Absence of Pharmacist From Prescription Filling Area

A free clinic 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 or an authorized person.

2. Dispensing of Prescriptions in the Absence of a Pharmacist

No free clinic may dispense prescription drugs pursuant to an original prescription drug order in the absence of a pharmacist from the prescription filling area. No free clinic may dispense prescription drugs pursuant to a refill prescription drug order in the absence of a pharmacist from the clinic premises.

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

An 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 free clinic;

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. Limitation on Prescription Authority

No free clinic may dispense Schedule II controlled substances.

5. Storage and Security

A free clinic shall ensure the security of drugs at all times. A free clinic shall keep drugs in a locked storage area during non-business hours. A free clinic must be protected by an alarm system.

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

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02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 16: OPERATION OF WHOLESALERS AND MANUFACTURERS

Summary: This chapter sets forth operational requirements for wholesale drug distributors, including wholesalers and manufacturers.

1. Purpose

The purpose of this chapter is to implement the *Federal Prescription Drug Marketing Act of 1987* by providing minimum standards, terms and conditions for the operation of wholesale drug distributors, including manufacturers.

2. Minimum Requirements for the Storage and Handling of Prescription Drugs and the Establishment and Maintenance of Prescription Drug Records

1. Personnel

A wholesale drug distributor shall employ adequate levels of personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

2. Facilities

All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed or displayed shall:

A. Be of suitable size and construction to facilitate cleaning, maintenance and proper operations;

B. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;

C. Have a quarantine area for storage of drugs that are outdated, damaged, defective, deteriorated, misbranded or adulterated, or that are in immediate or sealed secondary containers that have been opened;

D. Be maintained in a clean and orderly condition; and

E. Be free from infestation by insects, rodents, birds or vermin of any kind.

3. Security

All facilities used for wholesale drug distribution shall be secure from unauthorized entry:

A. Access from outside the premises shall be kept to a minimum and be well-controlled;

B. The outside perimeter of the premises shall be well-lighted;

C. Entry into areas where prescription drugs are held shall be limited to authorized personnel;

D. All facilities shall be equipped with an alarm system to detect entry after hours; and

E. All facilities shall be equipped with a security system that provides suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

4. Storage

A. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium.

B. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality and purity are not adversely affected.

C. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices and/or logs shall be utilized to document proper storage of prescription drugs.

D. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all stored drugs.

5. Examination of Materials

A. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

B. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

C. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all incoming and outgoing prescription drugs.

6. Returned, Damaged and Outdated Prescription Drugs

A. Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

B. Any prescription drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

C. If the conditions under which a prescription drug has been returned to the wholesaler cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be quarantined and physically separated from other prescription drugs and shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored or shipped before or during its return and the condition of the drug and its container, carton or labeling as a result of storage or shipping.

D. The recordkeeping requirements in Section 2(7) of this chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs.

7. Recordkeeping

Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

A. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

B. The identity and quantity of the drugs received and distributed or disposed of; and

C. The dates of receipt and distribution or other disposition of the drugs;

D. Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of these rules for a period of 2 years following disposition of the drugs;

E. Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.

8. Written policies and procedures

Wholesale drug distributors shall establish, maintain and adhere to written policies and procedures for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

A. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

B. A procedure to be followed for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals due to:

(1) Any action initiated at the request of the FDA or other federal, state or local law enforcement or other government agency, including the board;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacing existing merchandise with an approved product or new package design.

C. A procedure to ensure that wholesale drug outlets prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood or other natural disaster, or other situations of local, state or national emergency; and

D. A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or

destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

9. Responsible individuals

Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

10. Compliance with Law

A. Wholesale drug distributors shall operate in compliance with 21 USC §353(e), the other federal laws and rules specified in Chapter 29, Section 1 of the board's rules, and other applicable state and local laws and rules.

B. Wholesale drug distributors shall permit the board and authorized federal, state and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

C. Wholesale drug distributors that deal in controlled substances shall register with the DEA and shall comply with all applicable DEA rules.

11. Salvaging and Reprocessing

Wholesale drug distributors shall be subject to the provisions of any applicable federal, state or local laws or rules that relate to any drug product salvaging or reprocessing, including 21 CFR Parts 207, 210 and 211, Subpart K.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13751(3), 13758

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AMENDED:
March 11, 2012 – filing 2012-66

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 17: OPERATION OF NUCLEAR DRUG OUTLETS

Summary: This chapter incorporates by reference rules of the Maine Radiation Control Program applicable to nuclear drug outlets.

1. Compliance with Maine Radiation Control Program

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

1. Chapter 220, Part C, "Licensing of Radioactive Material (October 1, 2003);" and

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

Copies of these rules may be obtained from-

Maine Radiation Control Program
Department of Human Services
11 State House Station
Augusta, ME 04333

2. Obligations

A nuclear drug outlet shall register with the board as a retail drug outlet pursuant to Chapter 8 of the board's rules and is subject to all provisions of the board's rules that apply to retail drug outlets. A nuclear drug outlet shall comply with the rules identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive drugs; licensure by the Division of Health Engineering; and the employment and designation of authorized nuclear pharmacists. An authorized nuclear pharmacist shall comply with the rules identified in Section 1 of this chapter with respect to all aspects of radiopharmaceutical practice, including but not limited to the compounding, storage, dispensing, labeling and delivery of radioactive drugs; and the credentialing of such individual as an authorized nuclear pharmacist.

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

EFFECTIVE DATE:
November 8, 2004 - filing 2004-519

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:
November 8, 2004 - filing 2004-520

REPEALED:
December 11, 2013 – filing 2013-306

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 of21 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:
November 8, 2004 - filing 2004-521

AMENDED:
December 11, 2013 – filing 2013-307

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(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:
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REPEALED AND REPLACED:
March 11, 2012 – filing 2012-67

AMENDED:
December 11, 2013 – filing 2013-308

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 20-A: SELF-SERVICE CUSTOMER KIOSKS

Summary: This chapter sets forth requirements for self-service customer kiosks.

1. Scope

The provisions of this chapter apply to self-service customer kiosks for pickup of refill prescriptions that are located in retail pharmacies. A kiosk may be stocked only with refill prescriptions for noncontrolled substances. New prescriptions, or prescriptions for controlled substances, may not be delivered via kiosk. A self-service customer kiosk may operate only when the licensed pharmacy is open.

2. General Use

Subject to the limitations contained in Section 1 of this chapter, a prescription filled at a retail pharmacy in accordance with Chapter 19 of the board's rules, or a prescription filled at a central fill drug outlet in accordance with Chapter 21 of the board's rules, may be delivered to the patient or representative of the customer via a self-service kiosk located at the retail pharmacy where the prescription is dispensed, or the retail drug outlet that receives the filled prescription from a central fill drug outlet.

3. Placement Within Retail Pharmacy

A self-service customer kiosk must be located within, adjacent to or clearly within sight of the pharmacy. A self-service customer kiosk is deemed to be part of the licensed pharmacy.

4. Loading of Finished Refill Prescriptions

Only a pharmacist or pharmacy technician may load finished refill prescriptions available for delivery into a self-service customer kiosk for pickup by the patient or a representative of the patient.

5. Identification of Patient or Patient's Representative

A self-service customer kiosk must provide a method of identifying a patient or representative of the patient such that a finished prescription is delivered from a kiosk only to its intended recipient.

6. Opportunity for Counseling

A self-service customer kiosk must prominently notify customers that patient counseling is available at the pharmacy counter in connection with drugs delivered via the kiosk. Counseling may also be provided by a pharmacist reachable at a toll-free telephone number who has access to the patient profile. Instructions on how to contact a pharmacist via toll-free telephone must be displayed by the kiosk and must also be printed on the customer receipt.

[NOTE: See Chapter 25 of the board's rules, entitled "Patient Counseling."]

7. Physical Security; Restricted Access

A self-service customer kiosk must be—

A. Electronically protected against unauthorized access;

B. Be bolted to the floor or installed in a wall;

C. Be constructed in such manner as to prevent tampering, break-in and theft of inventory; and

D. Able to sound an alarm if break-in is attempted.

[NOTE: Chapter 13, Section 6(6) of the board's rules requires that self-service customer kiosks be monitored by security cameras.]

8. Removal of Unclaimed Prescriptions; Accountability

Only a pharmacist or pharmacy technician may remove unclaimed prescriptions from a self-service customer kiosk or open the kiosk for any purpose. The pharmacist in charge shall administer a system of accountability for self-service customer kiosks at a retail drug outlet, including but not limited to records of prescriptions delivered and a time log that identifies and describes the activity of each patient, representative of a patient, pharmacist and pharmacy technician who stocks, receives drugs from, removes drugs from or accesses the kiosk for any reason.

9. Testing

Before a self-service customer kiosk is deployed, the pharmacist in charge shall test the kiosk to ensure that it releases drugs properly. The pharmacist in charge must monitor performance of the kiosk on an ongoing basis and test the kiosk for accuracy whenever any change or upgrade is made to the automated pharmacy system.

10. Purity and Potency

The purity, potency, and integrity of the drugs contained in a self-service customer kiosk must be preserved.

11. Maintenance

The retail drug outlet and pharmacist in charge are responsible for timely and documented maintenance of self-service customer kiosks in accordance with the manufacturer's recommendations.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

EFFECTIVE DATE:
March 11, 2012 – filing 2012-68

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 21: CENTRAL PRESCRIPTION PROCESSING

Summary: This chapter sets forth requirements for central prescription processing.

1. Generally

1. Noncontrolled Drugs

A central fill drug outlet and/or central processing center may fulfill a request for the processing, filling or refilling of a noncontrolled prescription drug order from a retail drug outlet, rural health center or free clinic; or from 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 may deliver the processed, filled or refilled prescription drug order to the retail drug outlet or other health care facility identified in this subsection in accordance with the terms of this chapter.

2. Controlled Drugs

A central fill drug outlet and/or central processing center may fulfill a request for the processing, filling or refilling of a controlled prescription drug order from a retail drug outlet and may deliver the processed, filled or refilled prescription drug order to the retail drug outlet in accordance with the terms of this chapter.

2. Location and Licensure

The central fill drug outlet or central processing center must be located in the United States or its territories or the District of Columbia. If located in Maine, the facility must be registered as a retail drug outlet. If located outside of Maine, the facility must be registered in the manner of a mail order prescription pharmacy as set forth in Chapter 11 of the board's rules.

3. Contract or Common Ownership

A central fill drug outlet or central processing center that processes, fills or refills a prescription drug order must have a contract with or have the same owner as the retail drug outlet or other health care facility identified in Section 1(1) of this chapter from which it

received the prescription drug order. The contract must include provisions that protect the confidentiality of patient information.

4. Labeling

In addition to the information required by 32 M.R.S.A. §13794, the prescription container must clearly show:

1. The name and address of the originating drug outlet;

2. The name and address or the unique identifier of the central fill drug outlet (bar code or symbol acceptable);

3. Identifying information of the originating drug outlet, such as the tracking number (bar code or symbol acceptable); and

4. Patient information.

5. Policies and Procedures

1. Audit Trail

A drug outlet that utilizes central fill or central processing services shall have policies and procedures in place that include an audit trail that documents the prescription filling process and identifies the individuals accountable for each step of the process.

2. Performance of Final Check

The central fill drug outlet and the retail drug outlet or other health care facility identified in Section 1(1) of this chapter shall both perform a final check to ensure that the filled prescription corresponds to the prescription drug order, and that the prescription is correct in all respects and ready for dispensing. If there is no pharmacist on site at the point of care location and the drug is dispensed by an automated pharmacy system in accordance with Chapter 20 of the board's rules, the final check may be performed by a pharmacy technician under the direct supervision of a pharmacist, or by a person legally qualified under a health practice act to administer drugs.

3. DUR and Patient Counseling

The central fill drug outlet and the retail drug outlet or other health care facility identified in Section 1(1) of this chapter are both responsible for patient counseling and for compliance with the drug utilization review requirements contained in the Medicaid laws, rules and other materials specified in Chapter 29, Section 1(9) of the board's rules.

4. Notice to Patients

A retail drug outlet that utilizes central fill services must inform its patients, by posting or otherwise, that prescription drug orders accepted at the retail drug outlet may be filled by a central fill drug outlet.

6. Freedom of Choice

Systems providing for the electronic transfer of information shall not infringe on a patient's freedom of choice as to the provider of prescription services.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13784, 13785, 13794

EFFECTIVE DATE:
November 8, 2004 - filing 2004-523

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 22: SALE OF SCHEDULE V CONTROLLED SUBSTANCES

Summary: This chapter sets forth requirements for the sale of Schedule V controlled substances.

1. Applicability

This chapter applies to Schedule V controlled substances, and to exempt narcotic preparations as defined in 32 MRSA §13722(1)(E).

2. Retail Sale by Pharmacist

A pharmacist may sell an over-the-counter Schedule V product at retail to a person 18 years of age or older without a prescription drug order provided that the pharmacist obtains from the purchaser at time of sale photographic proof of identification as described in 32 MRSA §13795(1) for entry into the exempt narcotic log or record of disposition.

A pharmacist shall exercise professional discretion pursuant to 32 MRSA §13795(2) to ensure that the Schedule V product is being sold for medical purposes only

3. Limitation on Purchases

A drug outlet may not sell either of the following to the same patient in a 48 hour period without a prescription drug order:

1. No more than 240 ml of any other Schedule V product containing opium; or

2. No more than 120 ml of any other Schedule V product.

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

EFFECTIVE DATE:
November 8, 2004 - filing 2004-524

AMENDED:
March 11, 2012 – filing 2012-69

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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/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.]

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

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December 11, 2013 – filing 2013-309

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:
November 8, 2004 - filing 2004-526

AMENDED:
December 11, 2013 – filing 2013-310

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:
November 8, 2004 - filing 2004-527

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March 11, 2012 – filing 2012-70
December 11, 2013 – filing 2013-311

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

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Chapter 26: GENERIC SUBSTITUTION

Summary: This chapter defines and outlines the use of generic and therapeutically equivalent drugs by pharmacists.

[NOTE: PL 2003, c. 384, amending 32 M.R.S.A. §13781, now requires that a pharmacist must substitute a generic and therapeutic equivalent of the prescribed drug unless the practitioner has affirmatively directed otherwise. See the statute for full details, especially with regard to MaineCare prescriptions.]

1. Generic and Therapeutically Equivalent Drugs

1. Basis for Categorization

A generic and therapeutically equivalent drug, as defined in 32 M.R.S.A. §13702(11), is a drug that meets the following criteria:

A. Chemical Equivalents. Drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendial standards.

B. Bioequivalents. Chemical equivalents, which when administered to the same individuals in the same dosage regimen will result in comparable bioavailability.

C. Therapeutic Equivalents. Chemical equivalents, which when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy and/or toxicity.

2. Basis for Determination

In determining whether a drug is generic and therapeutically equivalent, the pharmacist shall rely upon Approved Drug Products With Therapeutic Equivalence Evaluations (U.S. Department of Health and Human Services) (electronic edition current through December 2003; last revised February 2, 2004) (the "Orange Book"). All "A"-coded drug products in the orange book are deemed to be generic and therapeutically equivalent. Substitutable "A"-coded drug products include, but are not limited to, those designated AA, AB, AN, AO, AP, or AT.

The board hereby incorporates the orange book into this chapter by reference. A copy of the Orange Book may be obtained from-

Superintendent of Documents
Government Printing Office
P.O. Box 371954
Pittsburgh, PA 15250-7954

The electronic version may be accessed on line at-
http://www.fda.gov/cder/ob/default.htm

This URL is subject to change.

3. Available Reference

Each drug outlet shall keep a copy of the Orange Book, or the information contained therein, readily accessible at all times.

4. Exception

Notwithstanding the provisions of this chapter, a pharmacist may dispense a "B"-coded drug product to the extent authorized by the MaineCare program.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13781

EFFECTIVE DATE:
November 8, 2004 - filing 2004-528

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

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Chapter 27: POSSESSION AND ADMINISTRATION OF NONCONTROLLED PRESCRIPTION DRUGS BY NURSES

Summary: This chapter defines the conditions under which nurses can possess and administer noncontrolled prescription drugs.

1. Possession

A registered nurse or advanced practice registered nurse who is an employee of a home health care provider as defined in 22 M.R.S.A. §2142(3), or a hospice program or hospice provider as defined in 22 M.R.S.A. §8621(10), may possess, in the course of employment, the following noncontrolled prescription drugs:

1. Adrenalin
2. Benadryl
3. Sterile Water
4. Sterile Normal Saline
5. Influenza Vaccines
6. Hepatitis B Vaccine
7. Mantoux Test Kit (for tuberculosis testing)
8. Heparin
9. Pneumonia Vaccine

2. Administration

In accordance with 32 M.R.S.A. §13810(2), the noncontrolled prescription drugs listed in Section 1 of this chapter must be administered in accordance with written protocols approved annually by the employer's professional advisory committee, which must include a physician licensed under Title 32, Chapter 36 or 48. The protocols shall include, at a minimum, guidelines that will ensure the integrity and security of these drugs during transport and when the employee is not on duty.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1), 13722, 13723, 13810

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November 8, 2004 - filing 2004-529

Part 5 - License Denial and Professional Discipline

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

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Chapter 28: ENFORCEMENT AND DISCIPLINARY PROCEDURES

Summary: This chapter sets forth a licensee's right to appeal certain board actions and specifies the enforcement and disciplinary procedures used by the board.

1. Appeal of License Denial

An applicant or licensee may appeal a license denial to the board by filing a request for hearing with the board within 30 days of the applicant's or licensee's receipt of notice of the denial. An adjudicatory hearing will be scheduled upon receipt of a timely appeal. Non-timely appeals will be denied without hearing.

2. Disciplinary Procedure

The board will follow the procedures for investigating and processing complaints contained in the Administrative Complaint Procedure followed by the Department of Professional and Financial Regulation, Office of Licensing and Registration for the professional and occupational licensing boards and registration programs administered by OLR.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(F), 13722, 13723, 13741

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November 8, 2004 - filing 2004-530

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

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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)

4. *Poison Prevention Packaging Act*, 15 USCS §1471 *et seq*. (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, 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, 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, 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, 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 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)

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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:
November 8, 2004 - filing 2004-532

AMENDED:
December 11, 2013 – filing 2013-313

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 31: PRACTICE OF FRAUD OR DECEIT

Summary: For purposes of 32 M.R.S.A. §13742(2)(A), the practice of fraud or deceit includes, but is not limited to, the conduct described in this chapter.

1. Practice of Fraud or Deceit in Obtaining a License or Registration

The practice of fraud or deceit in obtaining a license or registration includes, but is not limited, to:

1. Falsification or misrepresentation of the education or experience of the applicant;

2. Falsification or misrepresentation of a recommendation or report from a preceptor;

3. Cheating on a license examination;

4. Intentionally withholding or misrepresenting any information requested on an application, including any information regarding criminal or disciplinary action taken by any state against an applicant; or

5. Impersonating another applicant.

2. Practice of Fraud or Deceit in the Practice of Pharmacy

The practice of fraud or deceit in the practice of pharmacy includes, but is not limited, to:

1. Intentionally practicing or attempting to practice, or aiding another to practice, beyond the scope of the license or registration held;

2. Intentionally misrepresenting the type or status of license or registration held or qualifications to practice;

3. Committing or aiding another to commit fraud, deceit or corruption in billing, payment or insurance reimbursement procedures; or

4. Impersonating another licensee.

STATUTORY AUTHORITY: 32 M.R.S.A. §§ 13720, 13721(1)(F), 13722, 13723, 13741, 13742(2)(A)

EFFECTIVE DATE:
November 8, 2004 - filing 2004-533

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 32: ISSUANCE OF CITATIONS

Summary: This chapter lists the violations for which a citation may be issued, describes the licensee's right to request a hearing, and describes the time and manner in which the fine must be paid or a hearing requested.

1. List of Violations

An inspector may issue citations for the violations listed in Appendix A to this chapter upon personal observation or discovery of the violation charged. The fine for each violation is $200.

2. Service of Citation; Notice to Owner

The citation may be served on an individual licensee by hand delivery of the citation to the licensee or to a responsible employee at the drug outlet where the licensee practices pharmacy. The citation may be served on a drug outlet licensee by hand delivery of the citation to a responsible employee at the drug outlet. The inspector shall mail or deliver in hand a copy of the citation to the owner or designated agent of the drug outlet at which the violation occurred.

3. Right to Hearing

The citation shall inform the licensee that the licensee may pay the fine or may request a hearing before the board regarding the violation. If the licensee requests a hearing, the citation shall be processed in the same manner as a complaint for purposes of Chapter 28 of the board's rules, entitled "Enforcement and Disciplinary Procedures," except that the licensee's written response to the citation must be filed with the board along with the request for hearing.

4. Time for Payment or Request for Hearing

The licensee shall either pay the fine or request a hearing within 30 days following issuance of the citation. Failure to take either action within this 30 day period is a violation of the board's rules that may subject the licensee to further disciplinary action by the board, including but not limited to an additional fine and possible action against the license.

5. Board Action Following Hearing

The board may not impose a penalty following hearing other than $200, and may not assess costs otherwise authorized by 10 M.R.S.A. §8003-D.

6. Filing a Complaint Instead of Issuing a Citation

Nothing in this chapter shall prohibit an inspector or other representative of the board from filing a complaint pursuant to Chapter 28 , Section 2 of the board's rules in lieu of a citation for a violation listed in Appendix A to this chapter.

7. Citation Violations not Reportable

Fines paid in response to citations issued pursuant to this chapter shall not be reported to the National Association of Boards of Pharmacy or to any other person, organization or regulatory body that is not a part of Maine state government.

8. Citation Violations Constitute Discipline

Fines paid in response to citations issued pursuant to this chapter constitute discipline. The citations and records of fines paid shall be maintained by the Office of licensing and Registration and shall be treated as public records to the extent permitted by law.

STATUTORY AUTHORITY: 10 M.R.S.A. §8003-E; 32 M.R.S.A. §§ 13720, 13721(1)(F), 13722, 13723

EFFECTIVE DATE:
November 8, 2004 - filing 2004-534

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 33: ACCESS TO CERTAIN MEDICATIONS BY CERTIFIED MIDWIVES

Summary: This chapter implements PL 2007, c. 669 by: (a) regulating the sale of certain noncontrolled drugs and substances to certified midwives, (b) regulating the purchase and administration of certain noncontrolled drugs and substances by certified midwives, and (c) requiring certified midwives to record and report their purchase and administration of certain noncontrolled drugs and substances.

1. Scope

This chapter applies solely to the acquisition and administration of certain noncontrolled drugs and substances by certified midwives.

2. Sale of Drugs to Certified Midwives

1. Limited Formulary

A pharmacist may elect to sell to a certified midwife without a prescription only the following noncontrolled drugs and substances:

A. Oxygen, USP.;

B. Oxytocin injection 10 units/ml 1 ml, excluding the oxytocic drug methergine, for the sole purpose of postpartum control of maternal hemorrhage;

C. Phytonadione injection 2 mg/ml 0.5 ml (Vitamin K neonatal concentration);

D. Erythromycin ophthalmic ointment (for eye prophylaxis); and

E. The following local anesthetics and numbing agents for repair of lacerations:

(1) Lidocaine injection 1%;

(2) Bupivacaine injection 0.25%;

(3) Lidocaine topical spray 10%;

(4) Benzocaine topical spray 20%; and

(5) Lidocaine 4% topical anesthetic cream

2. **Verification of Certification**

A pharmacist shall verify the identification and certification of a certified midwife prior to selling any of the noncontrolled drugs and substances listed in Section 2(1) of this chapter to the certified midwife. Verification consists of:

A. Obtaining the name, address and telephone number of the certified midwife;

B. Viewing a valid, current certification card issued to the certified midwife by the American Midwifery Certification Board or the North American Registry of Midwives; and

C. In the discretion of the pharmacist, viewing one of the following forms of photographic identification of the certified midwife:

(1) A valid Maine motor vehicle operator's license;

(2) A valid Maine identification card issued under Title 29-A, section 1410;

(3) A valid United States passport; or

(4) A valid passport or motor vehicle operator's license of another state, territory or possession of the United States or a foreign country only if it:

(a) Contains a photograph of the certified midwife;

(b) Is encased in tamper-resistant plastic or is otherwise tamper-resistant; and

(c) Identifies the date of birth of the certified midwife.

3. **Delivery to Certified Midwife**

A pharmacist who elects to sell any of the noncontrolled drugs and substances listed in Section 2(1) of this chapter to a certified midwife must deliver the drug or substance in hand to the certified midwife personally.

4. **Records of Sale**

A retail pharmacy shall keep a log of oxytocin for intramuscular use and injectable vitamin K sold to certified midwives pursuant to this chapter. The log may be maintained as a separate document or may be integrated into another log of a similar nature. The log must contain the following information for each transaction:

A. The name, quantity, dosage and lot number of the drug sold; and

B. The name, address and telephone number of the midwife.

[NOTE: Retention and production of records of sale created pursuant to this chapter is governed by Chapter 24, Section 5 of the board's rules.]

3. **Administration of Certain Noncontrolled Drugs and Substances by Certified Midwives; Further Distribution or Transfer Prohibited**

A certified midwife may administer the noncontrolled drugs and substances listed in Section 2(1) of this chapter only in the course of the practice of midwifery. A certified midwife may not otherwise dispense, sell, give away or transfer the noncontrolled drugs or substances.

4. Storage of Certain Noncontrolled Drugs and Substances by Certified Midwives

A certified midwife shall store the noncontrolled drugs and substances listed in Section 2(1) of this chapter at appropriate temperatures and under appropriate conditions in accordance with manufacturers' requirements in the labeling of such drugs and substances, or with requirements in the current edition of an official compendium.

5. Records and Reporting

1. **Purchase and Destruction Records**

A certified midwife shall keep a log of injectable oxytocin and injectable vitamin K purchased by the midwife pursuant to this chapter. For each such purchase the log shall note:

A. The date of purchase;

B. The name and address of the retail pharmacy where the oxytocin or vitamin K was purchased;

C. The name of the selling pharmacist;

D. The quantity and dosage of oxytocin or vitamin K purchased;

E. The expiration date of the oxytocin or vitamin K purchased; and

F. A statement as to whether any quantity of the oxytocin or vitamin K remained unused upon the expiration date and, if any, the date and manner of destruction of the unused stock.

Purchase and destruction records must be maintained separately from the administration records required by Section 5(2) of this chapter.

2. **Administration Records**

A certified midwife shall keep a record of all noncontrolled drugs and substances administered by the certified midwife pursuant to this chapter. For each such administration the record shall contain:

A. The date of administration;

B. The route of administration;

C. A description of the place where the drug was administered (e.g., patient's home);

D. The name, quantity and dosage of the noncontrolled drug or substance administered;

E. The reason for administering the noncontrolled drug or substance to the patient;

F. A notation of any adverse reaction to the noncontrolled drug or substance administered, including a complete description of the steps taken by the certified midwife to respond to the adverse reaction and the condition of the patient afterwards; and

G. A notation of any medical emergency experienced by a patient to whom the noncontrolled drug or substance was administered, including a complete description of the steps taken by the certified midwife to respond to the emergency and the condition of the patient afterwards.

Administration records must be maintained separately from the purchase and destruction records required by Section 5(1) of this chapter.

3. **Reporting**

A. A certified midwife shall report any of the following in writing to the Department of Health and Human Services, the Maine Center for Disease Control and Prevention within 7 days of the event. The report shall be made on the form prescribed by that office:

(1) The administration of oxytocin for intramuscular use;

(2) Any time a patient experiences an adverse reaction to a noncontrolled drug or substance administered by the certified midwife, including oxytocin, with a complete description of the steps taken by the certified midwife to respond to the adverse reaction and the condition of the patient afterwards; and

(3) Any medical emergency experienced by a patient to whom a noncontrolled drug or substance was administered by the certified midwife, including oxytocin, with a complete description of all steps taken by the certified midwife to respond to the emergency and the condition of the patient afterwards.

[NOTE: The mailing address for the reports required by this subsection is Family Health Division, Maine Center for Disease Control and Prevention, 11 State House Station, Augusta, ME 04333-0011.]

B. A certified midwife shall provide the records of purchase, destruction and administration described in Section 5(1) and (2) to the board no later than September 1 of each year. Each annual report shall contain records of purchases, destruction and administrations that occurred during the preceding calendar year, provided that no record need be prepared for purchases, destruction or administrations that occurred prior to the effective date of this chapter.

4. **Retention and Production of Records**

A certified midwife shall retain the records of purchase, destruction and administration described in Section 5(1) and (2) of this chapter for a period of 5 years. A certified midwife shall produce the records to the board upon request.

STATUTORY AUTHORITY: 32 MRSA §§ 13720, 13722, 13723, 13811, 13812

EFFECTIVE DATE:
February 9, 2009 – filing 2009-49

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.

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. 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:

(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 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;

(c) 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.

(d) 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:

November 24, 2010- - filing 2010-612 (EMERGENCY)

July 5, 2011 – filing 2011-209

AMENDED:

December 11, 2013 – filing 2013-314

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.

10. 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.

11. 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.

12. 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.

13. 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

14. 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.

15. 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:
December 11, 2013 – filing 2013-315

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 ensuring that doses of opiate agonist treatment medications are prepared 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 of Pharmacist at Opioid Treatment Center**

The pharmacist in charge of an opioid treatment program or another licensed pharmacist authorized by the pharmacist in charge shall be physically present at the facility to prepare drugs for delivery as described in subsection 2 above, except that during any state of civil emergency declared by the Governor, no pharmacist will be required to be physically present to prepare drugs for delivery, provided that such drugs are prepared by either an advanced practice registered nurse, a registered professional nurse, or a licensed practical nurse who is (1) licensed by the State Board of Nursing; (2) licensed by the board as a pharmacy technician; and (3) explicitly designated by the pharmacist in charge to prepare drugs in the absence of a pharmacist. A pharmacist 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 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 MRS §§ 13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

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December 11, 2013 – filing 2013-316

AMENDED:
April 4, 2020 – filing 2020-089 (EMERGENCY)
July 7, 2020 – filing 2020-148

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:

December 11, 2013 – filing 2013-317

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 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.

STATUTORY AUTHORITY: 32 MRSA §§13720, 13721(1)(E), 13722(1)(B), 13723, 13751(3), 13752, 13752-A, 13753(1)(D)

EFFECTIVE DATE:
December 11, 2013 – filing 2013-318

Appendix A

VIOLATIONS FOR WHICH CITATION MAY BE ISSUED

CHAPTER 4: LICENSURE OF PHARMACISTS

Failure of a pharmacist to notify the board of a change of contact address within 30 days ..... §3

CHAPTER 7: REGISTRATION AND EMPLOYMENT OF PHARMACY TECHNICIANS

Failure of a pharmacy technician to notify the board of a change in work site, change of contract address or change in enrollment status within 30 days ..... §1(5)

Failure to supply adequate training to a pharmacy technician ..... §2

Failure to have a copy of the pharmacy technician training program on site at the drug outlet ..... §2

Failure of a pharmacist in charge to ensure proper registration of a pharmacy technician ..... §3(1)

Failure of a pharmacist in charge to conspicuously display a pharmacy technician's registration at the work site ..... §3(2)

Failure of a pharmacist in charge to notify the board of the commencement or cessation of a pharmacy technician's employment within 14 days ..... §3(3)

Permitting a pharmacy technician to practice beyond the scope of permissible duties ..... §§ 5, 7(1), 7(3)(A)

Violation of pharmacy technician deployment ratios ..... §§ 6, 7(2), 7(3)(B)

CHAPTER 8: REGISTRATION OF RETAIL DRUG OUTLETS

Alteration of prescription filling area prior to receiving board approval ..... §7

CHAPTER 13: OPERATION OF RETAIL DRUG OUTLETS

Retail drug outlet not open to the public for a minimum of 40 hours per week ..... §2(1)

Failure to prominently post in a public area of the store the days and hours that a retail drug outlet is scheduled to be open to the public ..... §2(2)

Failure of a retail drug outlet to timely report a deviation from its posted schedule ..... §2(5)

Operation of a retail drug outlet without a pharmacist in charge ..... §3(1)

Failure to perform duties and responsibilities of a pharmacist in charge ..... §3(2)

Filling or dispensing a prescription outside the prescription filling area of a retail drug outlet ..... §5

Failure to properly secure the prescription filling area ..... §6

Failure to identify a retail drug outlet with proper signage ..... §7

Failure to follow all procedures for the permanent closing of a retail drug outlet ..... §8

CHAPTER 14: PHARMACY SERVICES AT RURAL HEALTH CENTERS

Failure to comply with rule requirements applicable to pharmacy services at a rural health center ..... entire chapter other than §5

CHAPTER 15: OPERATION OF FREE CLINICS

Failure to comply with rule requirements applicable to the operation of a free pharmacy clinic ..... entire chapter other than §2

CHAPTER 16: OPERATION OF WHOLESALE DRUG OUTLETS AND MANUFACTURERS

Failure to comply with rule requirements applicable to the operation of wholesale drug outlet or manufacturer ..... entire chapter other than §2(10)

CHAPTER 18: STERILE PHARMACEUTICALS

Failure to maintain at the drug outlet a policy and procedure manual relating to sterile pharmaceuticals....§2
Failure to comply with the physical requirements for the making of sterile pharmaceuticals ....§3
Failure to comply with patient profile, labeling, recordkeeping, disposal and other requirements ....§5
Failure to protect personnel against cytotoxic drugs....§6
Failure to provide proper clinical services....§7
Failure to follow patient care guidelines ....§8
Failure to implement and follow an adequate quality assurance program ....§9

CHAPTER 19: RECEIPT AND HANDLING OF PRESCRIPTION DRUG ORDERS

Failure to include all required information on a prescription drug order ....§1
Failure to comply with requirements for prescription drug orders for controlled substances ....§2
Failure to comply with requirements for telephone prescription drug orders .... §3(1)
Failure to comply with requirements for facsimile prescription drug orders .... §3(2)
Refilling prescriptions more than 15 months after the date written ....§5
Failure to maintain required dispensing records of prescription drug orders ....§6
Failure to comply with requirements for automated data processing systems ....§7
Failure to comply with prescription drug transfer requirements....§§ 8, 9
Filling a prescription drug order 6 months or longer after the prescribing practitioner first became unavailable....§10
Failure to ensure the security and confidentiality of prescription drug orders, dispensing records, patient profiles and all other patient records....§12

CHAPTER 20: AUTOMATED PHARMACY SYSTEMS

Failure to comply with inspection requirements....§9

CHAPTER 21: CENTRAL PRESCRIPTION PROCESSING

Failure to comply with labeling requirements ....§4
Failure to maintain an audit trail .... §5(1)
Failure of a retail drug outlet that utilizes central fill services to notify patients that prescription drug orders accepted at the retail drug outlet may be filled by a central fill drug outlet.... §5(4)

CHAPTER 22: SALE OF SCHEDULE V CONTROLLED SUBSTANCES

Improper sale of Schedule V controlled substances....§§ 2, 3

CHAPTER 23: ACCOUNTING FOR PRESCRIPTION DRUGS

Failure to maintain contemporaneous perpetual inventory records for Schedule II controlled substances for 5 years....§1
Failure to report the theft, loss or unresolved inventory discrepancy of prescription drugs ....§3

CHAPTER 24: RETENTION OF RECORDS BY DRUG OUTLETS

Failure to comply with retention requirements.... entire chapter

CHAPTER 30: UNPROFESSIONAL CONDUCT

Failure to display or carry proof of licensure or registration .... §1(10)
Failure to establish and maintain effective controls to prevent prescription errors or misfills.... §1(15)

Failure to address or attempt to resolve a possible prescription error or situation of potential harm to a patient ..... §1(16)
Failure to properly preserve, refrigerate, secure or store all drugs in the drug outlet or pharmacy department ..... §1(18)
Failure of a drug outlet to notify the board within 7 days of the termination of employment of a pharmacist for any drug-related reason ..... §26

MAINE PHARMACY ACT
32 M.R.S.A. §§ 13701-13810

Failure to keep an adequate record of the sale of exempt narcotic preparations..... §13722(1)(E), last par.
Failure to substitute a generic drug when required to do so, or improper substitution of a generic drug..... §13781
Failure to properly explain directions the for use of a newly-prescribed medication or device ..... §13784(1)
Failure to maintain a patient profile record system with all required information ..... §13785
Improper purchase, sale or distribution of a manufacturer's drug sample ..... §13789
Failure to label a prescription drug with all required information ..... §13794