02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1: DEFINITIONS

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

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

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

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

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

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.

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1. Cleanliness and Sanitation

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

2. Hours of Operation; Posting of Hours

1. Minimum Hours of Operation

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

2. Posting of Schedule

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

3. Adherence to Posted Schedule

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

4. Deviations From Posted Schedule

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

5. Reporting of Deviations to Board

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

No report need be filed for:

A. A deviation of less than four hours duration;

B. A deviation resulting from severe weather conditions, fire, flood, disaster or natural or man-made catastrophe beyond the control of the pharmacy; or

C. Holiday closures.

6. Remedial Action by Board

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

3. Pharmacist in Charge

1. Generally

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

2. Responsibilities

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

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

B. The recordkeeping systems required in the practice of pharmacy for the purchase, sale, possession, storage and repackaging of drugs;

C. The security of the prescription filling area and its contents;

D. Ensuring that the prescription filling area is operated in conformance with good pharmaceutical practices;

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

F. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules; and

G. Ensuring that each pharmacist employed at the pharmacy for which the pharmacist in charge is responsible is licensed with the board.

3. Presence at Retail Drug Outlet

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

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

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

A. Death, incapacity, emergency medical leave or unexpected resignation or discharge of a pharmacist in charge;

B. Specialty practice setting which does not require a 30 hour/50% pharmacist in charge for reasonable protection of the population served; or

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

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

5. Emergency Requests

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

A. The board administrator or the administrator's designee may rule on the request on an interim basis until the board is able to address it; and

B. The retail pharmacy may operate under the supervision of a pharmacist pending the interim ruling of the board administrator or the administrator's designee.

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

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

5. Prescriptions to be Filled Only in Prescription Filling Area

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

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

6. Security of Prescription Filling Area

1. Absence of Pharmacist From Prescription Filling Area

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

2. Dispensing of Prescriptions in the Absence of a Pharmacist

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

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

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

A. Is taking a customary and reasonable work break;

B. Is in the vicinity of the store in which the retail pharmacy is located or is in a closed-shop pharmacy at the same location as the retail pharmacy;

C. Is not engaged in any activity that would interfere with his/her immediate availability; and

D. Is reachable by the pharmacy technician during the absence.

4. Deployment of Barrier

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

5. Alarm

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

6. Security Cameras

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

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

7. [deleted]

8. Designation of Authorized Persons and Authorized Pharmacy Technicians

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

9. Deliveries and Delivery Logs

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

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

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

7. Compounding

1. Scope

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

2. Operational Requirements

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

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

-or-

U.S. Pharmacopeial Convention
www.usp.org

3. Activity Records

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

8. Signs

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

9. Permanent Closing of a Retail Pharmacy

1. Notification

A. A retail pharmacy shall notify the board of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name and address of the pharmacy to be closed; the date of closure; the name and address of the pharmacy acquiring the prescription inventory; and the name and address of the pharmacy acquiring the prescription files and patient profiles.

B. A retail pharmacy shall notify the DEA of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the name, address, and DEA registration number of the pharmacy to be closed; the name, address, and DEA registration number of the pharmacy acquiring the controlled substances; and the date on which the transfer will occur.

C. A retail pharmacy shall notify the general public of the pharmacy's permanent closing at least 14 days prior to closing. The notice shall include the date of closure and the new location of the pharmacy's patient prescription files. Notice shall be given by prominent posting in a public area of the store and by display advertisement in a newspaper of general circulation in the area served by the pharmacy.

2. Closing day procedures

A. The retail pharmacy shall take a complete inventory of all controlled substances.

B. The retail pharmacy shall dispose of controlled substances as follows:

(1) If the controlled substances are being sold or given to another DEA registrant-

(a) The transfer of Schedule II controlled substances shall be made on closing day and memorialized by a properly executed DEA Form 222; and

(b) The transfer of Schedule III, IV, and V controlled substances shall be made on closing day and memorialized by invoice, with copies to each party and the board.

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

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

(1) If the prescription legend drugs are being sold or given to another pharmacy, the bulk transfer of such drugs shall be made on closing day and memorialized by invoice, with copies to each party.

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

D. Disposition of prescription files and patient profiles

(1) If the prescription files and patient profiles are being sold to another pharmacy or are being transferred to another pharmacy in the same chain, the retail pharmacy that is closing shall transfer the files and profiles on closing day. The recipient pharmacy must keep the files and profiles for the time required by Chapter 24 of the board's rules.

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

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

3. Reports and Returns Due After Closing

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

A. To DEA -

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

(2) Return of any unused DEA Form 222s;

(3) Copy of the controlled substances inventory and all schedules; and

(4) Copies of DEA Form 222 completed pursuant to Section 8(2)(B)(1)(a) of this chapter.

B. To the board -

(1) Return of the license for the closed retail pharmacy;

(2) Report that all signs indicating the presence of the closed pharmacy have been removed;

(3) Report that all labels and blank prescriptions have been destroyed;

(4) Report that the DEA license and all unused DEA Form 222s have been returned to the DEA;

(5) Report as to the disposition of controlled substances and prescription legend drugs made pursuant to Section 8(2)(B)and (C) of this chapter; and

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

4. Chemicals and Hazardous Materials

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

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

EFFECTIVE DATE:
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 25: PATIENT COUNSELING

Summary: This chapter sets forth the pharmacist's obligation to counsel patients.

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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

AMENDED:
March 11, 2012 – filing 2012-70
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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.

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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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