

# Notice of Agency Rule-making Proposal

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AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

CHAPTER NUMBER AND TITLE:

Chapter 1.....Definitions (amended)  
Chapter 6.....Pharmacy Student Internship Programs (sunsetting)  
Chapter 6-A.....Pharmacy Student Internship Programs (new)  
Chapter 7.....Registration and Employment of Pharmacy Technicians (amended)  
Chapter 12.....Licensure of Manufacturers and Wholesalers (amended)  
Chapter 13.....Operation of Retail Drug Outlets (amended)  
Chapter 16.....Operation of Wholesalers and Manufacturers (amended)  
Chapter 20.....Automated Pharmacy Systems (repeal and replace)  
Chapter 20-A....Self-Service Customer Kiosks (new)  
Chapter 22.....Sale of Schedule V Controlled Substances (amended)  
Chapter 25.....Patient Counseling (amended)

PROPOSED RULE NUMBER (*leave blank; assigned by Secretary of State*):

CONTACT PERSON FOR THIS FILING: Geraldine Betts, Board Administrator, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME 04333, tel: (207) 624-8625, email: [geraldine.l.betts@maine.gov](mailto:geraldine.l.betts@maine.gov)

CONTACT PERSON FOR SMALL BUSINESS INFORMATION (if different): same

PUBLIC HEARING (if any): November 3, 2011, 9:00 a.m., Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine

COMMENT DEADLINE: December 9, 2011

BRIEF \*SUMMARY: The proposed rules implement six major initiatives: (1) transfer of responsibility for overseeing student internships and student preceptors from retail pharmacies to pharmacy schools, (2) unified, reduced-cost licensure of student interns who also work as pharmacy technicians, (3) major revision of the requirements for use of an automated pharmacy system at a hospital, nursing home or other institution; (4) authorization for pharmacy technicians (advanced) to load an automated pharmacy system at a hospital or nursing home under the direct, remote supervision of a pharmacist (5) authorization for deployment of self-service customer kiosks in retail pharmacies (restrictions apply), and (6) a requirement that all wholesale distributors be verified-accredited wholesale distributors by January 1, 2013, provided that a wholesale distributor initially licensed by the board after January 1, 2012 may submit proof of accreditation no later than one year after the date of initial licensure. In addition, the proposed rules make various minor changes for clarity, readability, and consistency with the pharmacy law. The proposed rules and a chapter-by-chapter list of changes may be downloaded from [www.maine.gov/professionallicensing](http://www.maine.gov/professionallicensing).

IMPACT ON MUNICIPALITIES OR COUNTIES (if any): None

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STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S.A. §§13720, 13721(1), 13722, 13723, 13732, 13733, 13734, 13751, 13758, 13784

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (if different):

\* Check one of the following two boxes.

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- The above summary is for use in both the newspaper and website notices.
- The above summary is for the newspaper notice only. A more detailed summary / basis statement is attached.
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**Please approve bottom portion of this form and assign appropriate AdvantageME number.**

APPROVED FOR PAYMENT \_\_\_\_\_ DATE: \_\_\_\_\_  
(authorized signature)

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
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# Notice of Agency Rule-making Proposal

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## DETAILED BASIS STATEMENT / SUMMARY:

### **Chapter 1, Definitions**

- The following definitions have been added or amended in conjunction with the substantive changes discussed below: “APPE,” “direct supervision,” “IPPE,” “point of care location” and “VAWD.” The definition of “wholesale distributor” has been updated to reflect a change in statute.

### **Chapter 6, Pharmacy Student Intern Programs (sunsetting)**

- This chapter is replaced by the student internship program requirements contained in new Chapter 6-A. Because pharmacy students currently enrolled in out-of-state schools may be completing an internship under Chapter 6, the board will recognize student internships that meet the requirements of Chapter 6 with respect to pharmacist license applications filed through June 30, 2012. All applications for pharmacist licensure received on or after July 1, 2012 must document completion of an internship that meets the requirements of new Chapter 6-A.

### **Chapter 6-A, Pharmacy Student Intern Programs (new)**

- Pharmacy schools, not the board or retail pharmacies, are responsible for the administration of pharmacy student intern programs. This is a major change from the current rules.
- Student internship consists of an initial pharmacy practice experience (“IPPE”) and advanced practice pharmacy experience (“APPE”) as administered by an accredited pharmacy school. Although current standards of the American College of Clinical Pharmacy provide for a 300 hour IPPE and a 1440 APPE, for a combined total of 1,740 hours, the proposed rules carry forward the 1500-hour floor contained in the current Chapter 6.
- A student intern will receive one pharmacy technician intern license, renewable annually, that will expire 1 year after the intern’s receipt of the Pharm.D. The unified license will cover service during the IPPE and APPE plus any employment of the licensee as a pharmacy technician outside of the IPPE/APPE. This will end the current need for multiple pharmacy technician licenses during a student’s academic career and post-graduate pending licensure as a pharmacist.
- There will be an initial fee, but no renewal fees, for the unified pharmacy technician intern license. The student intern must verify enrollment annually on line. Maintenance of matriculation is an ongoing requirement of the pharmacy technician intern license. The license will automatically terminate upon the student’s dropping out of or expulsion from pharmacy school. The licensee must notify the board within 10 days if the licensee has dropped out of or has been expelled from pharmacy school.
- The pharmacy school is responsible for hiring preceptors. For an IPPE or APPE administered in Maine, a preceptor pharmacist must also be licensed in good standing by the board and have at least 2 years of practice experience as a licensed pharmacist in any state.
- A student intern’s completion of an IPPE or APPE must be verified by the preceptor pharmacist in a manner acceptable to the board. A student intern must report to the board annually all non-IPPE or -APPE hours worked as an ordinary pharmacy technician. The hours must be verified by the pharmacist in charge or supervising pharmacist.
- For foreign-educated graduates, the substance of the current internship rule (Chapter 6) has been folded into the unified pharmacy technician intern license described above. Internship remains at a straight 1,500 hours, of which at least 500 hours must be completed in the United States. Preceptors are practicing pharmacists.

### **Chapter 7, Registration and Employment of Pharmacy Technicians (amended)**

- A pharmacy technician (advanced) is now authorized to perform certain duties relating to automated pharmacy systems without needing to be in the physical presence of the supervising pharmacist. See the revised definition of “direct supervision” in Chapter 1, Section 14 of the

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proposed rules.

### **Chapter 12, Licensure of Manufacturers and Wholesalers (amended)**

- All wholesale distributors must be accredited by the verified-accredited wholesale distributor program (“VAWD”) administered by the National Association of Boards of Pharmacy no later than January 1, 2013, provided that a wholesale distributor initially licensed by the board after January 1, 2012 may submit proof of accreditation no later than one year after the date of initial licensure.
- VAWD accreditation must be continually maintained by the wholesaler and is an ongoing requirement of licensure renewal.
- The license application process is significantly streamlined for VAWD-accredited wholesale distributors in the areas of license verification, disclosure and documentation of disciplinary actions, and provision of inspection reports.

### **Chapter 13, Operation of Retail Drug Outlets (amended)**

- Section 6 is amended to require security cameras to also monitor self-service customer kiosks.

### **Chapter 16, Operation of Wholesalers and Manufacturers (amended)**

- The title of the chapter has been changed to correspond to the terminology used in Chapter 12, Licensure of Manufacturers and Wholesalers. There are no changes to the text of the chapter.

### **Chapter 20, Automated Pharmacy Systems (repeal and replace)**

- Current Chapter 20 has been split into two subchapters covering, respectively: (a) automated pharmacy systems in a retail pharmacy and (b) automated pharmacy systems in a hospital, nursing home, prison or other institutional setting. Whereas the former category consists of robotic filling machines, the latter category consists of remote dispensing systems.
- Subchapter 1, dealing with automated pharmacy systems in retail pharmacies, is substantially similar to Chapter 20 in the current rules.
- Subchapter 2, dealing with automated pharmacy systems in an institutional setting, is substantially new. This type of automated pharmacy system is a mechanism for delivery of drugs to patients or clients when a pharmacist is not on-site. Designated categories of health care providers or corrections personnel may enter prescriptions into the system at a point of care location such as a hospital, nursing home or penal institution that is remote from the pharmacist in charge of the system. The pharmacist remotely authorizes the dispensing machine at the point of care location to release the prescribed medication in single-dose units that are automatically labeled with the patient’s name and all other label information required by law. Pharmacy technicians (advanced) will be authorized to accept delivery of canisters and stock dispensing machines, but will not be authorized to remove drugs from the machines.
- Subchapter 2 addresses the need for pharmacist control, user accountability, drug security, and protection against misfills in the following additional respects:
  - A delivery log is required to document a courier’s delivery of filled canisters from an automated pharmacy to a point of care location.
  - “Direct supervision” is defined in Chapters 1 and 7 to require 2-way audiovisual communication between a remote pharmacist and a pharmacy technician (advanced) at a point of care location.
  - Security cameras must monitor the front face of a remote dispensing machine and all faces that open for loading; Fifteen frames per second color is required.
  - A remote dispensing system must use barcoding and microchip technology to ensure that the drug and dosage put in a canister at a remote pharmacy is the drug and dosage actually dispensed at the point of care location.

Due to these protections, and unlike the dispensing of prescription drugs by a retail pharmacy or central fill drug outlet, no final check is required at the point of care location.

### **Chapter 20-A, Self-Service Customer Kiosks (new)**

- A retail pharmacy may install self-service customer kiosks for customer pick-up of finished prescriptions. Due to the mandatory counseling requirement for new prescriptions, kiosks are for refills only. A kiosk may offer the customer an opportunity for refill counseling by toll-free telephone; however, a kiosk must inform customers that counseling is available at the pharmacy counter. A kiosk may operate only when the licensed pharmacy is open. A kiosk must be alarmed and may not dispense controlled substances.

### **Chapter 22, Sale of Schedule V Controlled Substances (amended)**

- The text of this chapter has been updated to more closely conform to the governing statutes.

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**Chapter 25, Patient Counseling (amended)**

- The statutory limitation of counseling responsibilities in connection with prescriptions to patients in hospitals and institutions has been reproduced in this chapter verbatim to avoid confusion that may be caused by its omission. See 32 MRSA §13784(1).

# Rule-Making Fact Sheet

(5 MRSA §8057-A)

AGENCY: Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

NAME, ADDRESS, PHONE NUMBER OF AGENCY CONTACT PERSON: Geraldine Betts, Board Administrator, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME, (207) 624-8625

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DATE AND PLACE OF PUBLIC HEARING: November 3, 2011, 9:00 a.m., Department of Professional and Financial Regulation, 76 Northern Avenue, Gardiner, Maine

COMMENT DEADLINE: December 9, 2011

## PRINCIPAL REASON OR PURPOSE FOR PROPOSING THIS RULE:

- To transfer responsibility for overseeing student internships and student preceptors from retail pharmacies to pharmacy schools (Chapters 1, 6, 6-A)
- To implement a unified, reduced-cost license for student interns who also work as pharmacy technicians (Chapters 6, 6-A)
- To ensure pharmacist control, user accountability, drug security and protection against misfills in the use of an automated pharmacy system at a hospital, nursing home or other institution (Chapters 1, 20, 25))
- To authorize pharmacy technicians (advanced) to load an automated pharmacy system at a hospital or nursing home under the direct, remote supervision of a pharmacist (Chapters 1, 7, 20)
- To authorize deployment of self-service customer kiosks in retail pharmacies (Chapters 13, 20-A)

- To require all wholesale distributors licensed in Maine to become value-added accredited distributors (Chapters 1, 12)

## BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (PRIMARY SOURCES):

### **Student Internships and Preceptors**

- Letter dated July 31, 2008 from Dan R. Huff and Rodney A. Larson of Husson School of Pharmacy to board administrator Jeri Betts
- Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree, Accreditation Council for Pharmacy Education (2006), (hereinafter, “Accreditation Standards”), Standard No. 14: Curricular Core—Pharmacy Practice Experiences
- Accreditation Standards, Appendix C: Additional Guidance on Pharmacy Practice Experiences “Ensuring Quality Experiential Education,” American College of Clinical Pharmacy, *Pharmacotherapy* 2008;28(12):1548-1551
- Monograph, Licensing/Rule Change Issues Relating to Student Interns dated March 2, 2011 prepared by Jeffrey Frankel, OLR Staff Attorney

### **Automated Pharmacy Systems**

- Draft rule language from Maine Veterans Homes relating to automated pharmacy systems
- Analysis of “direct supervision” requirements in other states dated March 14, 2011 from Kelly J. Kash, CEO, Maine Veterans’ Homes
- Analysis of “direct supervision” requirements in other states dated April 22, 2011 from Jeffrey Frankel, OLR Staff Attorney
- Centers for Medicare and Medicaid Services (CMS) standards for locking/securing drugs in hospital pharmacy areas, 42 CFR §482.25(b)(2)
- Vendor and regulatory materials from manufacturer of InSiteRx Remote Dispensing System (Talyst)

### **Self-Service Customer Kiosks**

- Vendor materials from manufacturer of ScriptCenter prescription pick-up machine (Asteres)

### **Verified-Accredited Wholesale Distributors (“VAWD”) Program**

- National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD) Application Instructions dated September 2010

### **All**

- Professional judgment

## ANALYSIS AND EXPECTED OPERATION OF THE RULE:

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**Chapter 25, Patient Counseling (amended)**

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**FINDINGS UNDER CRITERIA CONTAINED IN EXECUTIVE ORDER 20 FY 11/12:**

- (A) The proposed rules will not negatively impact job growth or creation;
- (B) No fees are included in the proposed rule;
- (C) Retail drug outlets that elect to deploy a self-service customer kiosk will need to monitor the kiosk by security camera. Nursing homes, hospitals and prisons that elect to deploy an automated pharmacy system will need to monitor the drug dispensing machine by security camera, implement a secured access system, and maintain audit records of access to the system. There will be no other cost to licensees to comply with the proposed rules in comparison to the rules they replace. The proposed rules significantly reduce the complexity of the license application process for wholesale pharmacies who become verified-accredited wholesale distributors. The proposed rules significantly reduce the complexity and the expense of the licensing process for pharmacy students.
- (D) No other laws or rules address the subject matter of the proposed rules; and
- (E) Title 42 CFR §482.25(b)(2), part of the Code of Federal Regulations, sets forth standards for storage of drugs in hospital pharmacies. Chapter 20 of the proposed rules is consistent with the federal requirement.

FISCAL IMPACT OF THE RULE: None

***FOR RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:***  
ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:  
  
INDIVIDUALS OR GROUPS AFFECTED AND HOW THEY WILL BE AFFECTED:  
  
BENEFITS OF THE RULE:

*Note: If necessary, additional pages may be used.*

## Part 1-General Information

### 02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

### 392 MAINE BOARD OF PHARMACY

### Chapter 1: DEFINITIONS

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

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

#### **1-A. APPE. "APPE" is advanced pharmacy practice experience.**

1. **Authorized person.** An "authorized person" is a person other than a pharmacy technician (e.g., computer technician, bookkeeper) who the pharmacist in charge has designated to be present in the prescription filling area in the absence of a pharmacist pursuant to Chapter 13, Section 6(7).
2. **Authorized pharmacy technician.** An "authorized pharmacy technician" is a pharmacy technician authorized by the pharmacist in charge to be present in the prescription filling area during the absence of a pharmacist pursuant to Chapter 13, Section 6(7).
3. **Biological safety cabinet.** "Biological safety cabinet" is a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to NSF International Standard 49, "Class II (Laminar Flow) Biohazard Cabinetry" (February 14, 2003), which the board hereby incorporates into its rules by reference. A copy of Standard 49 is available from-

NSF International  
P.O. Box 130140  
789 N. Dixboro Road  
Ann Arbor, MI 48113-0140

4. **Blood.** "Blood" is whole blood collected from a single donor and processed either for transfusion or further manufacturing.
5. **Blood component.** "Blood component" is that part of blood separated by physical or mechanical means.
6. **Central fill drug outlet.** "Central fill drug outlet" is a drug outlet that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to it by a retail drug

- outlet, rural health center or free clinic; or by a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and returns the labeled and filled prescriptions to the retail drug outlet or other source of origin for delivery to the patient or the authorized agent of the patient.
7. **Centralized prescription processing.** "Centralized prescription processing" refers to the functions and activities of a central fill drug outlet and a central processing center. A central fill drug outlet and central processing center may, but need not, operate in the same facility.
  8. **Central processing center.** "Central processing center" is a drug outlet that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail drug outlet, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board.
  - 8-A. **Certified midwife.** "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.
  9. **Class 100 environment.** "Class 100 environment" is an atmospheric environment which contains fewer than 100 particles of 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209E, "Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones" (September 11, 1992), which the board hereby incorporates into its rules by reference. A copy of Federal Standard 209E is available from-  
  
Institute of Environmental Sciences  
940 E. Northwest Highway  
Mount Prospect, IL 60056
  10. **Class 1000 environment.** "Class 1000 environment" is an atmospheric environment which contains less than 1000 particles of 0.5 microns in diameter per cubic foot of air according to Federal Standard 209E.
  11. **Contact hour.** A "contact hour" is 60 minutes of participation in a continuing professional education activity described in 32 M.R.S.A. §13735 or Chapter 5 of the board's rules.
  12. **Cytotoxic.** "Cytotoxic" is a pharmaceutical that is capable of killing living human or animal cells.
  13. **DEA.** "DEA" is the United States Department of Justice, Drug Enforcement Administration.
  14. **Direct supervision.** "Direct supervision" is the ability of a pharmacist to:
    - (A) Oversee the actions of a pharmacy technician by being physically present within the same work area as the technician being supervised; ~~or~~

- (B) Direct the activities of a pharmacy technician who has no fixed workstation (e.g., visits individual patient rooms); or
- (C) Oversee the actions of a pharmacy technician (advanced) at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician (advanced).
- 14-A. Drug administration clinic.** “Drug administration clinic” is the administration of influenza or other vaccines identified in 32 MRSA §13831 on a mass basis at a scheduled event, with or without sign-up times, within or outside a retail pharmacy, rural health center or free clinic licensed under 32 MRSA §13751. “Drug administration clinic” does not include the administration of influenza or other vaccines to an individual on a walk-in or appointment basis at a retail pharmacy, rural health center or free clinic at any other time.
- 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.
- 18. Enteral.** "Enteral" means within or by way of the intestine.
- 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.
- 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.
- 24. Nuclear drug outlet.** "Nuclear drug outlet" is a drug outlet that compounds, stores, dispenses, labels or delivers any radioactive drug.
- 25. Parenteral.** "Parenteral" is a sterile preparation of drugs for injection through one or more layers of the skin.

- 26. Pharmacist on duty.** "Pharmacist on duty" is a pharmacist who performs the duties of a pharmacist at any given time.
- 27. Pharmacy intern.** "Pharmacy intern" is a pharmacy student or recent graduate engaged in the practice of pharmacy under the direct supervision of a pharmacist while enrolled in the internship program described in Chapter 6 of the board's rules.
- 27-A. Point of care location.** "Point of care location" means the premises where prescriptions filled by an automated pharmacy system that is not wholly located in a retail pharmacy are delivered or administered.
- 28. Practice setting.** "Practice setting" includes, but is not limited to, the place, area, site, or manner in which the practice of pharmacy may normally occur or transpire.
- 29. Pharmacy technician (advanced).** "Pharmacy technician (advanced)" is a pharmacy technician who has demonstrated to the board that he/she:
- (1) Holds the designation of Certified Pharmacy Technician (CPhT) issued by the Pharmacy Technician Certification Board, and has maintained the certification in full force and effect; or
  - (2) Has successfully completed the National Community Pharmacy Technician Training Program and passed the corresponding National Pharmacy Technician examination.
- 30. Prescription filling area.** "Prescription filling area" is the area used for compounding prescription legend drugs, for storing all drugs and devices which may be sold by prescription only, and for any other activities necessary to the practice of pharmacy.
- 31. Printout.** "Printout" is a hard copy produced by computer that is readable without the aid of any special device.
- 32. Retail drug outlet.** "Retail drug outlet" is:
- (1) A drug outlet located in a retail store; or
  - (2) A specialty drug outlet not located in a retail store, including but not limited to a nuclear drug outlet or a drug outlet that compounds sterile pharmaceuticals, that dispenses a drug upon a prescription drug order for a specific patient.
- 33. Sight-readable.** "Sight-readable" refers to a record that may be read from a computer screen, microfiche, microfilm, printout, or other method approved by the Board.
- 34. Sterile pharmaceutical.** "Sterile pharmaceutical" is a dosage form free from living microorganisms (aseptic).
- 35. Stop date.** "Stop date" is the length of time to administer medication. In institutional settings, the physician normally notes the length of time to administer medication on the drug order. In the absence of this notation, the policy of the institution shall determine the length of time various categories of drugs may be administered.

35-A. VAWD. "VAWD" is the Verified-Accredited Wholesale Distributor program administered by NABP.

- 36. Wholesale distribution.** "Wholesale distribution" is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, but does not include:
- (1) Intracompany sales, which include any internal sales transaction or transfer with any division, subsidiary, parent and affiliated or related company under the common ownership and control as the transferor;
  - (2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
  - (3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
  - (4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;
  - (5) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
  - (6) The sale of a drug by a retail drug outlet to licensed practitioners for office use when the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five (5) percent of that drug outlet's total annual prescription drug sales;
  - (7) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
  - (8) The distribution of drug samples by manufacturers' representatives or distributors' representatives;
  - (9) The sale, purchase or trade of blood and blood components intended for transfusion; or
  - (10) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR §203.23.
- 37. Wholesale distributor.** "Wholesale distributor" is anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label

distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A wholesale distributor includes a wholesaler as defined in 32 M.R.S.A. ~~§13702(26)~~13702-A(34).

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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

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

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**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.

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**1. Purpose**

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

**2. Qualifications****1. Academic Completion**

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

**2. Registration as Pharmacy Technician**

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

**3. Duration of Internship**

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

**4. Preceptor**

The pharmacist in charge shall designate one or more preceptor pharmacists for each pharmacy intern employed at the drug outlet. The preceptor shall direct the training of the intern to whom the preceptor is assigned. The preceptor shall have been engaged in the practice of pharmacy

for at least 2 years on a full-time basis immediately prior to serving as preceptor. A preceptor may be responsible for the training of multiple pharmacy interns.

## **5. Training Program**

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

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

## **6. Scope of Duties**

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

## **7. Completion of Internship**

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

## **8. Sunset**

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

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

EFFECTIVE DATE:

November 8, 2004 - filing 2004-508

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

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**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.

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**SUBCHAPTER 1****(PHARMACY STUDENTS EDUCATED IN THE UNITED STATES AND CANADA)****1. Scope**

The provisions of this subchapter apply to pharmacy internships for pharmacy students educated in the United States and Canada.

**2. Student Internship Program**

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

**3. Application for Student Internship in Maine**

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

**4. Qualifications for Licensure**

The applicant shall meet the qualifications for licensure as a pharmacy technician set forth in Chapter 7, Section 1(2) of the board's rules. In addition, the 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.

## **5. Issuance and Renewal of License**

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

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

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

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

A pharmacy technician license issued under this chapter authorizes the licensee to work as a student intern in an IPPE or APPE and to work as an ordinary pharmacy technician at all other times. When working in an IPPE or APPE, the licensee may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor or pharmacist on duty is responsible for all actions performed by the licensee. When not working in an IPPE or APPE, the licensee is regarded as an ordinary pharmacy technician for all purposes and is subject to all provisions and limitations in the board's rules pertaining to pharmacy technicians except to the extent that special provision is expressly made for student interns. When the licensee is not working in an IPPE or APPE, supervision of the licensee and responsibility for the actions of the licensee are governed by Chapter 7, Sections 4 and 5 of the board's rules

## **8. Preceptor Pharmacists**

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

## **9. Reporting**

### **A. Completion of IPPE/APPE**

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

### **B. Non-IPPE/APPE Hours**

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

## **SUBCHAPTER 2**

(PHARMACY STUDENTS EDUCATED IN A FOREIGN COUNTRY OTHER THAN CANADA)

### **1. Scope**

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

### **2. Student Internship Program**

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

### **3. Application for Student Internship**

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

#### **4. Qualifications for Licensure**

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

#### **5. Issuance and Renewal of License**

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

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

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

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

A pharmacy technician license issued under this chapter authorizes the licensee to work as a student intern and to work as an ordinary pharmacy technician outside of the internship. When working as a student intern, the licensee may assist a preceptor pharmacist or pharmacist on duty in the practice of pharmacy. The preceptor or pharmacist on duty is responsible for all actions performed by the licensee. When not working as a student intern, the licensee is regarded as an ordinary pharmacy technician for all purposes and is subject to all provisions and limitations in the board's rules pertaining to pharmacy technicians except to the extent that special provision is expressly made for student interns. When the licensee is not working as a student intern, supervision of the licensee and responsibility for the actions of the licensee are governed by Chapter 7, Sections 4 and 5 of the board's rules

#### **8. Preceptor**

The pharmacist in charge shall designate one or more preceptor pharmacists for each pharmacy intern employed at the pharmacy. The preceptor shall direct the training of the intern to whom

the preceptor is assigned. The preceptor shall have been engaged in the practice of pharmacy for at least 2 years on a full-time basis immediately prior to serving as preceptor. A preceptor may be responsible for the training of multiple pharmacy interns.

## **9. Training Program**

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

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

## **10. Reporting**

### **A. Completion of Internship**

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

### **B. Non-Internship Hours**

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

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

EFFECTIVE DATE:

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

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

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**1. Registration****1. Application**

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

**2. Qualifications**

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

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

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

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

### **3. Applicability of Chapter to Pharmacy Students and Graduates**

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

### **4. Term of Registration**

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

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

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

## **2. Training**

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

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

### **3. Administrative Responsibilities**

#### **1. Verification of Registration**

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

#### **2. Display of Registration Certificate**

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

#### **3. Notice of Employment and Non-Employment of Pharmacy Technicians**

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

#### **4. Notice of Termination of Employment for Drug-Related Reason**

The pharmacist in charge shall notify the board via letter, fax or email of the termination of employment of a pharmacy technician for any drug-related reason, including but not limited to adulteration, abuse, theft and diversion, and shall include in the notice the reason for the termination. Notice shall be provided within 7 days after the termination.

### **4. Supervision by Pharmacist in Charge**

#### **1. Generally**

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

#### **2. Retail Drug Outlets**

A pharmacy technician may engage in the practice of pharmacy at a retail drug outlet only under the direct supervision of a pharmacist [as defined in Chapter 1, Section 14\(A\) 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**

~~A pharmacy technician may perform the duties authorized by Chapter 7, Section 5(2), Chapter 20 (Automated Pharmacy Systems) and Chapter 21 (Central Prescription Processing) of the board's rules only under the direct supervision of a pharmacist. The pharmacist is responsible for the work of each pharmacy technician working under the direct supervision of the pharmacist. [deleted]~~

## **5. Permissible Duties**

### **1. Generally**

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

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

### **2. Automated Pharmacy Systems**

~~Pursuant to Section 4(3) of this chapter and Chapter 20 of the board's rules, a pharmacy technician may remove and label drugs from an automated pharmacy system, stock an automated pharmacy system, and perform other functions related to automated pharmacy systems. [deleted]~~

### **3. Limitations**

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

- A. Accept an original prescription drug order by telephone;
- B. Clinically evaluate a patient profile relative to drugs that have or will be dispensed;
- C. Perform patient counseling;
- D. Make decisions that require the education and professional training of a pharmacist; or

- E. Sign any federally-required controlled substance or inventory form.

#### 4. Responsibility of Pharmacist

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

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

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

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

#### 7. Pharmacy Technician (Advanced)

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

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

- A. ~~Receive~~ A pharmacy technician (advanced) may receive a transferred prescription for a noncontrolled drug pursuant to Chapter 19, Section 8(2) of the board's rules.

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

##### 2. Deployment of Additional Pharmacy Technicians

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

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

### **3. Verification of Status**

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

- A. Permit a pharmacy technician who is not registered as a pharmacy technician (advanced) to perform technician duties that may only be performed by a pharmacy technician (advanced); or
- B. Supervise pharmacy technicians in a ratio permitted by Section 7(2) of this chapter where 1 or more of the pharmacy technicians, as the case may be, is not a pharmacy technician (advanced).

### **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 M.R.S.A. §§~~13741-13742-A~~ and 1374.3](#) and Chapters 30, 31 and 32 of the board's rules.

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

EFFECTIVE DATE:

November 8, 2004 - filing 2004-509

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 12: ~~REGISTRATION LICENSURE~~ OF MANUFACTURERS AND ~~WHOLESALE DRUG OUTLETS~~WHOLESALE**

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

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**1. Scope**

This chapter applies to manufacturers and ~~wholesale drug outlets~~wholesalers.

**2. Accreditation by VAWD**

All licensed wholesalers must be accredited by VAWD. No later than January 1, 2013, all licensed wholesalers must submit to the board proof of current accreditation by VAWD, provided that a wholesale distributor initially licensed by the board after January 1, 2012 may submit proof of accreditation no later than one year after the date of initial licensure. Once issued, accreditation by VAWD must be continually maintained by the wholesaler and is an ongoing requirement of licensure renewal.

**23. Application for ~~Registration~~Licensure**

The manufacturer or ~~wholesale drug outlet~~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 ~~wholesale drug outlet~~wholesaler or manufacturer;
2. All trade or business names used by the ~~wholesale drug outlet~~wholesaler or manufacturer;
3. The name, address, 24-hour telephone number and email address of a contact person for the facility used by the ~~wholesale drug outlet~~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 ~~wholesale drug outlet~~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.
  - ED. 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. ~~Verification of licensure for~~A list of all jurisdictions in which the manufacturer or ~~wholesale drug outlet~~wholesaler ~~has at any time been~~is 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 ~~wholesale drug outlet~~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."

#### **34. 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.

#### **45. Minimum Qualifications**

The board will consider the following factors in determining the eligibility for ~~registration~~ 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. ~~Suspension or revocation~~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; ~~and~~
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

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#### **8. Accreditation by VAWD.**

#### **56. Change of Owner or Location; Change in Other Registration Information**

Upon a change of ownership, a manufacturer or ~~wholesale drug outlet~~wholesaler 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 manufacturer or ~~wholesale drug outlet~~wholesaler shall file a new application with the board ~~by first class mail~~ 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~~In the event of any other change in the information provided by the manufacturer or wholesale drug outlet in its most recent application, the manufacturer or wholesale drug outlet shall notify the board via letter, fax or email within 7 days after the change.~~

**67. Operation of Manufacturer or ~~Wholesale Drug Outlet~~Wholesaler**

A manufacturer or ~~wholesale drug outlet~~wholesaler shall comply with the rules of operation contained in Chapter ~~1716~~, "Operation of ~~Wholesale Drug Outlets~~Wholesalers and Manufacturers" of the board's rules.

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

EFFECTIVE DATE:

November 8, 2004 - filing 2004-514

## **Part 3 - Operation of Drug Outlets**

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**392 MAINE BOARD OF PHARMACY**

**Chapter 13: OPERATION OF RETAIL DRUG OUTLETS**

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**Summary:** This chapter sets forth operation requirements for retail drug outlets registered 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 drug outlet must be open to the public for a minimum of 40 hours per week unless waived by the board for good cause shown, and must be staffed by a pharmacist at all times that the drug outlet is open.

**2. Posting of Schedule**

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

**3. Adherence to Posted Schedule**

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

**4. Deviations From Posted Schedule**

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

## **5. Reporting of Deviations to Board**

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

No report need be filed for:

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

## **6. Remedial Action by Board**

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

## **3. Pharmacist in Charge**

### **1. Generally**

The business of a retail drug outlet 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 retail drug outlet may operate without a pharmacist in charge.

### **2. Responsibilities**

The pharmacist in charge is responsible legally and professionally for all activities related to the practice of pharmacy within the retail drug outlet 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;
- E. Notifying the board of termination of status as pharmacist in charge via letter, fax or email within 7 days of the termination; and
- F. The supervision of pharmacy technicians and performance of administrative responsibilities relating to pharmacy technicians as required by Chapter 7 of the board's rules.

### **3. Presence at Retail Drug Outlet**

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

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

Except as set forth in Section 3(5)(B) of this chapter, no pharmacist may register or serve as pharmacist in charge for more than one retail drug outlet 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. The board may grant approval only in the following circumstances upon a consideration of the nature and extent of the risk posed to the public:

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

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

## **5. Emergency Requests**

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

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

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

A retail drug outlet 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.

## **5. Prescriptions to be Filled Only in Prescription Filling Area**

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

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

## **6. Security of Prescription Filling Area**

### **1. Absence of Pharmacist From Prescription Filling Area**

A retail drug outlet 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 retail drug outlet may dispense prescription drugs pursuant to an original prescription drug order in the absence of a pharmacist from the prescription filling area. No retail drug outlet may dispense prescription drugs pursuant to a renewal prescription drug order in the absence of a pharmacist from the store premises.

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

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

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

### **4. Deployment of Barrier**

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

## **6. Security Cameras**

A retail drug outlet 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](#), the narcotics safe and the 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 retail drug outlet shall retain stored images for no less than 30 days after recordation and shall produce the stored images to the board upon request.

## **7. Implementation of Barrier, Alarm and Security Camera Requirements**

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

## **8. Designation of Authorized Persons and Authorized Pharmacy Technicians**

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

## **9. Deliveries and Delivery Logs**

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

outlet, the drugs received, and the name of the person accepting delivery on behalf of the institution.

## **7. Signs**

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

## **8. Permanent Closing of a Retail Drug Outlet**

### **1. Notification**

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

### **2. Closing day procedures**

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

- (a) The transfer of Schedule II controlled substances shall be made on closing day and memorialized by a properly executed DEA Form 222; and
  - (b) The transfer of Schedule III, IV, and V controlled substances shall be made on closing day and memorialized by invoice, with copies to each party and the board.
- (2) If the controlled substances are not being sold or given to another DEA registrant, the retail drug outlet shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all controlled substances in its possession, custody or control, together with appropriate inventory information. The drug outlet shall lawfully sell or dispose of these drugs within 60 days after closure. If the drug outlet fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the drug outlet. In the event of forfeiture as set forth herein, the retail drug outlet remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- C. The retail drug outlet shall dispose of prescription legend drugs as follows:
- (1) If the prescription legend drugs are being sold or given to another drug outlet, the bulk transfer of such drugs shall be made on closing day and memorialized by invoice, with copies to each party.
  - (2) If the prescription legend drugs are not being sold or given to another drug outlet, the retail drug outlet shall turn over to the board on closing day for safekeeping, at the sole expense of the drug outlet, all prescription legend drugs in its possession, custody or control, together with appropriate inventory information. The drug outlet shall lawfully sell or dispose of these drugs within 60 days after closure. If the drug outlet fails to lawfully sell or dispose of these drugs within that time, the drugs shall be deemed forfeit to the board on the 61st day after closure without need of any action by the board. The board shall then dispose of the drugs with no compensation to the drug outlet. In the event of forfeiture as set forth herein, the retail drug outlet remains liable for all costs incurred by the board in the transportation, safekeeping and disposition of the drugs.
- D. Disposition of prescription files and patient profiles
- (1) If the prescription files and patient profiles are being sold to another drug outlet or are being transferred to another drug outlet in the same chain, the retail drug outlet that is closing shall transfer the files and profiles on closing day. The recipient drug outlet must keep the files and profiles for the time required by Chapter 24 of the board's rules.

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

### **3. Reports and Returns Due After Closing**

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

- A. To DEA-
- (1) Name, address, and DEA number of the closed drug outlet;
  - (2) Return of any unused DEA Form 222s;
  - (3) Copy of the controlled substances inventory and all schedules; and
  - (4) Copies of DEA Form 222 completed pursuant to Section 8(2)(B)(1)(a) of this chapter.
- B. To the board-
- (1) Return of the license for the closed retail drug outlet;
  - (2) Report that all signs indicating the presence of the closed drug outlet have been removed;
  - (3) Report that all labels and blank prescriptions have been destroyed;
  - (4) Report that the DEA license and all unused DEA Form 222s have been returned to the DEA;
  - (5) Report as to the disposition of controlled substances and prescription legend drugs made pursuant to Section 8(2)(B) and (C) of this chapter; and
  - (6) Report as to the disposition of prescription files and patient profiles made pursuant to Section 8(2)(D) of this chapter.

#### **4. Chemicals and Hazardous Materials**

The retail drug outlet shall remove and dispose of all chemicals and hazardous materials prior to closing in accordance with the Hazardous Waste Management Rules of the Department of Environmental Protection identified in Chapter 23, Section 2(1) of the board's rules (as applicable). The drug outlet 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.

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

EFFECTIVE DATE:

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**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 16: OPERATION OF ~~WHOLESALE DRUG OUTLETS~~WHOLESALE AND MANUFACTURERS**

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

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**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.

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

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**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 20: AUTOMATED PHARMACY SYSTEMS**

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**Summary:** This chapter sets forth requirements for automated pharmacy systems.

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**SUBCHAPTER 1**  
**(RETAIL PHARMACIES)**

REPEAL AND REPLACE OF ENTIRE CHAPTER.
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**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, a pharmacy technician working under the direct supervision of a pharmacist as described in Chapter 1, Section 14(A) and Chapter 7, Section 4(3) of the board's rules, or a person legally qualified under a health practice act to administer drugs may stock, remove or label drugs from an automated pharmacy system. No person with access to an automated pharmacy system shall remove more drugs than necessary to fill a prescription.

**4. Verification**

The pharmacist on duty shall verify the prescription drug order entered into a computerized pharmacy profile that is interfaced to the automated pharmacy system in order to screen for drug allergy, prevent therapeutic duplication, and verify appropriate 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**

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 that include, by lot number, 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.

This 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, 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 and 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 canisters at a point of care location;
- B. Stock a dispensing machine at a point of care location;
- C. Remove drugs from a dispensing machine at a point of care location; and
- D. Perform other functions related to an automated pharmacy system.

Except as set forth in subsection 2 below, none of the foregoing duties may be performed by a medical technician, medical assistant, certified nursing assistant, mental health rehabilitation technician or any other person whose profession or occupation is not listed in this subsection.

## 2. Pharmacy Technicians (advanced)

A pharmacy technician (advanced) working under the direct supervision of a pharmacist as defined in Chapter 1, Section 14(A), (B) or (C) of the board's rules and as referenced in Chapter 7, Section 7(1)(B) of the board's rules may:

- A. Accept delivery of canisters at a point of care location;
- B. Stock a dispensing machine at a point of care location; and
- C. 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.

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. Filling of Canisters; Verification of Contents

An automated pharmacy system must use bar-coding and microchip technologies to ensure that the canisters to be loaded into a dispensing machine at a point of care location are filled with the intended medication in the intended strength, dosage form and quantity. The pharmacist in charge or pharmacist on duty shall verify that the canisters have been properly filled and labeled and shall initial the label on the canister to confirm verification.

## 6. Transport and Delivery

Filled canisters 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 containers 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. Loading of Canisters**

A dispensing machine at a point of care location must use bar-coding technology to confirm receipt of the canister at the machine and must use microchip technology to ensure that only the correct and pharmacist-verified canister can be secured and locked in the machine and that the contents of the canister 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 prescription 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 and may only dispense single-dose units of the prescribed medication. Medication must be dispensed in strip form. The dispensed medication must be labeled directly by the dispensing machine and the label must contain the information required by 32 MRSA §13794.

## **9. Verification; 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 allergy, 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.

### **2. 2-Way Communication**

There must also be a 2-way, real-time voice and video communication link in operation at all times (24/7) between the pharmacist in charge or pharmacist on duty and any person who services, stocks, logs on to or removes product from the machine.

### **3. Availability of Pharmacist**

A pharmacist must be available by telephone at all times (24/7) to consult with a pharmacy technician (advanced) or person legally qualified under a health care act to administer drugs regarding any drug dispensed by an automated pharmacy system if a pharmacist is not available at the point of care location where the drug is dispensed.

## **12. Training**

All persons given access to a dispensing machine at a point of care location must be adequately trained in the operation of the automated pharmacy system. Checklists and procedure manuals must be kept up-to-date and must be readily accessible at all times.

## **13. Development of Procedures**

The pharmacist in charge shall develop, implement, maintain and follow procedures for the safe and effective use of drugs dispensed from an automated pharmacy system. At a minimum, the procedures shall ensure that:

1. An automated pharmacy system requires a person to enter a user name and password, or other unique identifier, in order to access the system. User names, passwords and other unique identifiers are assigned or authorized only by the pharmacist in charge;
2. Audit records of access to the system, including records of the delivery, receipt, loading, unloading, and returning of canisters, and records of the dispensing of drugs,

- are electronically tracked and recorded by the system and are maintained by the pharmacist in charge, and that such records are available to the board upon request;
3. Before an automated pharmacy system is deployed at a new point of care location, the pharmacist in charge has tested and validated the system to ensure that the system is releasing drugs properly;
  4. The pharmacist in charge monitors an automated pharmacy system for proper use and tests the accuracy of the system at least every 6 months, and whenever any change or upgrade is made to the system;
  5. Timely and documented maintenance is performed on the dispensing machine and all other components of an automated pharmacy system in accordance with the manufacturer's recommendations;
  6. The purity, potency, and integrity of the drugs contained in the automated pharmacy system is preserved;
  7. The automated pharmacy system provides all records required by the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29 of the board's rules;
  8. In the event of a consumer-level recall, the pharmacist in charge can access records that include, by lot number, 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.
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STATUTORY AUTHORITY: 32 M.R.S.A. §§13720, 13721(1), 13722(1)(B-1), 13723, 13751(3)

EFFECTIVE DATE:

November 8, 2004 - filing 2004-522

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 20-A: SELF-SERVICE CUSTOMER KIOSKS**

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

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**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.

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

EFFECTIVE DATE:

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 22: SALE OF SCHEDULE V CONTROLLED SUBSTANCES**

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

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**1. Applicability**

This chapter applies to Schedule V controlled substances, and to exempt narcotic preparations as defined in 32 M-R-S-A: §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, ~~at time of sale, obtains suitable identification from the purchaser~~ 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. ~~The pharmacist may request proof of age when appropriate.~~

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

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**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION****392 MAINE BOARD OF PHARMACY****Chapter 25: PATIENT COUNSELING**

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**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.

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

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