STATE OF MAINE
DEPARTMENT OF THE SECRETARY OF STATE

Notice of Agency Rulemaking Proposal

AGENCY: 02-392 Department of Professional and Financial Regulation, Maine Board of Pharmacy
CHAPTER NUMBER AND RULE TITLE: Chapter 1, Definitions (Amend); Chapter 20-A, Self-Service Customer Kiosks (Amend); Chapter 21, Centralized Pharmacy Services (Amend current Chapter 21, Central Prescription Processing); Chapter 24, Retention of Records by Pharmacies (Amend); Appendix A, Violations For Which Citation May be Issued (Amend)
TYPE OF RULE: Routine Technical
PROPOSAL FILING NUMBER: [Leave Blank - Assigned by the Department of the Secretary of State]
BRIEF SUMMARY: In December 2025, the Board proposed to update its rules regarding centralized pharmacy services. After considering the comments submitted and additional information presented by board staff, the Board is proposing new versions of the rule chapters which set forth the requirements when multiple entities work together to perform centralized pharmacy services, which includes all activities, functions, obligations and responsibilities required by Board rules in connection with the processing, filling, refilling, or dispensing of a prescription drug order. Copies of the proposed rules and the rulemaking forms can be accessed at https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy.
PUBLIC HEARING *(include day, date, time, and location)*: N/A. Pursuant to 5 M.R.S. § 8052(1) and § 8053(7)(A), a hearing may be requested by five (5) interested persons by submitting a request in writing to the contact person for this filing.
COMMENT DEADLINE *(include day, date, and time)*: Monday, June 22, 2026 by 5:00 p.m. EST. Comments may be submitted in writing: (1) by e-mail to Kristin Racine at kristin.racine@maine.gov or (2) by mail to the Maine Board of Pharmacy, 35 State House Station, Augusta, ME 04333-0035.
CONTACT PERSON FOR THIS FILING *(include Name; Mailing address; Telephone number; Fax number; TTY (Teletypewriter) number; and Email address)***:**
Penny Vaillancourt, Director, Office of Professional and Occupational Regulation
35 State House Station, Augusta, ME 04333-0035
207-441-7153
207-624-8637
TTY users call Maine Relay 711
Penny.Vaillancourt@maine.gov
CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT *(if different)***:** N/A
FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES *(if any)***:** N/A
STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 13720, 13721, 13722, 13723, 13751(3), 13784, 13785, 13794
SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED *(if different)***:** N/A
AGENCY WEBSITE: https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy
EMAIL ADDRESS FOR OVERALL AGENCY RULEMAKING LIAISON:
Penny.Vaillancourt@maine.gov

Choose <u>one</u> of the following:

The summary provided above is for the newspaper notice only. See 5 M.R.S. § 8053, sub-§ 3 & sub-§7. A more detailed summary is attached for inclusion in the rulemaking notice posted on the Secretary of State's website. See 5 M.R.S. § 8053, sub-§ 3.

Please approve the bottom portion of this form and assign the appropriate AdvantageME number.

Approved for Payment: _____ _____ Date: 5/12/2026

(*Authorized Signature)*

FUND	AGENCY	ORG	APP	OBJ	PROGRAM	FUNDING Profile JVC	FUND Pri JVC	FUND Line JVC
014	02A	4380	01	4946	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

ADDITIONAL INFORMATION FOR THE WEB NOTICE

DETAILED SUMMARY:

The proposed rulemaking updates the Board's rules on centralized pharmacy services. The proposed changes remove unregistered facilities (as identified in 32 M.R.S. § 13721(1)(D) and Chapter 3 of Board rules), rural health centers and free clinics from the rule on centralized pharmacy services, clarifies that any centralized pharmacy services entity must be licensed by the Board pursuant to Chapter 8 (including closed-shop pharmacies) or Chapter 11 of Board rules, sets forth the requirements of the policies and procedures manual that must be maintained by each centralized pharmacy services entity performing or contracting for the performance of centralized pharmacy services, provides that a centralized pharmacy services entity may either deliver or mail medications to another centralized pharmacy services entity for final dispensing to the patient or dispense and deliver medications directly to the patient, subject to any restrictions contained in federal laws and regulations, and updates labeling and notice to patients requirements for prescriptions filled through centralized pharmacy services. The proposed rulemaking adds a definition for "DDA," the Drug Distributor Accreditation program administered by NABP and removes the outdated term "VAWD" or "Verified-Accredited Wholesale Distributor" program administered by NABP. The proposed changes to Chapter 20-A include adding pharmacy interns to those licensees who may load finished refill prescriptions into a self-service customer kiosk or remove unclaimed prescriptions from a self-service customer kiosk or open the kiosk, subject to the other requirements set forth in rule. The proposed changes include corresponding updates to Appendix A, Violations for Which Citation May be Issued, due to the changes to Chapter 21.

STATE OF MAINE
DEPARTMENT OF THE SECRETARY OF STATE

Rulemaking Fact Sheet

(see 5 M.R.S. § 8057-A(1))

Agency: 02-392 Department of Professional and Financial Regulation, Maine Board of Pharmacy
Name, Address, Telephone Number, and Email Address of Agency Contact Person:
Penny Vaillancourt, Director, Office of Professional and Occupational Regulation
35 State House Station, Augusta, ME 04333-0035
207-441-7153, TTY users call Maine Relay 711
Penny.Vaillancourt@maine.gov
Chapter Number and Rule Title: Chapter 1, Definitions (Amend); Chapter 20-A, Self-Service Customer Kiosks (Amend); Chapter 21, Centralized Pharmacy Services (Amend current Chapter 21, Central Prescription Processing); Chapter 24, Retention of Records by Pharmacies (Amend); Appendix A, Violations For Which Citation May be Issued (Amend)
Type of Rule: Routine Technical
Statutory Authority: 32 M.R.S. §§ 13720, 13721, 13722, 13723, 13751(3), 13784, 13785, 13794
Public Hearing(s) *(include day, date, time, and location)***:** N/A. Pursuant to 5 M.R.S. § 8052(1) and § 8053(7)(A), a hearing may be requested by five (5) interested persons by submitting a request in writing to the contact person for this filing.
Comment Deadline(s) *(include day, date, and time)***:** Monday, June 22, 2026 by 5:00 p.m. EST. Comments may be submitted in writing: (1) by e-mail to Kristin Racine at kristin.racine@maine.gov or (2) by mail to the Maine Board of Pharmacy, 35 State House Station, Augusta, ME 04333-0035.
Principal Reason(s) or Purpose for Proposing this Rule:
The proposed rulemaking will amend the Board's rules regarding centralized pharmacy services. The proposed rules set forth requirements when multiple entities work together to perform centralized pharmacy services, which includes all activities, functions, obligations and responsibilities required by Board rules in connection with the processing, filling, refilling, or dispensing of a prescription drug order. Copies of the proposed rules and the rulemaking forms can be accessed at https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy.

Is Material Incorporated by Reference into the Rule? No

Analysis and Expected Operation of the Rule:
It is expected the proposed rulemaking will modernize centralized pharmacy services rules, and specifically eliminate redundant tasks for the pharmacist at a retail pharmacy by repealing the portion of Board rules that required a final check on prescriptions filled by a centralized pharmacy services entity. Requiring a final check by the pharmacist may also introduce an unnecessary risk of error, loss or theft. The proposed rules task the centralized pharmacy services entities with ensuring compliance with all applicable laws and rules pursuant to established policies and procedures, as documented in a manual. The Board initially proposed changes to these chapters in December 2025, and based upon input received through public comments and additional information provided from board staff, the Board is proposing new versions of the rule chapters.

Brief Summary of Relevant Information Considered During Development of the Rule (including up to 3 primary sources relied upon):
Expertise of board members, comments submitted by and input received from the regulated community, information provided by board staff.

Estimated Fiscal Impact of the Rule:
Unknown. There may be some administrative and record-keeping costs associated with developing and maintaining any policies and procedures manuals required for centralized pharmacy services entities, but the rule may also reduce costs and administrative burden for retail pharmacies by eliminating the rule requiring redundant final checks on a filled prescription received from a centralized pharmacy services entity.

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

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

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

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

Note: If necessary, additional pages may be used.

Part 1-General Information

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 1: DEFINITIONS

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

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

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

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

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

2. [deleted]

3. [deleted]

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

5. Blood component. "Blood component" is that part of blood separated by physical or mechanical means.

6. [deleted] ~~**Central fill pharmacy**. "Central fill pharmacy" is a pharmacy that prepares prescription drug orders for dispensing pursuant to a valid prescription transmitted to it by a retail pharmacy, rural health center or free clinic; or by a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and returns the labeled and filled prescriptions to the retail pharmacy or other source of origin for delivery to the patient or the authorized agent of the patient.~~

7. Centralized ~~prescription processing~~ pharmacy services. "Centralized ~~prescription processing~~ pharmacy services" are any services involving or associated with the processing,

filling or refilling, or dispensing of a prescription drug order from a centralized pharmacy services entity, when performed by two or more entities, as set forth in Chapter 21 of these rules. Centralized pharmacy services include all activities, functions, obligations and responsibilities required by these rules in connection with the processing, filling, refilling, or dispensing of a prescription drug order, including, but not limited to ensuring prescriptions are properly received, handled, filled and dispensed, drug utilization review, confidentiality of patient information, patient counseling, employee training, drug storage, security and accounting and records retention. ~~refers to the functions and activities of a central fill pharmacy and a central processing center. A central fill pharmacy and central processing center may, but need not, operate in the same facility.~~

8. **Centralized ~~processing center~~** pharmacy services entity. "Centralized ~~processing center~~ pharmacy services entity" is any retail pharmacy located in Maine and licensed pursuant to Chapter 8 of these rules, or, if located outside of Maine, a facility licensed in the manner of a mail order prescription pharmacy as set forth in Chapter 11 of these rules. For the purposes of this section, a centralized pharmacy services entity may be a licensed pharmacy with a closed-shop pharmacy endorsement pursuant to Chapter 38 of these rules. ~~a pharmacy that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail pharmacy, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board.~~

8-A. **Certified midwife**. "Certified midwife" means a midwife certified by and in good standing with the North American Registry of Midwives or the American Midwifery Certification Board, provided that "certified midwife" does not include a certified nurse midwife licensed as an advanced practice registered nurse by the State Board of Nursing.

9. [deleted]

10. [deleted]

10-A. **Closed-shop pharmacy.** "Closed-shop pharmacy" is a pharmacy that purchases drugs for and dispenses drugs to a limited, institutional patient population such as residents of a long term care facility, assisted living program, residential care facility, intermediate care facility for persons with mental retardation, or residential mental health facility.

11. **Contact hour**. A "contact hour" is 60 minutes of participation in a continuing professional education activity described in 32 MRSA §13735 or Chapter 5 of the board's rules.

12. [deleted]

12-A. **DDA**. "DDA" is the Drug Distributor Accreditation program administered by NABP.

13. **DEA**. "DEA" is the United States Department of Justice, Drug Enforcement Administration.

14. **Direct supervision**. "Direct supervision" is the ability of a pharmacist to:

1. Oversee the activities of a pharmacy intern or pharmacy technician by being physically present within the same work area as the technician being supervised;

2. Direct the activities of a pharmacy intern or pharmacy technician who has no fixed workstation (e.g., visits individual patient rooms); or

3. Oversee the activities of a pharmacy intern or pharmacy technician at a point of care location remote from the pharmacist in control of an automated pharmacy system. Such supervision shall be exercised via 2-way, real-time voice and video communication between the supervising pharmacist and the pharmacy technician.

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

14-A. [deleted]

14-B. DHHS. "DHHS" means the Maine Department of Health and Human Services.

15. Drug sample. "Drug sample" is a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

16. Electronic device. An "electronic device" includes, but is not limited to, a facsimile machine, computer system, portable device, or any other system or equipment approved by the Board.

17. Electronic signature. "Electronic signature" is an electronic sound, symbol or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

17-A. Electronic prescription. "Electronic prescription" means a prescription that is generated on an electronic application and transmitted as an electronic data file.

18. [deleted]

18-A. Extended hospital pharmacy. "Extended hospital pharmacy" means a pharmacy owned by and located in a hospital licensed by the Maine Department of Health and Human Services that is further licensed by the board to dispense drugs as set forth in Chapter 35 of the board's rules.

19. FDA. "FDA" is the United States Department of Health and Human Services, Food and Drug Administration.

20. Hard copy. "Hard copy" is a prescription drug order which has been transferred to paper, whether by hand or by equipment, and is readable without the aid of any special devices.

20-A. IPPE. "IPPE" is the introductory pharmacy practice experience.

20-B. Medical oxygen. "Medical oxygen" means oxygen in liquid or gaseous form intended for therapeutic use.

21. **MPJE(r)**. "MPJE" is the Multistate Pharmacy Jurisprudence Examination.

22. **NABP(r)**. "NABP" is the National Association of Boards of Pharmacy.

23. **NAPLEX(r)**. "NAPLEX" is the North American Pharmacist Licensure Examination.

23-A. **Non-sterile compounding pharmacy.** "Non-sterile compounding pharmacy" means a pharmacy that engages in the compounding of drug products in a non-sterile environment.

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

24. **Nuclear pharmacy**. "Nuclear pharmacy" is a pharmacy that compounds, stores, dispenses, labels or delivers any radioactive drug.

25. **Parenteral**. "Parenteral" means by some other route than through the gastrointestinal tract such as, but not limited to, intravenous, subcutaneous, or intramuscular routes.

26. **Pharmacist on duty**. "Pharmacist on duty" is a pharmacist who performs the duties of a pharmacist at any given time.

27. **Pharmacy intern**. "Pharmacy intern" is a pharmacy student, recent graduate or foreign graduate engaged in the practice of pharmacy under the direct supervision of a pharmacist while enrolled in the internship program described in Chapter 6-A of the board's rules.

27-A. **Point of care location.** "Point of care location" means the premises where prescriptions filled by an automated pharmacy system that is not wholly located in a retail pharmacy are delivered or administered.

28. **Practice setting**. "Practice setting" includes, but is not limited to, the place, area, site, or manner in which the practice of pharmacy may normally occur or transpire.

29. [deleted]

30. **Prescription filling area**. "Prescription filling area" is the area used for compounding prescription legend drugs, for storing all drugs and devices which may be sold by prescription only, and for any other activities necessary to the practice of pharmacy.

31. **Printout**. "Printout" is a hard copy produced by computer that is readable without the aid of any special device.

32. **Retail pharmacy**. "Retail pharmacy" is:

1. A pharmacy located in a retail store; or

2. A specialty pharmacy not located in a retail store, including but not limited to a closed-shop pharmacy, sterile compounding pharmacy, extended hospital pharmacy and retail supplier of medical oxygen.

32-A. Retail supplier of medical oxygen. "Retail supplier of medical oxygen" means a person who sells or dispenses medical oxygen to a consumer—

1. Pursuant to a prescription from a practitioner; or

2. In circumstances where a prescription is required by federal law.

33. Sight-readable. "Sight-readable" refers to a record that may be read from a computer screen, microfiche, microfilm, printout, or other method approved by the Board.

34. Sterile pharmaceutical. "Sterile pharmaceutical" is any dosage form of a drug, including but not limited to, parenterals (e.g., injectables, surgical irrigants, and opthalmics) devoid of viable microorganisms.

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

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

35. Stop date. "Stop date" is the length of time to administer medication. In institutional settings, the physician normally notes the length of time to administer medication on the drug order. In the absence of this notation, the policy of the institution shall determine the length of time various categories of drugs may be administered.

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

36. Wholesale distribution. "Wholesale distribution" is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients, but does not include:

1. Intracompany sales, which include any internal sales transaction or transfer with any division, subsidiary, parent and affiliated or related company under the common ownership and control as the transferor;

2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

3. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

4. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract or otherwise;

5. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

6. The sale of a drug by a retail pharmacy to licensed practitioners for office use when the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five (5) percent of that pharmacy's total annual prescription drug sales;

7. The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

8. The distribution of drug samples by manufacturers' representatives or distributors' representatives;

9. The sale, purchase or trade of blood and blood components intended for transfusion; or

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

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

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

EFFECTIVE DATE:

~~November 8, 2004 – filing 2004-503~~

AMENDED:

~~February 9, 2009 – Section 8-A added, filing 2009-48~~
~~October 1, 2009 – Section 14-A, filing 2009-510 (EMERGENCY)~~
~~November 25, 2009 – Section 14-A, filing 2009-610~~
~~March 11, 2012 – filing 2012-60~~
~~December 11, 2013 – filing 2013-298~~
~~November 4, 2023 – filing 2023-218~~

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 20-A: SELF-SERVICE CUSTOMER KIOSKS

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

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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~~ centralized pharmacy services entity 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 a self-service kiosk located at ~~the retail drug outlet~~ a centralized pharmacy services entity that receives the filled prescription from a ~~central fill drug outlet~~ centralized pharmacy services entity.

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, pharmacy intern 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, pharmacy intern 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, pharmacy intern and pharmacy technician who stocks, receives drugs from, removes drugs from or accesses the kiosk for any reason.

9. Testing

Before a self-service customer kiosk is deployed, the pharmacist in charge shall test the kiosk to ensure that it releases drugs properly. The pharmacist in charge must monitor performance

of the kiosk on an ongoing basis and test the kiosk for accuracy whenever any change or upgrade is made to the automated pharmacy system.

10. Purity and Potency

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

11. Maintenance

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

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

EFFECTIVE DATE:

~~March 11, 2012 – filing 2012-68~~

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 21: ~~CENTRAL PRESCRIPTION PROCESSING~~ CENTRALIZED PHARMACY SERVICES

Summary: This chapter sets forth requirements for ~~central prescription processing~~ multiple entities covered by these rules to work together to perform centralized pharmacy services, which includes all activities, functions, obligations and responsibilities required by these rules in connection with the processing, filling or refilling, or dispensing of a prescription drug order.

SECTION 1. Generally

1. Noncontrolled Drugs

A ~~central fill drug outlet and/or central processing center~~ centralized pharmacy services entity may engage in centralized pharmacy services with respect to ~~fulfill a request for the processing, filling or refilling of~~ a noncontrolled prescription drug ~~order from a retail drug outlet, rural health center or free clinic; or from a dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not registered or licensed by the board, and may deliver the processed, filled or refilled prescription drug order to the retail drug outlet or other health care facility identified in this subsection in accordance with the terms of this chapter~~.

2. Controlled Drugs

A ~~central fill drug outlet and/or central processing center~~ centralized pharmacy services entity may engage in centralized pharmacy services with respect to ~~may fulfill a request for the processing, filling or refilling of~~ a controlled prescription drug order from a centralized pharmacy services entity ~~retail drug outlet and may deliver the processed, filled or refilled prescription drug order to the retail drug outlet in accordance with the terms of this chapter.~~ so long as the centralized pharmacy services entities have established policies and procedures sufficient to ensure compliance with all State and Federal laws, rules and regulations regarding the processing, filling or refilling, or dispensing of a controlled prescription drug order, and ensures compliance with those policies and procedures.

SECTION 2. General Requirements

1. Location and Licensure

~~The~~ A ~~central fill drug outlet or central processing center~~ centralized pharmacy services entity must be located in the United States or its territories or the District of Columbia.

Any centralized pharmacy services entity must be licensed with the board. If located in Maine, the entity must be licensed as a retail pharmacy pursuant to Chapter 8 of the board's rules, with or without a closed-shop pharmacy endorsement pursuant to Chapter 38 of these rules. If located outside of Maine, the entity must be licensed in the manner of a mail order prescription pharmacy as set forth in Chapter 11 of the board's rules.

~~If located in Maine, the facility must be registered as a retail drug outlet. If located outside of Maine, the facility must be registered in the manner of a mail order prescription pharmacy as set forth in Chapter 11 of the board's rules.~~

2. Contract or Common Ownership

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

Any centralized pharmacy services entity may engage in centralized pharmacy services provided that all pharmacies involved in the transactions pursuant to which the prescription is dispensed shall:

A. Have the same owner or have a written contract outlining the services to be provided and the responsibilities and accountabilities of each pharmacy; and

B. Jointly agree upon a policies and procedures manual; and

C. Share a common electronic file or have appropriate technology to allow access to sufficient information required to fill, refill, process or dispense a prescription drug order.

SECTION 3. Policies and Procedures Manual

Each centralized pharmacy services entity performing or contracting for the performance of centralized pharmacy services shall abide by the agreed upon policies and procedures manual that sets forth which entity is responsible for all tasks and responsibilities required by board rules as well as all Maine and Federal laws and rules regarding the performance of any centralized pharmacy services. The policies and procedures manual may be maintained in electronic or hard copy form.

1. The policies and procedures manual must include, but need not be limited to the following:

   A. The responsibilities of each centralized pharmacy services entity;

   B. The policies and procedures that protect confidentiality and ensure integrity of patient information;

C. Provision for compliance with all applicable federal and state laws and rules, specifically those regarding the processing, filling or refilling, or dispensing a controlled prescription drug order;

D. The mechanism for tracking each step of the processing and filling functions performed at each centralized pharmacy services entity and identification of the individuals accountable for each step of the process. All audit trails and related records are subject to the retention and production requirements of Chapter 24 of the board's rules;

E. Identifies the centralized pharmacy services entity responsible for patient counseling requirements of board rules;

F. Provision for compliance with the drug utilization review requirements contained in the Medicaid laws, rules and other materials specified in Chapter 29, Section 1(9) of the board's rules; and

G. Procedures when a prescription filled utilizing centralized pharmacy services is not received or the patient or patient's authorized agent comes in before such prescription is received.

2. Each participating centralized pharmacy services entity shall review the policies and procedures manual at least annually and such review shall be documented.

3. Each participating centralized pharmacy services entity shall maintain copies of the policies and procedures manual for at least five (5) years and make copies available to the board or its agents upon request.

SECTION 4. Delivery of Medications

A centralized pharmacy services entity may:

1. Deliver or mail medications to another centralized pharmacy services entity for final dispensing to the patient, or

2. Dispense and deliver medications directly to the patient, subject to any restrictions contained in federal laws and regulations.

SECTION 5. Labeling

Notwithstanding other applicable state or federal law or regulation, the label affixed to the prescription container filled by a central fill pharmacy shall include all information required by 32 M.R.S. § 13794.

The label must provide the contact information of the centralized pharmacy services entity identified pursuant to Section 3, subsection 1(E) of this chapter to contact if the patient has any questions about the prescription or medication.

SECTION 6. Notice to Patients

If centralized pharmacy services are utilized in the processing or dispensing of a prescription drug order, the centralized pharmacy services entity must notify the patient and provide the name(s) of the other pharmacies that may process or fill a prescription drug order.

The notification may be provided through a one-time notice to the patient or through use of a sign in a pharmacy.

SECTION 7. Unprofessional Conduct

Unprofessional conduct, as that term is used in Chapter 30, shall include, but is not limited to, the following:

1. Failing to meet the requirements of Chapter 21 regarding centralized pharmacy services, including but not limited to failing to establish, implement or enforce the required policies and procedures. If the established policies and procedures required by this Chapter designate which centralized pharmacy services entity is responsible for any given task or responsibility with sufficient specificity so that there is no dispute about which centralized pharmacy services entity bears responsibility, then only that centralized pharmacy services entity bears responsibility and may be found to have engaged in unprofessional conduct as to any failure to properly perform that task or responsibility.

2. Failing to maintain copies of any policy and procedures manual, audit trails or other materials required by Chapter 21, or failing to provide such materials to board staff on request.

~~**4. Labeling**~~

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

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

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

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

~~4. Patient information.~~

~~**5. Policies and Procedures**~~

~~**1. Audit Trail**~~

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

~~**2. Performance of Final Check**~~

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

~~**3. DUR and Patient Counseling**~~

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

~~**4. Notice to Patients**~~

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

~~**6.**~~**SECTION 8.** **Freedom of Choice**

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

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

EFFECTIVE DATE:

~~November 8, 2004 - filing 2004-523~~

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 24: RETENTION OF RECORDS BY PHARMACIES

Summary: This chapter sets forth record retention requirements for pharmacies.

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1. Patient Profiles

A pharmacy shall retain each patient profile, including patient profiles maintained on an automated data processing system pursuant to Chapter 19, Section 7 of the board's rules, for 5 years from the date of last entry.

2. Prescription Drug Orders

1. Controlled Drugs - Written or Faxed Prescriptions

A pharmacy shall retain each written or faxed prescription drug order for a controlled drug for 2 years. For manually-processed orders, the retention period begins on the date of first fill. For orders processed by an automatic data processing system, the retention period begins on the date of last fill.

2. Noncontrolled Drugs; Manual Recordkeeping

A. A pharmacy shall retain each written or faxed prescription drug order for a noncontrolled drug that was manually processed for 2 years from the date of first fill.

B. A pharmacy may retain a scanned or microfiched unadulterated copy of the prescription drug order in place of the original. The scan or microfiche must include any information appearing on the reverse side of the prescription drug order.

3. Noncontrolled Drugs; Automatic Data Processing System

Prescription drug orders for noncontrolled drugs that were processed by an automated data processing system in accordance with Chapter 19, Section 7 of the board's rules need not be retained.

3. ~~Central Fill, Central Processing~~ Centralized Pharmacy Services

A ~~central fill pharmacy or central processing center~~ centralized pharmacy services entity shall retain all records relating to the receipt, processing, handling and movement of prescription drug orders and prescription drugs to and from originating pharmacies and dispensing pharmacies, including the audit trail required by Chapter 21, Section 3(1)(D) ~~5(1)~~ of the board's rules, for 2 years from the date of last fill.

4. All Other Records

Unless otherwise specified in these rules, the retention period for all other records that a pharmacist or pharmacy is required to create, including records created by an automated pharmacy system in accordance with Chapter 19, Section 7 of the board's rules, is 2 years from the date of creation.

5. Production at Time of Inspection

A pharmacist or pharmacy shall produce to an inspector of the board, upon request of the inspector, any and all records which the pharmacist or pharmacy is required to retain. Production of records for the most recent 12-month period must be made immediately at the time of inspection or investigation. The balance of the records requested must be produced within 3 business days of the request.

STATUTORY AUTHORITY: 32 M.R.S.~~A~~ §§ 13720, 13721(1), 13722(1)(B-1), 13723(7), 13785

EFFECTIVE DATE:
~~November 8, 2004 - filing 2004-526~~

AMENDED:
~~December 11, 2013 - filing 2013-310~~

Appendix A
VIOLATIONS FOR WHICH
CITATION MAY BE ISSUED

CHAPTER 4: LICENSURE OF PHARMACISTS
Failure of a pharmacist to notify the board of a change of contact address within 30 days ..... §3

CHAPTER 7: REGISTRATION AND EMPLOYMENT OF PHARMACY TECHNICIANS
Failure of a pharmacy technician to notify the board of a change in work site, change of contract address or change in enrollment status within 30 days..... §1(5)
Failure to supply adequate training to a pharmacy technician..... §2
Failure to have a copy of the pharmacy technician training program on site at the drug outlet..... §2
Failure of a pharmacist in charge to ensure proper registration of a pharmacy technician ..... §3(1)
Failure of a pharmacist in charge to conspicuously display a pharmacy technician's registration at the work site ..... §3(2)
Failure of a pharmacist in charge to notify the board of the commencement or cessation of a pharmacy technician's employment within 14 days ..... §3(3)
Permitting a pharmacy technician to practice beyond the scope of permissible duties ..... §§ 5, 7(1), 7(3)(A)
Violation of pharmacy technician deployment ratios ..... §§ 6, 7(2), 7(3)(B)

CHAPTER 8: REGISTRATION OF RETAIL DRUG OUTLETS
Alteration of prescription filling area prior to receiving board approval..... §7

CHAPTER 13: OPERATION OF RETAIL DRUG OUTLETS
Retail drug outlet not open to the public for a minimum of 40 hours per week..... §2(1)
Failure to prominently post in a public area of the store the days and hours that a retail drug outlet is scheduled to be open to the public ..... §2(2)
Failure of a retail drug outlet to timely report a deviation from its posted schedule..... §2(5)
Operation of a retail drug outlet without a pharmacist in charge..... §3(1)
Failure to perform duties and responsibilities of a pharmacist in charge ..... §3(2)
Filling or dispensing a prescription outside the prescription filling area of a retail drug outlet..... §5
Failure to properly secure the prescription filling area..... §6
Failure to identify a retail drug outlet with proper signage..... §7
Failure to follow all procedures for the permanent closing of a retail drug outlet..... §8

CHAPTER 14: PHARMACY SERVICES AT RURAL HEALTH CENTERS
Failure to comply with rule requirements applicable to pharmacy services at a rural health center..... entire chapter other than §5

CHAPTER 15: OPERATION OF FREE CLINICS
Failure to comply with rule requirements applicable to the operation of a free pharmacy clinic..... entire chapter other than §2

CHAPTER 16: OPERATION OF WHOLESALE DRUG OUTLETS AND MANUFACTURERS
Failure to comply with rule requirements applicable to the operation of wholesale drug outlet or manufacturer..... entire chapter other than §2(10)

CHAPTER 18: STERILE PHARMACEUTICALS

Failure to properly preserve, refrigerate, secure or store all drugs in the drug outlet or pharmacy department ..... §1(18)
Failure of a drug outlet to notify the board within 7 days of the termination of employment of a pharmacist for any drug-related reason ..... §26

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

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

Small Business and Economic Impact Statement

(5 M.R.S. § 8052(5-A))

AGENCY: 02-392, Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation, Maine Board of Pharmacy

NAME, ADDRESS, PHONE NUMBER, E-MAIL OF AGENCY CONTACT PERSON: Penny Vaillancourt, Director, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME 04333-0035, 207-441, 7153, TTY Users call Maine Relay 711, Penny.Vaillancourt@maine.gov.

CHAPTER NUMBER AND RULE TITLE:

Chapter 1, Definitions (Amend)
Chapter 20-A, Self-Service Customer Kiosks (Amend)
Chapter 21, Centralized Pharmacy Services (Amend current Chapter 21, Central Prescription Processing)
Chapter 24, Retention of Records by Pharmacies Amend)

TYPES AND NUMBER OF SMALL BUSINESSES SUBJECT TO THE RULE: Title 5 M.R.S. § 8052 (5-A) defines "small business" as businesses that have 20 or fewer employees. The Board of Pharmacy does not collect sufficient information to reliably estimate the number of licensees that are small businesses as defined in 5 M.R.S. § 8052(5-A).

PROJECTED REPORTING, RECORD-KEEPING AND OTHER ADMINISTRATIVE COSTS REQUIRED FOR COMPLIANCE WITH THE PROPOSED RULE, INCLUDING THE TYPE OF PROFESSIONAL SKILLS NECESSARY FOR PREPARATION OF THE REPORT OR RECORD: There may be record-keeping and administrative costs involved with development of the policies and procedures manual required by the rulemaking.

PROBABLE IMPACT ON AFFECTED SMALL BUSINESSES: Minimal.

LESS INTRUSIVE OR LESS COSTLY, REASONABLE ALTERNATIVE METHODS OF ACHIEVING THE PURPOSES OF THE PROPOSED RULE: Unknown. The proposed rulemaking is intended to modernize Board rules that apply to centralized pharmacy services, specifically to no longer require a pharmacist at a retail pharmacy to do a final check on a prescription that was prepared and sent to them from a centralized pharmacy services entity.