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 retail pharmacy, rural health center or free clinic (hereafter, collectively, a "retail drug outlet"), or from an entity identified as a Facility Not Registered or Licensed by the Board pursuant to Chapter 3 of these rules or any other facility that is not registered or licensed by the Board, when performed by two or more entities, as set forth in Chapter 21 of these rules. ~~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.~~ Centralized pharmacy services includes 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.

8. **Centralized ~~processing center~~pharmacy services entity**. "Centralized ~~processing center~~ pharmacy services entity" is any entity engaged in centralized pharmacy services.~~a pharmacy that performs processing functions including, but not limited to, drug utilization review, claims submission, claims resolution and adjudication, data entry, refill authorizations, interventions and other phone calls for more than one retail pharmacy, rural health center or free clinic; dispensary, hospital pharmacy, extended care facility, boarding home, nursing home, drug abuse treatment center, penal institution, family planning center, medical clinic or any other facility that is not licensed or registered by the board~~.

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

9. [deleted]

10. [deleted]

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

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

12. [deleted]

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

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

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

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

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

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

14-A. [deleted]

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

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

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

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

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

18. [deleted]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

29. [deleted]

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

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

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

1. A pharmacy located in a retail store; or

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

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

1. Pursuant to a prescription from a practitioner; or

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

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

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

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

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

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

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

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

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

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

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

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

5. The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical

reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

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

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

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

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

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

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

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

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

AMENDED:
February 9, 2009 – Section 8-A added, filing 2009-48
October 1, 2009 – Section 14-A, filing 2009-510 (EMERGENCY)
November 25, 2009 – Section 14-A, filing 2009-610
March 11, 2012 – filing 2012-60
December 11, 2013 – filing 2013-298
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 the retail drug outlet 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 or pharmacy technician may load finished refill prescriptions available for delivery into a self-service customer kiosk for pickup by the patient or a representative of the patient.

5. Identification of Patient or Patient's Representative

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

6. Opportunity for Counseling

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

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

7. Physical Security; Restricted Access

A self-service customer kiosk must be—

A. Electronically protected against unauthorized access;

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

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

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

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

8. Removal of Unclaimed Prescriptions; Accountability

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

9. Testing

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

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

10. Purity and Potency

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

11. Maintenance

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

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

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

Marked-up version , proposed to repeal and replace current rule

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.

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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 retail drug outlet (as that term is used in the definition of "centralized pharmacy services") ~~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 entity has 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.

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. If located in Maine, the ~~facility~~centralized pharmacy services entity must be registered as a retail drug

outlet. If located outside of Maine, the ~~facility~~centralized pharmacy services entity 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~~centralized pharmacy services entity 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.~~other centralized pharmacy services entity ~~The contract must include provisions that protect the confidentiality of patient information~~.

3. Labeling

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

~~1~~A. The name and address of the originating ~~drug outlet~~centralized pharmacy services entity;

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

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

4D. Patient information.

4. Notice to Patients

A retail drug outlet that utilizes ~~central fill~~centralized pharmacy 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~~centralized pharmacy services entity.

~~5~~ 3. Policies and Procedures

1. Policies and Procedures Manual

Any centralized pharmacy services entities engaging in centralized pharmacy services must jointly establish policies and procedures (documented in a policies and procedures manual) that set forth which entity is responsible for all tasks and responsibilities required by these rules as well as all Maine and Federal rules regarding the performance of any centralized pharmacy services.

The policies and procedures that must be covered include, but are not limited to:

A. As set forth in Section 1(2) of this Chapter, 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;

B. Ensure there is an audit trail that documents the prescription filling process and identifies the individuals accountable for each step of the process;

C. Ensure that the patient counseling requirements of these rules are met;

D. Ensure 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

E. Otherwise ensure compliance with all rules of the board with respect to all aspects of centralized pharmacy services.

2. Retention of Records

A. All entities required by this Chapter to promulgate a policies and procedures manual must maintain copies of all policies and procedures manuals for at least five years and provide such copies to Board staff on request; and

B. All audit trails and related records required by this Chapter are subject to the record retention and production requirements of Chapter 24 of the Board's rules.

3. Unprofessional Conduct

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

A. 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 may be found to have engaged in unprofessional conduct as to any failure to properly perform that task or responsibility.

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

~~**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.~~

~~6~~ 4. 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

Clean Version with all Changes

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

392 MAINE BOARD OF PHARMACY

Chapter 21: CENTRALIZED PHARMACY SERVICES

Summary: This chapter sets forth requirements for 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 centralized pharmacy services entity may engage in centralized pharmacy services with respect to a noncontrolled prescription drug.

2. Controlled Drugs

A centralized pharmacy services entity may engage in centralized pharmacy services with respect to a controlled prescription drug order from a retail drug outlet (as that term is used in the definition of "centralized pharmacy services") so long as the centralized pharmacy services entity has 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

A centralized pharmacy services entity must be located in the United States or its territories or the District of Columbia. If located in Maine, the centralized pharmacy services entity must be registered as a retail drug outlet. If located outside of Maine, the centralized pharmacy services entity 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 centralized pharmacy services entity that processes, fills or refills a prescription drug order must have a contract with or have the same owner as the other centralized pharmacy services entity.

3. Labeling

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

A. The name and address of the originating centralized pharmacy services entity;

B. The name and address or the unique identifier of the centralized pharmacy services entity (bar code or symbol acceptable);

C. Identifying information of the originating centralized pharmacy services entity, such as the tracking number (bar code or symbol acceptable); and

D. Patient information.

4. Notice to Patients

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

SECTION 3. Policies and Procedures

1. Policies and Procedures Manual

Any centralized pharmacy services entities engaging in centralized pharmacy services must jointly establish policies and procedures (documented in a policies and procedures manual) that set forth which entity is responsible for all tasks and responsibilities required by these rules as well as all Maine and Federal rules regarding the performance of any centralized pharmacy services.

The policies and procedures that must be covered include, but are not limited to:

A. As set forth in Section 1(2) of this Chapter, 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;

B. Ensure there is an audit trail that documents the prescription filling process and identifies the individuals accountable for each step of the process;

C. Ensure that the patient counseling requirements of these rules are met;

D. Ensure 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

E. Otherwise ensure compliance with all rules of the board with respect to all aspects of centralized pharmacy services.

2. Retention of Records

A. All entities required by this Chapter to promulgate a policies and procedures manual must maintain copies of all policies and procedures manuals for at least five years and provide such copies to Board staff on request; and

B. All audit trails and related records required by this Chapter are subject to the record retention and production requirements of Chapter 24 of the Board's rules.

3. Unprofessional Conduct

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

A. 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 may be found to have engaged in unprofessional conduct as to any failure to properly perform that task or responsibility.

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

SECTION 4. 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. §§ 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 ~~5~~3(~~1~~b) 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

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 (repeal and replace current Chapter 21, Central Prescription Processing); Chapter 24, Retention of Records by Pharmacies (Amend)

Type of Rule: Routine Technical

Proposal Filing Number: [Leave Blank - Assigned by the Department of the Secretary of State]

Brief Summary: 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.

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)*: Friday, January 16, 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(1), 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

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Choose one of the following:

The summary provided above is for publication in both the newspaper and website notices.

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

Approved for Payment: _____ Date: Click or tap to enter a date.

(*Authorized Signature)*

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ADDITIONAL INFORMATION FOR THE WEB NOTICE

Detailed Summary:

Click or tap here to enter text.

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
35 State House Station, Augusta, ME 04333-0035
207-441-7153
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 (repeal and replace current Chapter 21, Central Prescription Processing); Chapter 24, Retention of Records by Pharmacies (Amend)
Type of Rule: Routine Technical
Statutory Authority: 32 M.R.S. §§ 13720, 13721(1), 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)***:** Friday, January 16, 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 [*see* 5 M.R.S. § 8057-A(1)(A)]:
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 [*see* 5 M.R.S. § 8056(2-A)]**?** No

Analysis and Expected Operation of the Rule [*see* 5 M.R.S. § 8057-A(1)(B) & (D)]**:**
It is expected the proposed rulemaking will modernize centralized pharmacy services rules, and specifically eliminate redundant tasks for the pharmacist at a retail drug outlet or other health care facility 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.

Brief Summary of Relevant Information Considered During Development of the Rule (including up to 3 primary sources relied upon)[*see* 5 M.R.S. §§ 8057-A(1)(E) & 8063-B]**:**

Expertise of board members and input from the regulated community.

Estimated Fiscal Impact of the Rule [*see* 5 M.R.S. § 8057-A(1)(C)]**:**
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 a pharmacist at a retail drug outlet to perform a final check 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.