

Prince Edward Island Pharmacy Board Regulation Policy

POLICY FOR PRINCE EDWARD ISLAND PHARMACIES WISHING TO PARTICIPATE IN A CENTRALIZED PRESCRIPTION FILLING (CENTRAL FILL) PROCESS

November 2011

Introduction

An overburdened healthcare system, the pharmacy profession's expanded scope of practice, and increased pressures to manage the costs associated with drug distribution have created a demand for pharmacists to enhance their efficiency.

The use of centralized prescription processing (Central fill) systems can support enhanced efficiency by freeing the pharmacy from labour-intensive distribution functions. However, the appropriate use of these systems can create unanticipated negative consequences and compromise patient safety and care. Therefore, pharmacy owners, pharmacists, and particularly pharmacy managers have a professional responsibility to assure compliance with this policy and to ensure they have appropriate policies, procedures and quality assurance programs in place to address safety, accuracy, security and patient confidentiality.

Purpose

To enable efficient drug distribution systems within the practice of pharmacy in Prince Edward Island while assuring safety, accuracy, security and patient confidentiality for the protection of the public.

Policy

“Centralized prescription processing” (central fill) means the processing by a *central fill pharmacy* of a request from, the *originating pharmacy* to prepare a prescription drug order or to perform processing functions such as packaging medication to be dispensed pursuant to a prescription.

The *central fill pharmacy* is defined as a community (Class I) pharmacy accredited by the Prince Edward Island Pharmacy Board acting as an agent of the originating pharmacy to fill or process prescription orders.

The *originating pharmacy* is defined as the patient contact pharmacy accredited by the Prince Edward Island Pharmacy Board that uses a central fill pharmacy to fill or process prescription orders.

1. Centralized prescription processing can occur only in between **licensed pharmacies** physically located in Prince Edward Island.
2. Pharmacists involved in central prescription processing, the pharmacist in charge and owner of both pharmacies are responsible for:
 - a. Maintaining the Standards of Practice;
 - b. The provision of adequate security to protect the confidentiality and integrity of patient information and product;
 - c. Accurate record keeping, labeling, and legislative requirements ensuring that the prescription drug order has been adequately prepared;
 - d. Maintenance of a mechanism for tracking the prescription drug order through the stages of the patient care and drug product preparation process, including information on pharmacy personnel involved.
3. It must be readily identifiable that the medication was filled by a central fill pharmacy and not by the originating pharmacy. Options include, but are not limited to, the prescription label, an auxiliary label, or a code on the prescription label.
4. The central fill pharmacy must have the same ownership as the originating pharmacy or a legally binding contract with the originating pharmacy explicitly outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and provincial laws and regulations.
 - a. The agreement will be signed by the owner and the pharmacist in charge of the central fill pharmacy and the originating pharmacy.
 - b. A new agreement will be signed upon change of ownership or pharmacist in charge within 7 days of any changes.
 - c. This agreement will be available to the Prince Edward Island Pharmacy Board upon request.
5. The originating pharmacy is responsible to provide the PEIPB with 30 days advance notice, in a form provided by the PEIPB, of the intent to operate or utilize the services of a central fill pharmacy.
6. Until such time as the Office of Controlled Drugs and Substances provides direction as to the manner in which centralized prescription processing can occur in compliance with the CDSA and its regulations, drugs listed in the CDSA and regulations (e.g. narcotics, controlled drugs, benzodiazepines and other targeted substances, etc.) cannot be processed by centralized prescription processing.

Responsibility of the Originating Pharmacy

1. The *originating pharmacy* (patient contact pharmacy) is the pharmacy that bears the responsibility, under the Pharmacy Act, for receiving the order from the patient or their agent and providing the medication to the patient.
2. The *originating pharmacy* must ensure that systems are in place which guards patient safety throughout the entire process.
3. The prescription authority (i.e. the prescription) and documentation relating to the prescription and the patient remains in the *originating pharmacy*.
4. The *originating pharmacy* remains responsible for meeting all legislative requirements and the standards of practice for pharmacists on all prescriptions which includes reviewing all prescriptions and indentifying and resolving drug related problems. All interactions with the patient, their agent and health care professionals are the responsibility of the *originating pharmacy*.
5. The *originating pharmacy* must ensure that the patient knows and understands that prescriptions may be processed by a central fill pharmacy and that there may be transfer of personal health information.

Responsibility of the Central Fill Pharmacy

1. The *central fill pharmacy* is responsible for meeting all legislative requirements, Standards of Practice and the terms of the agreement including but not limited to the accuracy of labeling, packaging, processing and record keeping of the drug product preparation.
2. The *central fill pharmacy* is responsible for the safety and integrity of the drug product until received by the originating pharmacy. There must be an established process in place that gives assurance to the originating pharmacy of this integrity.

Pharmacy's Policies and Procedures Manual

A policies and procedures manual of the central fill process will be maintained by both the central fill and originating pharmacies. The manual will outline:

1. How the patient confidentiality and privacy of patient health information will be maintained and meet the requirements of any provincial or federal legislation;
2. How the parties will comply with provincial and federal legislation, standards and regulatory policy;

3. The processes involved in the processing of each prescription from the originating pharmacy to the central fill pharmacy and the return to the originating pharmacy for dispensing as well as the procedure for auditing these processes;
4. The procedures for ensuring that all prescription labels meet the requirements set forth by the Prince Edward Island Pharmacy Board and the mechanism used to identify on the prescription label or auxiliary label all pharmacies involved in dispensing the prescription order;
5. How the central fill pharmacy will process the records of requests from the originating pharmacy and maintain them for the purpose of filing and record keeping. All records will be maintained at the central fill pharmacy for a minimum of two years.
6. The process to establish effective two-way communication between pharmacies or pertinent patient prescription information;
7. The continuous quality assurance program in place with participation by both pharmacies involved in the central fill process which objectively and systematically monitors the quality and integrity of the process and continuously reviews this data to improve, maintain and support patient care, ensure patient safety and confidentiality, and resolve identified problems.

**CENTRAL FILL
PHARMACY AGREEMENT**

THIS AGREEMENT made effective as of _____

BETWEEN:

_____ ¹
The owner of _____ # _____ ²
(The “Central Fill Community Pharmacy”)

-and-

_____ ³
The owner of _____ # _____ ⁴
(The “Originating Pharmacy”)

WHEREAS:

- The pharmacist-in-charge of the Originating Pharmacy holds a pharmacy permit;
- The pharmacist-in-charge of Central Fill Pharmacy holds a community pharmacy permit;
- Pharmacists employed by the Originating Pharmacy dispense drugs to patients of the Originating Pharmacy and require the services of the Central Fill Pharmacy to compound or repackage drugs, or both, so that the pharmacists at the Originating Pharmacy can dispense those drugs to patients of the of the Originating Pharmacy;
- The “Central Fill Pharmacy” is willing to compound or repackage drugs, or both, or the Originating Pharmacy;

¹ Insert legal name of the owner of the Central Fill Community Pharmacy
² Insert name and permit number of the Central Fill Community Pharmacy
³ Insert legal name of the owner of the Originating Pharmacy
⁴ Insert name and permit number of the Originating Pharmacy

- The Originating Pharmacy and the Central Fill Pharmacy wish to enter into an agreement for the provision of compounding or repackaging services, or both, by the Central Fill Pharmacy;
- The Originating Pharmacy and the Central Fill Pharmacy recognize that under the terms of the Pharmacy Act and Regulations, the pharmacist-in-charge of the Central Fill Pharmacy must ensure that the Central Fill Community Pharmacy only provides pharmacy services to the Originating Pharmacy under the terms of a written contract that includes the terms required by the Board and is in the form required by the Registrar of the Board;
- By signing this Agreement, the pharmacist-in-charge and the owner of the Central Fill Pharmacy and the pharmacist-in-charge and the owner of the Originating Pharmacy each recognize their duties and responsibilities under the Pharmacy act and Regulations under this Agreement

THEREFORE the Originating Pharmacy and the Central Fill Pharmacy mutually covenant and agree as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 In this Agreement:

“Agreement” includes the Schedules to the Agreement and any amendment made to this Agreement or the Schedules;

“Board” mean the P.E.I. Pharmacy Board;

“Originating pharmacy permit” means a pharmacy permit issued under section 14 of the P.E.I. Pharmacy Authorization Regulations;

“Central Fill Pharmacy permit” means a Community pharmacy permit also under section 14 of the P.E.I. Pharmacy Authorization Regulation;

“Dispense” means to provide a drug pursuant to a prescription;

“Drug” means a substance or combination of substances referred to in section 1(h) of the Pharmacy Act or defined as an emergency release drug or a special access drug under the P.E.I. Pharmacy Act and Regulations and any combination of such substance or substances with any other substance;

2. RECORDS TO BE KEPT SEPARATE

- 2.1 If the Central Fill Community Pharmacy operates as a standard community pharmacy under a community pharmacy permit, the Central Fill Community Pharmacy shall keep the records relating to its operations as a standard community pharmacy separate and distinct from the records relating to the Services it provides under this Agreement.

3. ACCESS TO RECORDS

- 3.1 The Central Fill Community Pharmacy shall, on reasonable notice in writing from the Originating Pharmacy:
- (a) provide the Originating Pharmacy with access to any records relating to the provision of the Services under this Agreement; and
 - (b) provide the Originating Pharmacy with a true copy of any records relating to the provision of the Services under this Agreement.
- 3.2 The Central Fill Community Pharmacy may charge a reasonable fee for copying records required to be provided under article 3.1 (b).

4. ACCESS TO INFORMATION ABOUT INGREDIENTS

- 4.1 The Central Fill Community Pharmacy shall provide the Originating Pharmacy with the following information about each drug that is compounded or repackaged under this Agreement:
- (a) a list of ingredients;
 - (b) the strength of each ingredient;

5 EMERGENCY CONTACT INFORMATION

Both the Central Fill Community Pharmacy and the Originating Pharmacy shall maintain, in Schedule "A", a current list of Emergency Contact Information.

6 REVIEW OF AGREEMENT ON OR BEFORE THE THIRDDANNIVERSARY

- 6.1 In the event that the term of this Agreement is greater than 3 years, the parties agree that they shall meet to review this Agreement on or before the third anniversary of the date of Agreement is first signed to ensure that the terms of the Agreement are current and relevant.
- 6.2 The parties shall:
- (a) keep minutes of the meetings

- (b) ensure that the minutes are signed by the pharmacist-in-charge of each party;
- (c) provide a copy of the minutes to the Registrar on request.

7 SIGNATURE OF LICENSEE AND OWNER REQUIRED

- 7.1 This Agreement is not in effect unless it is signed by both the owner and the pharmacist-in-charge of each party.

WHEREFORE THE PARTIES to this Agreement have duly executed this Agreement as of the date written above.

**Legal Name of the Owner Of The
CENTRAL FILL COMMUNITY
PHARMACY**

Per: _____
Signature of owner

Per: _____
Signature of pharmacist-in-charge

**Legal Name of the Owner of
The ORIGINATING PHARMACY**

Per: _____
Signature of owner

Per: _____
Signature of pharmacist-in-charge

EMERGENCY CONTACT INFORMATION

Originating Pharmacy:

Name of Individual	Times Available As Emergency Contact	Contact Information
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:

EMERGENCY CONTACT INFORMATION

Central Fill Community Pharmacy:

Name of Individual	Times Available As Emergency Contact	Contact Information
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info:
		Phone #: Email Address: Other Contact Info: