



Guidance for Centralized Prescription Filling

March 2016

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 labor 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 pharmacy managers have a professional responsibility to assure compliance with *The PEI Pharmacy Act and General Regulations* and to ensure they have appropriate policies, procedures and quality assurance programs in place to address safety, accuracy, security and patient confidentiality.

“Centralized prescription processing” (central fill) means the preparation and packaging of a prescription drug on behalf of a pharmacy (originating pharmacy) by a central fill pharmacy.

1. Centralized prescription processing can occur only in between 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. The central fill pharmacy must have 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. This agreement will be made available to the Prince Edward Island College of pharmacists upon request
4. Pharmacies must ensure that it is easily identifiable that the medication was filled by a central fill pharmacy and not by the originating pharmacy and the label must include:
 - a) the name, business address and business contact information of the central fill pharmacy or,
 - b) a code that represents the central-fill pharmacy.
 5. The originating pharmacy is responsible for providing the PEI College of Pharmacists with a copy of the completed Central Fill Agreement Form at least 14 days in advance of utilizing the services of a central fill pharmacy or providing a central fill service.
 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* 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 protects patient safety throughout the entire process.
3. The original 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 identifying 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.
 - a) The originating pharmacy must provide notice to the public at least 30 days in advance and each day that the originating pharmacy is utilizing the services of a central fill pharmacy.
 - b) The notification must be in writing and posted in an area of the pharmacy where prescriptions are submitted by patients or their representative.
 - i) Pharmacies are encouraged to provide additional notification such as bag stuffers/stickers, etc.
 - c) The notification must indicate, in a prominent font, that:
 - i) Prescription drugs dispensed in the pharmacy may be packaged and prepared in a central-fill pharmacy,
 - ii) Personal information of the patient may be shared with the central-fill pharmacy,
 - iii) The name, business address and business contact information of the central-fill pharmacy.
 - d) If a patient submits a prescription after notice has been given of the utilization of the central-fill pharmacy services, the patient is deemed to have provided consent to have the prescription prepared and packaged by the central-fill pharmacy, unless otherwise stated by the patient.

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 Act and Regulations 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 10 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.

Approved March 2016	Reviewed:
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Central Fill Pharmacy Agreement

THIS AGREEMENT made effective as of

1 _____ 2

Between: _____ , # _____
3 4

AND _____ , # _____

¹ Insert legal name of the owner and the name of the Central Fill Pharmacy

² Insert the permit number of the Central Fill Pharmacy

³ Insert legal name of the owner and the name of the Originating Pharmacy

⁴ Insert the permit number of the Originating Pharmacy

WHEREAS:

- The managing pharmacist of the Originating Pharmacy holds a pharmacy permit;
- The managing pharmacist of Central Fill Pharmacy holds a 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;
- The Originating Pharmacy and the Central Fill Pharmacy wish to enter into an agreement for the provision of compounding or repackaging services, or both, for 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 Pharmacy only provides pharmacy services to the Originating Pharmacy under the terms of a written contract that includes the terms required by the College and is in the form required by the Registrar of the College;
- By signing this Agreement, the managing pharmacist and the owner of the Central Fill Pharmacy and the managing pharmacist 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

- “College” mean the P.E.I. College of Pharmacists;
- “Originating pharmacy permit” means a pharmacy permit issued under the P.E.I. Pharmacy Act;
- “Central Fill Pharmacy permit” means a retail pharmacy permit also under the P.E.I. Pharmacy Act;
- “Dispense” means to provide a drug pursuant to a prescription;
- “Drug” means a substance or combination of substances used or intended to be used in or on the body or a person or animal referred to in section 1(d) of the P.E.I. Pharmacy Act

2. Records to be Kept Separate

2.1 If the Central Fill Pharmacy operates as a retail pharmacy under a retail pharmacy permit, the Central Fill Pharmacy shall keep the records relating to its operations as a retail 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 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.

4. Access to Information About Ingredients

4.1 The Central Fill 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; (c) lot and expiry of each product in the compound; and (d) the DIN of each product in the compound if available.



5. Emergency Contact Information

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

6. Signature of Licensee and Owner Required

6.1 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 Pharmacy

Per _____ Per _____
Signature of owner Signature of managing pharmacist

Legal Name of the Owner of The Originating Pharmacy

Per _____ Per _____
Signature of owner Signature of managing pharmacist



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 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: