

Practice Direction Central Fill

1.1 Expected Outcome

This document is a practice direction by Council concerning the provision of central fill services through the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act*

1.2 Document Jurisdiction (Area of Practice)

Compliance is expected from all pharmacies in Manitoba that provide centralized prescription processing services to another pharmacy or obtain centralized prescription processing services from another pharmacy.

1.3 Regulatory Authority Reference

Sections 38 and 74 of *The Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction central fill.

2.0 Practice Direction

- 2.1 Conditions for participation in a central fill process
 - 2.1.1 Centralized prescription processing can only occur in and between Manitoba licensed pharmacies.
 - 2.1.2 There must be an agreement binding the "patient contact" pharmacy and the "central fill" pharmacy:
 - 2.1.2.1 If the two pharmacies have common ownership, this agreement may take the form of a corporate policy.
 - 2.1.2.2 If the two pharmacies have different owners, the agreement must be signed by the owners and pharmacy managers of both pharmacies.
 - 2.1.2.3 A new agreement must be signed within 7 days of any change in ownership or pharmacy manager.
 - 2.1.2.4 The agreement will be available to the College of Pharmacists of Manitoba upon request
 - 2.1.2.5 The agreement must outline the services and responsibilities ensuring all Manitoba and Canadian legislative requirements are met including but not limited to *The Personal Health Information Act* and the *Personal Information Protection and Electronic Documents Act*.
 - 2.1.2.6 The agreement must describe an audit trail that records all individuals involved in the processing of each prescription.
 - 2.1.3 Enable the sharing of sufficient information to perform the agreed functions.

2.2 Responsibilities of the Patient Contact pharmacy

- 2.2.1 Receives prescription from the patient or their agent. Retains a copy of the prescription and forwards the original prescription to the Central Fill pharmacy pursuant to section 74 of the Regulations.
- 2.2.2 Assesses the therapeutic and legal validity of the prescription, insofar

- as to intervene should they believe the medication as prescribed is unsafe or fraudulent.
- 2.2.3 Meets all legislative requirements, Standards of Practice, Practice Directions and the terms of the agreement including but not limited to the accuracy of labeling, packaging, processing and record keeping of the prescription.
- 2.2.4 With the exception of a drug dispensed in a hospital pharmacy, ensures that the patient or their agent knows, understands and has consented to the fact that
 - the prescription will be processed by a Central Fill pharmacy and that there will be a transfer of personal health information. Consent may be a one-time recorded event.
- 2.2.5 Reviews all prescriptions for the purpose of identifying and resolving drug related problems and initiating therapeutic interventions when appropriate.
- 2.2.6 Provides patient counseling and patient care.
- 2.2.7 Distributes medication to the patient or their agent, as appropriate.
- 2.2.8 Maintains the safety and integrity of the drug product from the time it is received from the Central Fill pharmacy until it is received by the patient.

2.3 Responsibilities of the Central Fill pharmacy

- 2.3.1 Assesses the therapeutic and legal validity of the prescription, insofar as to intervene should they believe the medication as prescribed is unsafe or fraudulent.
- 2.3.2 Meets all legislative requirements, Standards of Practice, Practice Directions and the terms of the agreement including but not limited to the accuracy of labeling, packaging, processing and record keeping of the prescription.
- 2.3.3 Maintains the safety and integrity of the drug product until it is received by the Patient Contact pharmacy or the patient, where the product is distributed directly to the patient from the Central Fill Pharmacy.
- 2.3.4 May include as outlined in the agreement with the patient contact pharmacy:
 - 2.3.4.1 Performing a drug utilization review
 - 2.3.4.2 Completing claims adjudication
 - 2.3.4.3 Obtaining refill authorizations
 - 2.3.4.4 Initiating therapeutic interventions
- 2.4 Responsibilities of the owner(s) and pharmacy managers of both pharmacies:
 - 2.4.1 Security of all data transmission.
 - 2.4.2 Accurate record keeping and labeling that is in compliance with all legislative requirements.
 - 2.4.3 Maintenance of a continuous quality assurance program with participation from 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.

3.0 Documentation

3.1 Documentation is to be recorded in a readily retrievable manner either electronically or in written form.

4.0 Compliance Adjudication

4.1 All documentation must be readily accessible and open to regulatory review

5.0 Appendices

Not applicable

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is been published on the College website.

Development Source: Regulatory Reference: Consultation Close: Authorized by Council: Effective Date: Revised:

Review Due:

Standards of Practice Committee
Section 38 and 74, *The Pharmaceutical Regulations*December 2, 2013
December 9, 2013
April 11, 2014