



Practice Direction Clinical Practice Pharmacies

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction of Council concerning the implementation of Clinical Practice Pharmacies through the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act (Act)*.

1.2 Document Jurisdiction (Area of Practice)

This practice direction is to be followed by all licenced pharmacists practicing in a Clinical Practice pharmacy, as defined in section 36 of *The Pharmaceutical Regulations* to *The Pharmaceutical Act*.

1.3 Regulatory Authority Reference

Section 36 of the regulations to the Act allows Council to create this practice direction.

2.0 Practice Direction

2.1 Clinical information requests

- 2.1.1 The pharmacy manager must ensure the pharmacy has the minimum information resources as determined by Council.
- 2.1.2 All clinical information requests must be handled by a licenced pharmacist, or a pharmacy resident (a person on the academic register) or a student or intern under the supervision of a licenced pharmacist.
- 2.1.3 The pharmacy manager shall ensure the information sources will meet the clinical information needs of the pharmacy and the patients served.
- 2.1.4 The licenced pharmacist shall use professional expertise and judgment in processing clinical information requests. This includes:
 - 2.1.4.1 Obtaining the necessary background information so that the request is received in a complete and understandable form;
 - 2.1.4.2 Interpreting the clinical information request;
 - 2.1.4.3 Systematically and thoroughly conducting a literature search;
 - 2.1.4.4 Evaluating the literature in an accurate, unbiased manner;
 - 2.1.4.5 Formulating a relevant, coherent and informative response, and
 - 2.1.4.6 Communicating the response in a verbal and/or written form in a manner that is clear and understandable to the recipient.
- 2.1.5 The licenced pharmacist shall contribute to the drug literature, by reporting any adverse events that have impacted upon patient safety.
- 2.1.6 The licenced pharmacist shall be aware of more extensive

sources of information and the procedures necessary to access them.

- 2.1.7 Access to services shall be available during all regular hours of operation. Where "on-call" service exists, information on how to access afterhours clinical information services shall be posted.

2.2 Documentation

- 2.2.1 **Patient Information:** Licenced pharmacists shall maintain patient profiles for all patients, and that patient profile information shall include:
 - 2.2.1.1 Demographic information: name, address, telephone number, date of birth (age), gender;
 - 2.2.1.2 Clinical information such as allergies and sensitivities and, where significant, disease state and/or chronic conditions;
 - 2.2.1.3 A comprehensive list of medications (e.g. drug name, strength);
 - 2.2.1.4 Use of relevant devices (e.g. self testing, compliance devices, etc.);
 - 2.2.1.5 Relevant prior and present medical conditions;
 - 2.2.1.6 Non-prescription, herbal and homeopathic drug use;
 - 2.2.1.7 Non-medicinal use of drugs, alcohol, tobacco;
 - 2.2.1.8 Laboratory and/or physical examination results, if available.
- 2.2.2 **Intervention Information:** Licenced pharmacists shall obtain the best possible medication history of the patient, from available sources such as the patient, DPIN profile, prescribers, other health care professionals, etc. When providing complete clinical services, licenced pharmacists will intervene and appropriately document the following:
 - 2.2.2.1 Actual and potential medication related problems that are to be monitored;
 - 2.2.2.2 Actual and potential adverse effects that are to be monitored;
 - 2.2.2.3 Compliance;
 - 2.2.2.4 Drug discontinuations;
 - 2.2.2.5 Counseling on medications.
- 2.2.3 When an intervention is required, at the discretion of the licenced pharmacist, the licenced pharmacist shall promptly forward the assessment, recommendations, and results to the most appropriate practitioner and, if appropriate, the community licenced pharmacist, along with recommendations to enhance patient care and quality of life. After an intervention has occurred, and the recommendations have been made, the licenced pharmacist shall follow up with the patient within a reasonable timeframe to ensure the recommendation has enhanced patient care.

2.3 Record keeping

- 2.3.1 In addition to the requirements of section 79 of the regulations and in compliance with the practice direction related to Standard of

Practice #10: Documentation & Records, the licenced pharmacist must retain records described in this practice direction for five (5) years.

2.4 Security

- 2.4.1 Safeguards must be implemented in the receiving and sending of data to ensure patient personal health information is kept confidential.
- 2.4.2 The pharmacy must be constructed in a manner of materials that protect the records from unauthorized access.

2.5 Privacy

- 2.5.1 When accessing patient medication profile information, the clinical practice pharmacy licenced pharmacist must document:
 - 2.5.1.1 Written permission from the patient for access to their personal health information;
 - 2.5.1.2 A description of the information being requested with respect to patient care;
 - 2.5.1.3 The name of the licenced pharmacist requesting the information and reason for the request;

2.6 Patient Counseling

- 2.6.1 Licenced pharmacists must comply with the practice direction regarding counseling the patient with respect to content, follow-up and privacy as stated in the community pharmacy, as well all other practice requirements applicable to a patient accessing the pharmacy services.
- 2.6.2 Content of the patient counseling information needs to be individualized for the needs of the patient, the condition(s) being treated and the knowledge and communication level of the patient.
- 2.6.3 All counseling areas must:
 - 2.6.3.1 Have acoustic and visual privacy;
 - 2.6.3.2 Have sound panels or opaque glass, unless in a separate room;
 - 2.6.3.3 Ensure ready access to the reference resources and patient profile;
 - 2.6.3.4 Ensure the physical needs of the patient are met.

2.7 Policies and procedures manual

- 2.7.1 Written policies and procedures for pharmacy services shall guide all personnel in the performance of their duties.
- 2.7.2 A comprehensive policy and procedures manual will contain information relating to professional responsibilities, protecting confidentiality and integrity of patient information, compliance with federal and provincial regulations and an operational Quality Assurance Program.
- 2.7.3 These policies and procedures shall be updated as circumstances in the pharmacy change (e.g. change of ownership, change of manager, etc.) or at a minimum of every three years, and dates to indicate the time of the last review and/or revision.
- 2.7.4 The policy and procedure manual shall be reviewed and approved by the

Registrar before a Clinical Practice Pharmacy Licence is granted. A pharmacy owner may appeal to Council if their Clinical Practice Pharmacy Licence is not approved by the Registrar.

2.8 Hours of operation

- 2.8.1 All pharmacies must be open for at least twenty-five (25) hours over a minimum of four (4) days per week unless the pharmacy manager or owner can demonstrate to Council that fewer hours will safely meet the needs of the patients receiving care from the pharmacy.
- 2.8.2 A licenced pharmacist does not need to be on site during all hours of operation of the pharmacy, but the practice of pharmacy or any required supervision cannot occur without a licenced pharmacist on site and the remaining staff must have access to the licenced pharmacist working off-site in case of urgent situations requiring the involvement of a licenced pharmacist.

2.9 Patient access

- 2.9.1 The principle pharmacy entrance must have the following posted if patient consultations occur in the pharmacy:
 - 2.9.1.1 Hours of operation;
 - 2.9.1.2 Call-back information;
 - 2.9.1.3 The pharmacy is licensed by the College of Pharmacists of Manitoba as a Clinical Pharmacy, and does not dispense medication, fill prescriptions or keep any medication for sale on the premises.
- 2.9.2 If patient consultations occur exclusively outside of the pharmacy, patients must have access to the clinical pharmacy by telephone, e-mail, and facsimile during business hours.

2.10 Location requirements

- 2.10.1 The clinical practice pharmacy must:
 - 2.10.1.1 Be located in an area that meets the municipal zoning requirements to operate a business;
 - 2.10.1.2 Have access for patients to enter the pharmacy that is not part of private residence access if patient consultations occur in the pharmacy;
 - 2.10.1.3 Be accessible by a dedicated telephone number, e-mail address, and facsimile machine for the pharmacy;
 - 2.10.1.4 Have the records stored securely and be readily accessible for inspection and review by the College;
 - 2.10.1.5 Post the name of the pharmacy and the hours of operation at the patient access.

3.0 Compliance Adjudication

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

4.0 Appendices

4.1 "Appendix A" establishes the minimum site requirements for Clinical Practice Pharmacies.

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 has been published on the College website.

Development Source:	Standards of Practice Committee
Regulatory Reference:	Section 36(1), 36(2), <i>The Pharmaceutical Regulations</i>
Consultation Close:	January 23, 2014
Authorized by Council:	February 10, 2014
Effective Date:	February 14, 2014
Revised:	October 5, 2015
Review Due:	