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.

2.8 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 Exterior signage

2.9.1 The principle entrance must have the following posted:

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.

2.10 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
2.10.1.3 Be accessible by a dedicated telephone number 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.

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<th>Development Source:</th>
<th>Standards of Practice Committee</th>
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<tbody>
<tr>
<td>Regulatory Reference:</td>
<td>Section 36(1), 36(2), The Pharmaceutical Regulations</td>
</tr>
<tr>
<td>Consultation Close:</td>
<td>January 23, 2014</td>
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<tr>
<td>Authorized by Council:</td>
<td>February 10, 2014</td>
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<td>Revised:</td>
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Appendix A

to the Practice Direction Entitled “Clinical Practice Pharmacies”

Clinical Practice Pharmacy Standards (Minimum Pharmacy Site Requirements):
(Effective January 1, 2014)

1) The Premises must:

a) Be readily accessible to the public in person, by telephone, and by facsimile machine;
b) Be well ventilated and sufficiently lit and of cleanliness suitable to the College of Pharmacists of Manitoba;
c) Have a patient counseling area suitable to the College of Pharmacists of Manitoba,
d) Not contain any drugs (unless patient’s own medication that is being stored for administration, or emergency response medications to be on site should a patient have an anaphylactic response to drug administration) available for sale;
e) Have a sanitary sink that is:
   I. Kept in a clean condition, and
   II. Supplied with hot and cold water.
f) Provide security of information in compliance with federal and provincial privacy legislation and any additional security measures approved by Council. Patient information displayed on computer screens must not be visible to any person in the public area of a pharmacy unless the information is being used as part of a patient counseling session, the information relates to the patient being counseled and it can only be viewed by the patient being counseled or their delegate.

2) The Pharmacy must:

a) Limit access to secure areas to authorized personnel only;
b) Have a facsimile machine only accessible to pharmacy personnel;
c) Have internet access for the purposes of email, electronic fan out, and information research;
d) If the pharmacy stores any patient’s own medication for administration, have a refrigerator that is:
   i. Clean and in good working order;
   ii. Dedicated to the storage of pharmaceuticals and related products;
   iii. Capable of maintaining the temperature defined by the manufacturer of product stored in the refrigerator.
e) Have a waste container of either plastic, metal or similar material.
3) The Minimum Library Requirements are:

   a) College of Pharmacists of Manitoba Manual* containing current Federal and Provincial pharmacy related statutes and information;
   b) Policy and procedures Manual* that includes minimum content as required by Council;
   c) Interaction references for drugs, herbs, nutraceuticals and food*;
   d) Information references for drugs, herbs and nutraceuticals*;
   e) Counseling references for drugs*, and
   f) All other reference material consistent with the standards of practice and pharmacy practice in that location and type of practice (e.g. geriatric, paediatric, pre-natal & maternal, medical dictionary, etc)*.

   *May be in hardcopy or electronic format

Application may be made to Council for Exceptions or Waives to the Requirements of this Document.