New Pharmacy Openings

The following documents can be found in this package:

1) 2020 Pharmacy Licence Application
2) Part 7 of the Pharmaceutical Act regarding pharmacies
3) Part 6 of the Pharmaceutical Regulations regarding pharmacies
4) Part 7 of the Pharmaceutical Regulations regarding Standards of Practice
5) Standard 15: Pharmacy Facilities Practice Directions that includes pharmacy minimum standards
6) Standard 12: Records and Information Practice Directions
7) Minimum Pharmacy Policy and Procedure Manual Content
8) Application for DPIN
9) College Approval of Corporation and/or Pharmacy (Business) Name form

The original 2020 Pharmacy Licence Application must be returned with the accompanying fee before a licence number will be issued. Please attach a pharmacy floor plan.

The DPIN application form must be forwarded BY THE APPLICANT to Manitoba Health.

The ever-increasing number of new pharmacy openings has presented workload management challenges for pre-licencing applications. **As a result, arrangements for the pre-licence inspection process should be made well in advance.** The opening and practise business plans of the applicant should be adjusted accordingly.

To arrange a pre-opening inspection, please contact the College at (204) 233-1411, or by e-mail: khunter@cphm.ca.

Thank you.
2020 APPLICATION FOR PHARMACY LICENCE
FOR A NEW COMMUNITY PHARMACY

I (We), _____________________________________________________________ (Name of Pharmacy Licence Holder; for example: 123456 Manitoba Ltd.) hereby make application for a Pharmacy Licence to conduct a pharmacy under the provisions of The Pharmaceutical Act in the Province of Manitoba until the 31st day of December, 2020.

Pharmacy Business Name(s): ___________________________________________________________________

Pharmacy Address*: __________________________________________________________________________

* [ ] Additional buildings, facilities and/or premises are being used as part of this pharmacy licence and details of the location(s) and description of activities at each location is attached to this application.

Corporation’s (9 digit) Business Number: _______________________________

Telephone #1: _____________________________ Telephone #2: _____________________________

Fax Number(s): ______________________________

Primary E-mail Address: ________________________________________________

Primary Website: ____________________________________ (Please list additional email and website address on separate paper)

Business Hours of Operation: ___________________________________________________________

Lock and Leave: YES  or   NO  If Lock and Leave, list hours: _____________________________________________

Expected Date of Opening: ___________________________________  (Must be no less than 30 days after the College has received this application and all supporting documents, or at such other time as may be acceptable to the registrar.)

All Applications Must Attach:
1. A sketch / floorplan showing the physical layout of the pharmacy;
2. A description of the pharmacy services to be provided; and
3. If a Lock & Leave permit is also being requested, a sketch that includes the Lock & Leave area and the larger retail operation.

This pharmacy meets the minimum $5,000,000 commercial general liability insurance requirement under a policy through the following insurance company (and evidence will be provided to the College such as a letter from the insurance broker or the insurer, a copy of the policy declaration page or a copy of the policy itself): ___________________________________________

Does this pharmacy conduct business or practice pharmacy with the following:

<table>
<thead>
<tr>
<th>Service</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Fill</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Distance care (international prescription service (IPS))</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Distance care (non-international prescription service)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>External dispensing</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Lock and Leave</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Personal care home (long term care)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Satellite pharmacy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Secondary hospital</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterile compounding</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Any above noted services, the application must provide additional details with this application.

For Office Use Only: Licence #: ________________________________
Approved By: _____________________________________________
Date Approved: ________________________________
* Please be advised for those pharmacies that apply for a Distance Care (International Prescription Service (IPS) component of the Pharmacy licence, the 2020 Pharmacy licence will be issued with the condition the pharmacies include the Council approved disclaimer that will advise their clients, and potential clients, the licensing authority in Manitoba has some limitations regarding the enforcement of the public protection provisions of the provincial legislation for clients outside of Canada. The IPS component of the Pharmacy licence is defined as, “A pharmacy that fills prescriptions for patients who have not physically attended the pharmacy to receive their medication due to their residence and citizenship being outside Canada.” (An IPS component may not be needed for a pharmacy located near the American border where the patient physically enters into Canada to receive their medical care in Manitoba.)

**Pharmacy Manager:**  (please print) ____________________________
No. of hours/week on site _______________

**Licensed Pharmacists (please print and include licence number)**
____________________________ ____________________________
____________________________ ____________________________

**Pharmacy Students and Interns**
____________________________
____________________________
____________________________

**Pharmacy Technicians** (qualified and listed by the College)
____________________________ ____________________________
____________________________ ____________________________
____________________________ ____________________________

We confirm the above pharmacy will be conducted in accordance with the provisions of *The Pharmaceutical Act*, other legislation and rules related to the practice of pharmacy and the provisions of and regulations made under the *Food and Drugs Act* and *Controlled Drugs and Substances Act of Canada*. We declare that neither the pharmacy manager nor the applicant owner (legal and beneficial owners, officers, directors and/partners, as applicable to the ownership for this pharmacy) have been subject to disciplinary, criminal or administrative sanctions associated with the practice of pharmacy or the operation of a pharmacy in any jurisdiction.

I grant permission for the College of Pharmacists of Manitoba to access drug wholesale records for this pharmacy.

**Signature of Pharmacy Manager** ____________________________

**Signature of CEO or Pharmacy Owner** ____________________________

**Print Name of CEO or Pharmacy Owner** ____________________________

**Date of Application** ____________________________

Page 2 of 4
Pre-Opening Inspection Fee: $852.45 + $42.62 = $895.07

Licence Fee: If licensing between January 1 & June 30:
Pharmacy Licence Fee $1,659.44 + $82.97 = $1,742.41
Pharmacy Licence Fee $1,659.44 + IPS Fee $7,518.65 + GST $458.90 = $9,636.99

Licence Fee: If licensing between July 1 & December 31:
Pharmacy Licence Fee $975.66 + $48.78 = $1,024.44
Pharmacy Licence Fee $975.66 + IPS $4,511.18 + GST $274.34 = $5,761.18

Section 1 – Must be completed by Corporations (Partnerships and Sole Proprietorships, please see Section 2 below.)

1. A copy of the Articles of Incorporation (or equivalent, if an extra-provincial corporation) for the applicant, and any amendments thereto;
2. Where the applicant is an extra-provincial corporation, a copy of the Application for Registration and Certificate of Registration showing the applicant to be registered to conduct business in Manitoba; and
3. Where the applicant intends to conduct business under a name other than its own name, a copy of the Business Name Registration, or a search (uncertified) or Certificate of Search (under \textit{The Business Names Registration Act}) for each business name confirming registration.

Identify by name(s) and address(es), the legal and beneficial ownership of the shares** in the corporation *

____________________________________________________________________________________________

____________________________________________________________________________________________

____________________________________________________________________________________________

**If any of the Shareholders of the applicant are corporations, then also provide all of the information above for any such corporate Shareholders.

Where any person is listed as an owner, or director or legal or beneficial owner of shares of the corporation applying for the licence has an interest in any other pharmacy in Canada, disclosure of the name(s) and address(es) of such pharmacy or pharmacies *

____________________________________________________________________________________________

____________________________________________________________________________________________

____________________________________________________________________________________________
Section 2 - Partnerships and Sole Proprietorships

Where the applicant intends to conduct business under a name other than its own name, a copy of the Business Name Registration, or a search (uncertified) or Certificate of Search (under The Business Names Registration Act) for each business name confirming registration.

Identify by name and addresses all of the partners*** of the partnership*:

________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

*** For Partnerships, if any of the Partners are corporations, all the information above regarding Corporations must also be provided for any such corporate Partners.

Where any person is listed as an owner, director or legal or beneficial owner of shares of the corporation applying for the licence has an interest in any other pharmacy in Canada, disclosure of the name(s) and address(es) of such pharmacy or pharmacies *

________________________________________________________________________________________
________________________________________________________________________________________

*Please attach lists as necessary
PART 7
PHARMACIES

Pharmacy licence

63 No person shall establish or operate a pharmacy except under the authority of a pharmacy licence issued under this Part for a pharmacy of that category.

Application for licence

64(1) An applicant for a pharmacy licence must, at least 30 days before the date the applicant intends to operate a pharmacy, or at such other time as may be acceptable to the registrar, file an application with the registrar for a pharmacy licence of the category of pharmacy that the applicant intends to operate, in a form and disclosing such information as may be required by the by-laws.

Contents of application

64(2) The application must include

(a) the location and work to be performed at each facility to be included under the pharmacy licence;

(b) evidence satisfactory to the registrar

(i) respecting the ownership of the pharmacy, and if the applicant is a corporation, respecting the legal and beneficial ownership of the corporation's shares, the names of the corporation's officers and directors, and confirmation that the corporation is in good standing under The Corporations Act,

(ii) that the premises are suitable for the purpose of a pharmacy, and

(iii) that a member will be physically present in the pharmacy at all times required by the standards of practice and all relevant practice directions;

(c) the name or names under which the pharmacy will conduct business, and evidence satisfactory to the registrar that the name or names will not contravene the code of ethics adopted under section 76;

(d) the name of a member who will be designated as the pharmacy manager;

(e) evidence satisfactory to the registrar that

(i) the applicant,

(ii) if the applicant is a corporation, the corporation's legal and beneficial owners, officers and directors, and

(iii) if the applicant is a partnership, its partners,

have not been subject to disciplinary, criminal or administrative sanction in any jurisdiction which, in the opinion of the registrar, would make it inappropriate for the applicant to operate a pharmacy;

(f) an undertaking that the pharmacy will be operated in accordance with this Act, the by-laws, the code of ethics, the standards of practice and all relevant practice directions; and

(g) any other information required by the regulations.

Pharmacy manager

64(3) The person designated to be the pharmacy manager under clause (2)(d) must

(a) satisfy the registrar that he or she has not been subject to disciplinary, criminal or administrative sanction in any jurisdiction which, in the opinion of the registrar, would make it inappropriate for him or her to act as a pharmacy manager;

(b) satisfy the registrar that he or she meets any other qualifications set out in the regulations; and

(c) provide the registrar with an undertaking that the pharmacy will be operated in accordance with this Act, the by-laws, the code of ethics, the standards of practice and all relevant practice directions.

Separate application for facility

64(4) An applicant must file a separate application for a separate facility that is part of the pharmacy operation, if required by the regulations.
Application by a corporation

64(5) If the applicant is a corporation, the application must set out
(a) the name and address of every director of the corporation; and
(b) the name of every director of the corporation who is a member.

Application by a partnership

64(6) If the applicant is a partnership, the application must
(a) set out the name and address of each partner, and indicate whether or not each partner is a member; and
(b) identify whether each partner is a general partner, a limited partner, or both a general and a limited partner.

Issuance of a pharmacy licence

65(1) The registrar must issue a pharmacy licence to the applicant, in a form prescribed by the by-laws, if the applicant
(a) meets all of the requirements of section 64;
(b) meets any other requirements specified in the regulations; and
(c) pays the fee provided for in the by-laws for the appropriate category of pharmacy licence.

Terms or conditions

65(2) The registrar may issue a pharmacy licence subject to any terms or conditions he or she considers advisable.

Duration

65(3) A pharmacy licence remains in force for the time prescribed in the by-laws.

Register of licensed pharmacies

65(4) The registrar must enter in the register of licensed pharmacies the name of a person to whom a licence is issued under this Part.

Application for renewal of a pharmacy licence

66(1) An owner may apply for renewal of a pharmacy licence, before the date the licence expires or such other time as may be acceptable to the registrar, by filing an application and completing the other requirements of section 64.

Renewal of a pharmacy licence

66(2) The registrar must renew a pharmacy licence if the applicant
(a) meets all of the requirements of section 64;
(b) meets any other requirements specified in the regulations; and
(c) pays the renewal fee provided for in the by-laws for the appropriate category of pharmacy licence.
Subsections 65(2) to (4) apply, with the necessary changes, to the renewal of a pharmacy licence.

Appeal

67 If the registrar refuses to issue or renew a pharmacy licence, or issues or renew a licence subject to terms or conditions, the applicant may appeal the registrar's decision, and sections 21 and 22 apply with the necessary changes.

Obligations of owner

68 The owner of a licensed pharmacy must
(a) ensure that a member is physically present in the pharmacy at all times required by the standards of practice and all relevant practice directions;
(b) ensure that the pharmacy licence, and the pharmacist licence of every member employed in the pharmacy, is displayed in a conspicuous public place in the pharmacy;
(c) notify the registrar in writing of the name of the pharmacy manager and every member, student and intern employed by the owner, and notify the registrar of any change in the employment of those persons within
seven days after the change; and
(d) comply with any other requirements specified in the regulations.

Complaints
69 A complaint against a pharmacy must be dealt with under Part 6 as a complaint against the owner or the pharmacy manager, or both.

Change in ownership of pharmacy
70 If
(a) the ownership or control of a pharmacy changes in the manner and to the extent prescribed in the regulations; or
(b) in a pharmacy owned or operated by a corporation, a majority of the shares of the corporation are sold, transferred or otherwise disposed of;
the holder of the pharmacy licence must notify the registrar within seven days after the change, and the registrar may cancel the licence and require that an application for a new pharmacy licence under this Part be made.

Carrying on business of a bankrupt person
71 An owner who becomes bankrupt or insolvent or makes an assignment for the benefit of creditors must so notify the registrar, and the trustee in bankruptcy, receiver, receiver-manager or assignee may operate the pharmacy for the purposes of the bankruptcy, insolvency or assignment if the pharmacy continues to be overseen by a pharmacy manager.

Use of titles: any retail or wholesale business
72(1) No person except an owner shall use any of the following titles in connection with a retail or wholesale business:
(a) "pharmacy" or "apothecary";
(b) "drug" or "drugs";
(c) "pharmacist", "pharmaceutical chemist", or "druggist";
or a variation or abbreviation of any of those titles, or an equivalent in another language.

Use of titles: retail or wholesale business implying that it is licensed
72(2) No person except an owner shall use any of the following titles, in connection with a retail or wholesale business, in a manner that implies that the business is licensed under this Act:
(a) "prescription", "prescriptions", or "Rx";
(b) "medicine" or "medicines";
or a variation or abbreviation of any of those titles, or an equivalent in another language.
PART 6
PHARMACY LICENCES

APPLICATION FOR PHARMACY LICENCE

Pharmacy licence application

30(1) In addition to the requirements of subsection 64(2) of the Act, an applicant for a pharmacy licence must provide the following to the registrar:

(a) confirmation that the pharmacy is located in Manitoba and, subject to section 31, the address and description of the practice of pharmacy being performed at each facility covered by the pharmacy licence;

(b) the proposed hours of operation of the pharmacy, including hours for each facility covered by the pharmacy licence;

(c) evidence of insurance if required by Part 16;

(d) evidence satisfactory to the registrar that the owner, if required by law, is registered to conduct business in Manitoba;

(e) the main Uniform Resource Locator (URL) of any website used by or affiliated with the pharmacy and access by the registrar to any website.

30(2) An applicant for a pharmacy licence must apply for one or more of the following categories of pharmacy licence:

(a) community pharmacy;

(b) hospital pharmacy;

(c) clinical practice pharmacy.

30(3) An applicant for a community pharmacy or hospital pharmacy licence must indicate whether one or more of the following additional components to the licence is being applied for:

(a) central-fill component described in section 38;

PARTIE 6
LICENCES DE PHARMACIE

DEMANDES DE LICENCE PHARMACIE

Demandes de licence de pharmacie

30(1) En plus de satisfaire aux exigences du paragraphe 64(2) de la Loi, les personnes qui demandent une licence de pharmacie doivent fournir au registraire :

a) une attestation indiquant que la pharmacie est située au Manitoba et, sous réserve de l'article 31, l'adresse de chaque établissement autorisé ainsi qu'une mention de son cadre d'exercice;

b) les heures d'ouverture envisagées, y compris celles de chaque établissement autorisé;

c) une preuve d'assurance si la partie 16 l'exige;

d) une preuve démontrant au registraire que le propriétaire est, si les règles de droit l'exigent, dûment autorisé à exploiter une entreprise au Manitoba;

e) les informations — notamment l'adresse URL principale — permettant l'accès aux sites Web dont la pharmacie se sert, seule ou avec d'autres.

30(2) La demande vise l'une ou plusieurs des catégories suivantes de licence de pharmacie :

a) pharmacie de quartier;

b) pharmacie d'hôpital;

c) pharmacie clinique.

30(3) Les auteurs de demandes de licence de pharmacie de quartier ou d'hôpital indiquent si les services suivants doivent également être autorisés :

a) services de préparation centralisée visés à l'article 38;
(b) secondary hospital component described in section 39;

(c) personal care home component described in section 40;

(d) distance care component described in section 41;

(e) external dispensing component described in section 42;

(f) satellite pharmacy described in section 43.

30(4) An applicant for a community pharmacy may also apply for a lock and leave component under section 37.

30(5) An applicant who applies for multiple categories or components of a pharmacy licence must meet the requirements of each category or component applied for.

Separate applications if different buildings

31(1) An applicant must apply for separate pharmacy licences if the facility used as a pharmacy is not contained within one building or within one building and an adjoining building.

31(2) Despite subsection (1), a separate application is not required for a facility that is not in the same or adjoining buildings if it is

(a) an external dispensing site described in section 42;

(b) a satellite facility described in section 43; or

(c) used only to store drugs or records or as a home office.

31(3) Every facility that is to be included under a pharmacy licence must be located at a fixed location, and may not be mobile or transportable unless approved by the council.

b) services en milieu hospitalier offerts directement aux patients et visés à l'article 39;

c) services destinés aux résidants de foyers de soins personnels et visés à l'article 40;

d) services à distance visés à l'article 41;

e) services de distribution externe visés à l'article 42;

f) services de pharmacie satellite visés à l'article 43.

30(4) Les auteurs de demandes de licence de pharmacie de quartier peuvent également demander d'offrir des services dans un poste de pharmacie visé à l'article 37.

30(5) Les auteurs dont les demandes de licence visent plusieurs catégories ou services de pharmacie doivent satisfaire aux exigences applicables à chacun d'entre eux.

Demandes individuelles

31(1) Les pharmacies qui se trouvent dans plusieurs bâtiments non contigus doivent faire l'objet de licences distinctes et, par conséquent, de demandes individuelles en vue de leur obtention.

31(2) Le paragraphe (1) ne s'applique pas aux pharmacies qui se trouvent dans plusieurs bâtiments non contigus dans les cas suivants :

a) il s'agit de centres de distribution externe visés à l'article 42;

b) il s'agit de pharmacies satellites visées à l'article 43;

c) les locaux servent uniquement à l'entreposage de médicaments ou de documents ou à titre de bureau à domicile.

31(3) Les licences sont délivrées uniquement à l'égard d'établissements permanents, sauf si le conseil autorise des pharmacies mobiles.
Operation restricted to licence category or component

32(1) The operation of a pharmacy must be restricted to the type of service covered by the category of licence and any components to the licence.

32(2) However, a member may provide care inconsistent with a component of their pharmacy licence if

(a) urgent and life threatening patient care is needed;

(b) the care will be provided for a period no longer than seven days; and

(c) written notice has been given to the registrar.

Inspection of newly-licensed premises

33(1) If an application for a pharmacy licence is for a location that is not currently licenced, the registrar may require the pharmacy to be inspected by an inspector appointed under Part 10 of the Act.

33(2) The applicant must provide the following to an inspector carrying out an inspection:

(a) a description of the pharmacy services to be provided by the proposed pharmacy;

(b) evidence satisfactory to the registrar that the pharmacy has the facilities, equipment, and staff required to operate the pharmacy in a safe and legal manner;

(c) a sketch of the physical layout of the proposed pharmacy;

(d) if the application includes a lock and leave component, a sketch of the larger retail operation, including a depiction of the area within which the pharmacy is to be located.

33(3) After carrying out an inspection, the inspector must report his or her findings to the registrar and the applicant.

Activités conformes et services autorisés

32(1) La pharmacie exerce ses activités conformément à sa catégorie de licence et aux services que celle-ci vise.

32(2) Les membres peuvent déroger à leur licence dans les cas suivants :

a) il s’agit d’une urgence et la vie du client est en danger;

b) les services seront offerts pendant un maximum de sept jours;

c) un avis écrit a été remis au registre.

Inspection des établissements titulaires d’une nouvelle licence

33(1) Le registraire peut exiger que les pharmacies dont les établissements ne sont pas déjà autorisés soient inspectés conformément à la partie 10 de la Loi.

33(2) Tout auteur de demande fournit à l’inspecteur :

a) des précisions sur les services de pharmacie qui seront offerts;

b) une preuve le convainquant que l’établissement dispose des installations, du matériel et du personnel nécessaires en vue d’un fonctionnement sûr et légal;

c) un croquis de l’aménagement projeté des lieux;

d) s’il a également l’intention d’ouvrir un poste de pharmacie, un croquis de l’ensemble de l’établissement de vente au détail ainsi que de l’emplacement où se trouvera la pharmacie.

33(3) Après l’inspection, l’inspecteur communique au registraire et aux auteurs de demandes ses conclusions.
CATEGORIES OF PHARMACY LICENCES

Community pharmacy licence

34(1) An applicant for a pharmacy licence must specify that the applicant is applying for a community pharmacy licence if

(a) the pharmacy will offer the retail sale of drugs to the public; and

(b) it is intended that the pharmacy will serve patients or their agents who will attend the pharmacy in person to receive their drugs.

34(2) In addition to the requirements of subsection 30(1), an applicant for a community pharmacy licence must provide evidence satisfactory to the registrar that

(a) the facility will be accessible to the public;

(b) the hours of operation will meet the needs of the community served by the pharmacy as determined by an hours-of-operation policy set by the council;

(c) the facility will be staffed and managed by members who have the requisite knowledge, skill and judgment to operate a community pharmacy; and

(d) the facility will comply with practice directions respecting community pharmacies.

Hospital pharmacy licence

35(1) An applicant for a pharmacy licence must specify that the applicant is applying for a hospital pharmacy licence if the pharmacy will be located within a hospital and serve in-patients and out-patients of the hospital.

35(2) In addition to the requirements of subsection 30(1), an applicant for a hospital pharmacy licence must provide evidence satisfactory to the registrar that

(a) the hours of operation will meet the needs of the hospital or hospitals served by the pharmacy as determined by an hours-of-operation policy set by the council;

Licence de pharmacie de quartier

34(1) La demande de licence vise l'exploitation d'une pharmacie de quartier et doit comporter une mention en ce sens si :

(a) la pharmacie vendra au détail des médicaments au public;

(b) les clients ou leurs mandataires se rendront sur place pour obtenir des services et des médicaments.

34(2) En plus de satisfaire aux exigences du paragraphe 30(1), l’auteur de la demande de licence de pharmacie de quartier doit démontrer au registraire :

(a) que le public aura accès à l’établissement;

(b) que les heures d’ouverture répondront aux besoins de la population du quartier, ceux-ci étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;

(c) que le personnel et la direction de l’établissement seront composés de membres ayant les connaissances, les compétences et le jugement nécessaires pour assurer son exploitation;

(d) que l’établissement se conformera aux directives professionnelles pertinentes.

Licence de pharmacie d’hôpital

35(1) La demande de licence vise une pharmacie d’hôpital et comporte une mention en ce sens si l’établissement se trouve dans un hôpital et offre ses services aux patients hospitalisés ou non.

35(2) En plus de satisfaire aux exigences du paragraphe 30(1), l’auteur de la demande de licence de pharmacie d’hôpital doit démontrer au registraire :

(a) que les heures d’ouverture répondront aux besoins de l’hôpital ou des hôpitaux qui font affaire avec elle, ces besoins étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;
(b) the facility will comply with the practice directions for a hospital pharmacy; and

(c) the facility will be staffed and managed by members who have the knowledge, skill and judgment to operate a hospital pharmacy.

Clinical practice pharmacy licence

36(1) An applicant for a pharmacy licence must specify that the applicant is applying for a clinical practice pharmacy licence if

(a) the pharmacist or pharmacy will not dispense, prepare for dispensing or sell drugs or products

(i) that are listed in the Manual, or

(ii) for which a drug identification number or natural health product number has been issued under the Food and Drugs Act (Canada); and

(b) either

(i) the pharmacist will provide care to patients and advise health care professionals about enhancing patient care, or

(ii) the use of the pharmacy is for the sole purpose of training and educating pharmacy personnel.

36(2) An applicant for a clinical practice pharmacy licence must provide evidence satisfactory to the registrar that

(a) the hours of operation will meet the needs of the persons served by the pharmacy as determined by an hours-of-operation policy set by the council;

(b) the facility will be staffed and managed by members who have the requisite knowledge, skill and judgment to operate a clinical practice pharmacy; and

(c) the facility will comply with practice directions respecting a clinical practice pharmacy.

Licence de pharmacie clinique

36(1) La demande de licence vise une pharmacie clinique et comporte une mention en ce sens si les exigences indiquées à l’alinéa a) ou b) sont remplies :

a) la pharmacie ou le pharmacien ne fourniront ni ne vendront un médicament ou un produit indiqués dans le manuel ou une drogue ou un produit de santé naturel comportant respectivement, en vertu de la Loi sur les aliments et drogues (Canada), une identification numérique ou un numéro d’identification et ne prépareront pas d’ordonnance avec ceux-ci;

b) selon le cas :

(i) le pharmacien offrira des soins aux clients et conseillera les professionnels de la santé sur l’amélioration de ces soins,

(ii) l’établissement servira uniquement à la formation du personnel en pharmacie.

36(2) L’auteur de la demande de licence de pharmacie clinique doit démontrer au registraire :

a) que les heures d’ouverture conviennent aux besoins des utilisateurs de l’établissement, ces besoins étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;

b) que le personnel et la direction de l’établissement seront composés de membres ayant les connaissances, les compétences et le jugement nécessaires pour assurer son fonctionnement;

c) que l’établissement se conformera aux directives professionnelles pertinentes.
COMPONENTS OF COMMUNITY AND
HOSPITAL PHARMACY LICENCES

Lock and leave component

Application for lock and leave component
37(1) An applicant for a community pharmacy licence may apply for a lock and leave component if
(a) the pharmacy is located within a larger operation; and
(b) the applicant intends to close off the dispensary and the public access to drugs listed on Schedule 3 of the Manual when the larger retail operation remains open.

37(2) In addition to the requirements for a community pharmacy licence, an applicant for a lock and leave component must provide evidence satisfactory to the registrar that
(a) the lock and leave component will be open at least 25 hours over a minimum of four days per week, unless the applicant can demonstrate to the council that fewer hours will meet the needs of the community and that a member will be available to respond to patients at least 37.5 hours per week;
(b) the lock and leave component will be secure when not in operation and, in particular, that
(i) the dispensary will be secured and drugs listed on Schedule 3 of the Manual will not be available for sale, and
(ii) no person other than a member or a pharmacy technician will be able to enter the dispensary or access drugs listed on Schedule 3 of the Manual;
(c) the facility will comply with the practice directions for a lock and leave component.

SERVICES AUTORISÉS DANS LES
PHARMACIES DE QUARTIER ET LES
PHARMACIES D'HÔPITAUX

Postes de pharmacie

Demande visant un poste de pharmacie
37(1) Tout auteur de demande de licence de pharmacie de quartier qui satisfait aux exigences indiquées ci-dessous peut également solliciter une autorisation visant un poste de pharmacie :
(a) la pharmacie est située dans un établissement plus grand;
(b) en cas de besoin de fermer l'officine pendant l'ouverture de l'établissement, l'auteur a l'intention de veiller à ce qu'elle soit sous clé et que l'accès aux médicaments indiqués à l'annexe 3 du manuel soit par conséquent interdit.

37(2) En plus de satisfaire aux exigences concernant les licences de pharmacie de quartier, toute personne désirant obtenir un poste de pharmacie doit démontrer au registraire :
(a) que le poste sera ouvert chaque semaine pendant un minimum de 25 heures réparties sur une période de 4 jours, sauf si elle prouve au conseil que les besoins horaires de la clientèle sont inférieurs et qu'un membre offrira chaque semaine ses services aux clients pendant au moins 37,5 heures;
(b) que le poste sera bien mis sous clé pendant sa fermeture et notamment :
(i) qu'il sera impossible d'avoir accès à l'officine et de vendre les médicaments indiqués à l'annexe 3 du manuel,
(ii) que seuls un membre ou un préparateur pourront pénétrer dans l'officine ou avoir accès aux médicaments en question;
(c) que l'établissement se conformera aux directives professionnelles pertinentes.
**Central-fill component**

**38(1)** An applicant for a community pharmacy or hospital pharmacy licence must apply for a central-fill component if the pharmacy will store and prepare drugs for dispensing for other pharmacies.

**38(2)** An applicant for a central-fill component must provide evidence satisfactory to the registrar that

(a) the hours of operation will meet the needs of the pharmacies served by the central-fill pharmacy;

(b) the central-fill pharmacy will not interact directly with patients for whom prescription services are provided;

(c) the central-fill pharmacy has a quality assurance program relating to work performed at the facility and the pharmacies to which it provides services; and

(d) the facility will comply with the practice directions for a central-fill pharmacy.

**38(3)** Unless a drug is being dispensed for a hospital, a pharmacy that uses the services of another pharmacy with a central-fill component must, before dispensing the drug, inform the patient that

(a) the drug will be prepared for dispensing at another facility; and

(b) the name of the central-fill pharmacy.

---

**Services de préparation centralisée**

**38(1)** L’auteur d’une demande de licence de pharmacie de quartier ou d’hôpital qui a l’intention d’entreposer des médicaments pour d’autres établissements ou de préparer des ordonnances pour eux doit également solliciter une autorisation à cet égard.

**38(2)** La personne qui sollicite l’autorisation en question doit démontrer au registraire :

a) que les heures d’ouverture répondent aux besoins des pharmacies faisant partie de la clientèle;

b) que le personnel offrant les services n’aura pas de rapports directs avec les clients qui recevront les ordonnances;

c) que des programmes d’assurance de la qualité ont été mis en place à l’égard de ses propres services et de ceux qu’offrent ses clients;

d) que l’établissement se conformera aux directives professionnelles pertinentes.

**38(3)** Toute pharmacie qui fait appel à une autre pharmacie offrant des services de préparation centralisée est tenue, avant de fournir les médicaments au client, de lui indiquer que la préparation de l’ordonnance aura lieu dans un autre établissement ainsi que le nom des services en question. Le présent paragraphe ne s’applique pas aux médicaments fournis à un hôpital.
Secondary hospital services component

39(1) An applicant for a community pharmacy or hospital pharmacy licence must apply for a secondary hospital services component if the facility will provide pharmacy services for hospital patients.

39(2) An applicant for a secondary hospital services component must provide evidence satisfactory to the registrar that

(a) the hours of operation will meet the needs of the hospital or hospitals served by the pharmacy as determined by an hours-of-operation policy set by the council; and

(b) the facility will comply with practice directions respecting secondary hospital services.

Personal care home component

40(1) An applicant for a community pharmacy licence or hospital pharmacy licence must apply for a personal care home component if the pharmacy will serve residents of a personal care home.

40(2) An applicant for a personal care home component must provide evidence satisfactory to the registrar that

(a) the facility will be staffed and managed by members with the requisite knowledge, skill and judgment to serve residents of a personal care home;

(b) the hours of operation will meet the needs of the personal care home served by the pharmacy as determined by an hours-of-operation policy set by the council; and

Services en milieu hospitalier offerts directement aux patients

39(1) L’auteur d’une demande de licence de pharmacie de quartier ou d’hôpital qui a l’intention d’offrir, en milieu hospitalier, des services aux patients, doit également solliciter une autorisation à l’égard de ces services.

39(2) La personne qui sollicite l’autorisation en question doit démontrer au registraire :

a) que les heures d’ouverture répondent aux besoins des hôpitaux faisant partie de la clientèle, ces besoins étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;

b) que l’établissement se conformera aux directives professionnelles pertinentes.

Services destinés aux résidants de foyers de soins personnels

40(1) L’auteur d’une demande de licence de pharmacie de quartier ou d’hôpital qui a l’intention d’offrir des services aux résidants de foyers de soins personnels doit également solliciter une autorisation à cet égard.

40(2) L’auteur qui sollicite l’autorisation en question doit démontrer au registraire :

a) que le personnel et la direction de l’établissement seront composés de membres ayant les connaissances, les compétences et le jugement nécessaires pour offrir des services aux résidants des foyers;

b) que les heures d’ouverture conviennent aux besoins des résidants, ces besoins étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;
(c) the facility will comply with practice directions respecting servicing a personal care home facility.

c) que l’établissement se conformera aux directives professionnelles pertinentes.

**Distance care component**

**Distance care component**

**41(1)** An applicant for a community pharmacy or hospital pharmacy licence must apply for a distance care component if it is intended that the pharmacy will also serve patients who do not reside in Manitoba and who will not attend the pharmacy in person.

**41(2)** An applicant for a distance care component must provide evidence satisfactory to the registrar that

(a) the pharmacy will be open at least 25 hours over a minimum of four days per week;

(b) the pharmacy can be contacted by distant patients with reasonable ease and without charge for the contact;

(c) a member will be available to respond to contacts from distant patients at least 37.5 hours per week;

(d) subject to any regulation made under clause 73(2)(c) of the Act, if the pharmacy serves patients described in subsection (1) who reside outside Canada, the pharmacy must post on any website home page maintained by the pharmacy, and include in any patient care agreement or bulletin for the solicitation of business, a disclaimer approved by the council; and

(e) the facility will comply with the practice directions respecting distance care pharmacies.

**Services à distance**

**Services à distance**

**41(1)** L’auteur d’une demande de licence de pharmacie de quartier ou d’hôpital qui a l’intention d’offrir des services à distance à des clients qui n’habitent pas au Manitoba et ne se rendront donc pas sur place pour obtenir ces services doit également solliciter une autorisation à cet égard.

**41(2)** L’auteur qui sollicite l’autorisation en question doit démontrer au registraire :

a) que la pharmacie sera ouverte pendant un minimum de 25 heures sur une période hebdomadaire d’au moins 4 jours;

b) que les clients à distance pourront communiquer avec la pharmacie gratuitement et facilement;

c) qu’un membre offrira ses services pendant au moins 37.5 heures par semaine pour donner suite aux demandes des clients à distance;

d) sous réserve des règlements pris en vertu de l’alinéa 73(2)c) de la *Loi* et si la pharmacie compte parmi ses clients visés au paragraphe (1) des personnes qui résident à l’extérieur du Canada, que l’établissement affichera sur sa page d’accueil et dans tout document de prospection ou convention de services un avertissement approuvé par le conseil;

e) que l’établissement se conformera aux directives professionnelles pertinentes.
External dispensing component

External dispensing component
42(1) The following definitions apply in this section.

"external dispensing site" means a place where drugs or medications are stored, prepared and packaged and then dispensed directly to patients. Such a site is either staffed by a pharmacy technician or consists only of a mechanical automated dispensing system. (« centre de distribution externe »)

"main pharmacy" means a community pharmacy or hospital pharmacy licensed under this Part that wishes to operate an external dispensing site. (« emplacement principal »)

42(2) An applicant for a community pharmacy or hospital pharmacy licence must apply for an external dispensing component if the pharmacy will operate an external dispensing site.

42(3) An applicant for an external dispensing component must provide evidence satisfactory to the registrar that

(a) the external dispensing site will be located in a Manitoba community that does not have reasonable access to pharmacy services as determined by a policy set by the council;

(b) the technology and equipment of the external dispensing site will comply with any practice directions respecting external dispensing;

(c) the hours of operation of the external dispensing site will meet the needs of the community in which it is located as determined by an hours-of-operation policy set by the council;

(d) the external dispensing site will meet the physical requirement set out in the standards of practice;

(e) a member will conduct an on-site inspection of the external dispensing site at least once every two months and in compliance with any applicable practice directions;

Services de distribution externe

Services de distribution externe
42(1) Les définitions qui suivent s'appliquent au présent article.

« centre de distribution externe » Endroit où des médicaments sont entreposés, préparés et emballés puis distribués directement aux clients. Sauf dans les cas où il s'agit d'un appareil distributeur automatique, le centre compte un préparateur parmi son personnel. ("external dispensing site")

« emplacement principal » Pharmacie de quartier ou pharmacie d'hôpital qui est autorisée sous le régime de la présente partie et qui désire ouvrir un centre de distribution externe. ("main pharmacy")

42(2) L'auteur d'une demande de licence de pharmacie de quartier ou d'hôpital qui a l'intention d'ouvrir un centre de distribution externe doit également solliciter une autorisation à cet égard.

42(3) L'auteur qui sollicite l'autorisation en question doit démontrer au registraire :

a) que le centre de distribution externe se trouvera dans une localité de la province où les services de pharmacie sont insuffisants selon la directive adoptée par le conseil à cet égard;

b) que la technologie et le matériel du centre seront conformes aux directives professionnelles concernant la distribution externe;

c) que les heures d'ouverture du centre répondront aux besoins de la population de la localité, ceux-ci étant établis conformément aux exigences de la directive adoptée par le conseil à cet égard;

d) que l'aménagement physique du centre sera conforme aux directives professionnelles;

e) que le membre procédera sur place, au moins tous les deux mois, à la vérification du centre selon les directives professionnelles;
(f) the external dispensing site will be linked to the main pharmacy by computer and by a live two-way video and audio telecommunication link, so that patients and health care professionals can communicate with a member at the main pharmacy, and supervision can be provided to any pharmacy technician at the external dispensing site;

(g) the external dispensing site will not be open when the main pharmacy is not, unless the external dispensing site is an automated dispensing system, in which case a member at the main pharmacy must be accessible to patients using a video and audio telecommunication link described in clause (f);

(h) the main pharmacy must be accessible to the patients serviced by the external dispensing site at least 37.5 hours per week, contact information must be well publicized, and patients must be able to contact the main pharmacy without charge for the contact;

(i) no medication covered by the M3P program is stored or dispensed from the external dispensing site; and

(j) the external dispensing site and the main pharmacy must have a policy and procedure manual available setting out the following:

(i) the records that must be kept,

(ii) the requirement that standards of practice and practice directions regarding patient counselling must be complied with,

(iii) the procedures with respect to performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling before dispensing,

(iv) the requirement that a pharmacist be involved in the sale of non-prescription scheduled drugs.

(f) que le centre sera relié à l'emplacement principal au moyen d'un ordinateur et d'un système de communication audiovisuel bidirectionnel qui permettront, d'une part, aux clients et aux professionnels de la santé d'échanger avec un membre se trouvant à cet emplacement et, d'autre part, de surveiller les préparateurs du centre de distribution externe;

(g) que le centre de distribution externe et l'emplacement principal seront tous deux ouverts en même temps, sauf si le centre est automatisé, auquel cas le système visé à l’alinéa f) doit permettre aux clients de communiquer avec le membre;

(h) que les clients du centre peuvent communiquer gratuitement avec l'emplacement principal pendant au moins 37,5 heures par semaine et que les renseignements sur la façon d’entrer en communication sont clairement diffusés;

(i) qu’aucun médicament visé par le Programme n’est entreposé dans le centre ni fourni depuis celui-ci;

(j) que le centre et l’établissement principal se sont dotés d’un guide faisant état :

(i) des documents qui doivent être conservés,

(ii) de l’obligation incombant aux personnes qui donnent des conseils à la clientèle de respecter les normes et les directives professionnelles applicables à cet égard,

(iii) de la procédure applicable au moment du contrôle final permettant de vérifier que les médicaments sont bien emballés ou réemballés, placés dans le bon contenant et bien étiquetés,

(iv) de l’obligation incombant aux pharmaciens de se charger de la vente de médicaments sans ordonnance qui figurent dans le manuel.
Satellite pharmacy component

Requirements for satellite pharmacy component

43(1) An applicant for a satellite pharmacy component must provide evidence satisfactory to the registrar that

(a) the satellite facility will be located in a Manitoba community that does not have reasonable access to pharmacy services as determined by a policy set by the council;

(b) the satellite facility and equipment will be suitable to meet the needs of the care provided;

(c) non-medicinal products or non-medical devices will not be sold;

(d) the satellite pharmacy computer will be linked to the primary pharmacy computer that has access to DPIN;

(e) a member will be on-site during all hours of operation;

(f) drugs will not be left on-site when the satellite is not open;

(g) the telephone number and address of the primary pharmacy will be identified on all printed materials and prescription labels.

43(2) An application under subsection (1) must also describe

(a) the needs of the community;

(b) the collaborative practice, in which at least one other health care professional in the practice is a physician or a registered nurse (extended practice), that will occur; and

(c) the location, suitability for the practice of pharmacy and the hours of operation.

Services de pharmacie satellite

Services de pharmacie satellite

43(1) L’auteur qui sollicite une autorisation à l’égard de services de pharmacie satellite doit démontrer au registraire :

a) que la pharmacie satellite se trouvera dans une localité de la province où les services de pharmacie sont insuffisants selon la directive adoptée par le conseil à cet égard;

b) que la pharmacie satellite et son matériel permettront de répondre aux besoins de la clientèle;

c) que seuls des produits médicinaux et du matériel médical y seront vendus;

d) que l’ordinateur de la pharmacie satellite sera relié à celui de l’établissement principal ayant accès au Réseau;

e) qu’un membre sera toujours sur place pendant les heures d’ouverture;

f) que les médicaments seront retirés des lieux pendant les heures de fermeture;

g) que le numéro de téléphone et l’adresse de l’établissement principal seront indiqués sur tous les imprimés et les étiquettes d’ordonnance.

43(2) La demande visée au paragraphe (1) comporte également des renseignements au sujet des éléments suivants :

a) les besoins de la localité;

b) le mode d’exercice interprofessionnel qui sera utilisé, étant entendu qu’au moins un médecin ou une infirmière ayant un champ d’exercice élargi fera partie du personnel;

c) l’emplacement de la pharmacie, le caractère approprié de celui-ci pour l’exercice de la profession et les heures d’ouverture.
LICENCE RENEWALS

Renewal of pharmacy licence

44 A pharmacy licence may be renewed upon the applicant meeting the requirements of section 66 of the Act and confirming, in a manner acceptable to the registrar, that no changes have occurred in the premises, operation or ownership of the pharmacy that would affect the existing licence.

CHANGES IN PHARMACY OPERATION OR OWNERSHIP

If pharmacy closes

45(1) If a pharmacy ceases to operate for any reason, it is the joint responsibility of the owner and the pharmacy manager to

(a) advise the registrar in writing as to where the records required to be maintained under the Act and this regulation will be located;

(b) arrange for the secure storage of the records for the retention period required under section 79 and ensure that patients are able to access their records during that period in accordance with The Personal Health Information Act;

(c) surrender the pharmacy licence to the registrar for cancellation;

(d) dispose of all drugs in a manner permitted by law;

(e) remove, cancel or recall any signs and advertising indicating that a pharmacy is being operated at the location;

RENOUNVELLEMENT DES LICENCES

Renouvellement de la licence de pharmacie

44 Les auteurs qui satisfont aux exigences de l'article 66 de la Loi et qui démontrent de manière convaincante au registraire que les locaux, le fonctionnement ou les droits de propriété n’ont fait l’objet d’aucun changement qui aurait une incidence sur les licences de pharmacie peuvent les faire renouveler.

CHANGEMENT AU CHAPITRE DU FONCTIONNEMENT OU DES DROITS DE PROPRIÉTÉ

Fermeture de la pharmacie

45(1) Si la pharmacie met fin à ses activités pour quelque raison que ce soit, il incombe à son propriétaire et à son gérant de prendre conjointement les mesures suivantes :

(a) informer par écrit le registraire de l’endroit où se trouveront les documents devant être tenus sous le régime de la Loi et du présent règlement;

(b) veiller à ce que les documents soient conservés en sécurité pendant le délai de garde visé à l’article 79 et à ce que les clients puissent y avoir accès pendant cette période conformément à la Loi sur les renseignements médicaux personnels;

(c) remettre la licence au registraire en vue de son annulation;

(d) se départir des médicaments conformément aux règles de droit;

(e) enlever, annuler ou retirer les affiches et la publicité indiquant qu’une pharmacie exerce des activités;
(f) at least 30 days before ceasing operation if reasonably possible, and in accordance with practice directions, inform patients of the closure and

(i) provide them with the name and contact information of the pharmacy where patient prescription records are to be transferred, as long as the patient does not advise the pharmacy otherwise, and

(ii) inform them that a patient who does not wish their prescription record transferred to the pharmacy mentioned in the notice may require a transfer to another pharmacy specified by the patient;

(g) provide a copy of the notice under clause (f) to the registrar.

45(2) The owner or pharmacy manager must comply with clauses (1)(a) to (e) within seven days of the operation ceasing. But with respect to clause 1(d), the registrar may approve an extension of the seven-day period.

45(3) If a pharmacy ceases operation temporarily, the owner or pharmacy manager must notify the registrar in accordance with practice directions of

(a) the nature of the closure; and

(b) the arrangements that have been made to ensure continuing patient care during the closure.

Ownership changes that may result in licence cancellation

46 The following are changes for the purpose of section 70 of the Act:

(a) in the case of a pharmacy owned by a corporation, any disciplinary, criminal or administrative sanction against a legal or beneficial owner, officer or director of the corporation such that clause 64(2)(e) of the Act is no longer met:

46(2) Le propriétaire ou le gérant de la pharmacie se conforment aux alinéas (1)a) à e) dans les sept jours suivant la cessation des activités. Le registraire peut toutefois autoriser une prorogation du délai accordé pour la prise de la mesure visée à l’alinéa (1)d).

45(3) Si la cessation des activités est temporaire, le propriétaire ou le gérant de la pharmacie avise le registraire de ce qui suit conformément aux directives professionnelles :

(a) la nature de la fermeture;

(b) les mesures prises pour assurer le service à la clientèle pendant la fermeture.

Motifs d’annulation de la licence

46 Les mesures prévues à l’article 70 de la Loi s’appliquent dans les cas suivants :

(a) si une corporation est propriétaire de la pharmacie, ses dirigeants ou administrateurs ou le propriétaire en common law ou le propriétaire bénéficiaire de ses actions ont fait l’objet de sanctions disciplinaires, pénales ou administratives, lesquelles ont entraîné le non-respect des exigences prévues à l’alinéa 64(2) e) de la Loi:
(b) in the case of a pharmacy owned by a partnership, any disciplinary, criminal or administrative sanction against a partner such that clause 64(2)(e) of the Act is no longer met.

Changes about which the registrar must be notified

47(1) If the owner of a pharmacy is a corporation, the owner must advise the registrar of any change

(a) in the directors of the corporation; or

(b) of the ownership of 50% or more of the voting shares of the corporation.

If the requirements of section 64 of the Act and of this Part continue to be met, the licence is unaffected.

47(2) If the owner of a pharmacy is a partnership, the owner must advise the registrar of any change in the members of the partnership, or of the general or limited partnership, or of the managing partner. If the requirements of sections 64 of the Act and of this Part continue to be met, the licence is unaffected.

47(3) If the pharmacy manager changes, the owner must advise the registrar of the change and surrender the pharmacy licence to the registrar. Upon payment of the fee prescribed in the by-laws, the registrar must issue a new licence to the owner unless the owner no longer meets the requirements of section 64 of the Act or of this Part.

47(4) If the name of the owner changes, or the name or names under which the pharmacy conducts business changes, the owner must advise the registrar of the change and surrender the pharmacy licence to the registrar. Upon payment of the fee prescribed in the by-laws, the registrar must issue a new licence to the owner, unless the owner no longer meets the requirements of section 64 of the Act or of this Part.

Obligation d’aviser le registraire

47(1) La corporation qui est propriétaire d’une pharmacie est tenue d’aviser le registraire de tout changement concernant ses administrateurs ou les détenteurs d’au moins 50 % de ses actions avec droit de vote. La licence demeure valide si les exigences de l’article 64 de la Loi et de la présente partie sont respectées.

47(2) La société en nom collectif qui est propriétaire d’une pharmacie est tenue d’aviser le registraire de tout changement concernant ses associés, ses commandités, ses commanditaires ou son associé directeur. La licence demeure valide si les exigences de l’article 64 de la Loi et de la présente partie sont respectées.

47(3) Le propriétaire d’une pharmacie dont le gérant quitte ses fonctions est tenu d’en aviser le registraire et de lui remettre la licence de son établissement. Sur versement des droits fixés par règlement administratif, le registraire délivre une nouvelle licence au propriétaire s’il satisfait toujours aux exigences de l’article 64 de la Loi ou de la présente partie.

47(4) En cas de changement de nom du propriétaire ou de nom commercial d’une pharmacie, le propriétaire en avise le registraire et lui remet sa licence. Sur versement des droits fixés par règlement administratif, le registraire délivre une nouvelle licence au propriétaire concerné s’il satisfait toujours aux exigences de l’article 64 de la Loi ou de la présente partie.
47(5) If a pharmacy moves, or if the premises from which the pharmacy operates are renovated or changed in a substantial way, the owner must advise the registrar of the change, and the registrar may require the owner to surrender the pharmacy licence. Upon payment of the fee prescribed in the by-laws and a pre-opening inspection under section 33, the registrar must issue a new licence to the owner unless the owner no longer meets the requirements of section 64 of the Act or of this Part.

47(6) When an owner is required to advise the registrar about a change under this section, notice must be given to the registrar within seven days of the change, except that 30 days advance notice is required under subsection (4).

Change of hours

48 If a pharmacy changes its hours of operation, the pharmacy manager or owner must immediately advise the registrar of the change, and the registrar must note the change in the college records.

Converting licence category or component

49(1) If the owner of a pharmacy intends to change the operation in a manner that would require a licence of a different or additional category or component, the owner must, at least 30 days before the anticipated change, must apply for a new licence in accordance with this Part.

49(2) If the applicant

(a) meets all of the requirements for the issuance of a licence of each requested category or component; and

(b) pays the fee specified in the by-laws;

the registrar must issue a new pharmacy licence of the appropriate category and components.

47(5) Le propriétaire d’une pharmacie qui déménage ou dont les locaux font l’objet de rénovations ou de modifications importantes est tenu d’en aviser le registraire et, si celui-ci l’exige, de lui remettre sa licence. Sur versement des droits fixés par règlement administratif et à la suite de l’inspection visée à l’article 33, le registraire délivre une nouvelle licence au propriétaire s’il satisfait toujours aux exigences de l’article 64 de la Loi ou de la présente partie.

47(6) Les avis exigés en application du présent article sont donnés dans les 7 jours suivant la survenance de l’événement en question, sauf dans le cas visé au paragraphe (4), où le préavis est de 30 jours.

Modification des heures d’ouverture

48 Le gérant ou le propriétaire d’une pharmacie qui change ses heures d’ouverture en avise sans tarder le registraire. Celui-ci consigne les renseignements dans les registres de l’Ordre.

Modification de la catégorie de la licence ou des services autorisés

49(1) Le propriétaire qui a l’intention de modifier le fonctionnement de sa pharmacie et qui, de ce fait, doit être titulaire d’une licence autorisant une catégorie d’établissement ou des services différents ou supplémentaires donne un préavis d’au moins 30 jours au registraire et demande une nouvelle licence conformément à la présente partie.

49(2) Le registraire est tenu de délivrer une nouvelle licence de pharmacie de la catégorie voulue et autorisant les services demandés si l’auteur :

a) satisfait à toutes les exigences prévues;

b) verse les droits que prévoient les règlements administratifs.
Converting licence category or component — extenuating circumstances
50(1) Despite any other provision of this regulation, if, because of extenuating circumstances, the owner of a pharmacy wishes to operate temporarily in a manner that would require a pharmacy licence of a different category or component but is unable to give the 30-day notice required by section 49, the owner must

(a) complete the application form approved by the council;

(b) advise the registrar of the nature of the operation intended to be conducted;

(c) provide evidence satisfactory to the registrar that the owner's temporary operation will not place patient safety at risk; and

(d) pay the fee specified in the by-laws.

50(2) The registrar may approve an application under subsection (1) if he or she is satisfied that doing so is necessary to meet the needs of the community. The approval may be for a period of not more than three months, with or without conditions.

GENERAL REQUIREMENTS

Pharmacy manager requirements
51 In addition to the requirements of subsection 64(3) of the Act, a pharmacy manager must

(a) be a member;

(b) not be a pharmacy manager at more than one pharmacy, unless approved by the council; and

(c) demonstrate to the registrar's satisfaction that he or she will personally and adequately supervise the operation of the pharmacy.

Circonstances atténuantes en cas de modification de la catégorie de la licence ou des services autorisés
50(1) Malgré les autres dispositions du présent règlement, le propriétaire d'une pharmacie qui désire en modifier temporairement le fonctionnement et qui, de ce fait, doit être titulaire d'une licence autorisant une catégorie d'établissement ou des services différents, mais qui ne peut donner le préavis indiqué à l'article 49 est tenu de se conformer aux exigences suivantes :

a) remplir la formule de demande que prévoient les règlements administratifs;

b) informer le registraire de la nature des activités qu'il envisage;

c) convaincre le registraire que les activités temporaires seront sûres pour la clientèle;

d) verser les droits que prévoient les règlements administratifs.

50(2) Le registraire approuve la demande s'il est convaincu qu'il doit le faire pour répondre aux besoins de la population. L'autorisation est valide pendant un maximum de trois mois et peut être assortie de conditions.

EXIGENCES GÉNÉRALES

Exigences applicables aux gérants de pharmacie
51 En plus de satisfaire aux exigences du paragraphe 64(3) de la Loi, les gérants de pharmacie doivent :

a) être membres de l'Ordre;

b) exercer leurs fonctions dans un seul établissement, sauf autorisation contraire du conseil;

c) démontrer au registraire qu'ils surveilleront personnellement et correctement les activités de l'établissement.

46
Accurate disclosure
52 An applicant for a pharmacy licence must provide information that is truthful and accurate to the best of the applicant's knowledge and, after a licence is issued, must update the information if it changes during the duration of the licence.

Safe use of automation
53 A pharmacy manager must take reasonable steps to ensure that any automated or computerized system used in prescription filling processes in the pharmacy, or any component of the pharmacy, are in good working order and perform their intended tasks in a safe, secure and appropriate manner.

Permitted business names for pharmacies
54 A pharmacy must conduct business
(a) under a single business name, unless otherwise approved by the council; and
(b) only under a business name registered to the owner for use in Manitoba under The Business Names Registration Act, or under a valid franchise or use agreement.

Licence must be displayed
55 A pharmacy must display its pharmacy licence in a location visible to the public at each facility included under the pharmacy licence.

Exactitude des renseignements
52 Les auteurs de demandes de licence fournissent au registraire des renseignements qui, à leur connaissance, sont exacts et les mettent à jour s'il y a lieu au cours de la période de validité de la licence.

Usage sûr des systèmes automatisés ou informatiques
53 Les gérants de pharmacie prennent les mesures voulues pour que les systèmes automatisés ou informatiques servant à remplir les ordonnances ou à offrir des services soient en bon état et fonctionnent de manière sûre et appropriée.

Noms commerciaux autorisés
54 Les pharmacies exercent leurs activités :

a) sous un seul nom commercial, sauf autorisation contraire du conseil;

b) sous un nom commercial enregistré par le propriétaire pour usage au Manitoba sous le régime de la Loi sur l’enregistrement des noms commerciaux ou conformément à un contrat de franchisage ou à un accord d’utilisation du nom valide.

Affichage de la licence
55 La licence de pharmacie doit être affichée à un endroit bien en vue dans chaque établissement autorisé.
PART 7
STANDARDS OF PRACTICE

Standards of practice

56(1) The following standards of practice are established:

1. **Patient counselling**
   Each time a drug is dispensed pursuant to a prescription, a member must provide the patient with sufficient information to enable the patient to safely and effectively manage his or her drug therapy.

2. **Referring a patient**
   A member must refer the patient to another appropriately qualified regulated health professional when
   
   (a) the care or treatment required by the patient is beyond the scope of the member’s professional practice or competence;

   (b) the patient’s condition cannot be effectively treated within the practice of pharmacy; or

   (c) the patient’s condition has not adequately or appropriately responded to drug therapy or other therapy provided by the member.

3. **Collaborative care**
   A member must work collaboratively with other health care professionals and others who provide care to the patient, as circumstances require, in order to provide integrated care and avoid duplication of services.

   When a member and one or more other persons are providing care to a patient, the member must

   (a) treat the other provider with respect;

PARTIE 7
NORMES PROFESSIONNELLES

Normes professionnelles

56(1) Les normes professionnelles qui suivent sont adoptées :

1. **Conseils à la clientèle**
   Chaque fois qu’un médicament est fourni selon une ordonnance, les membres communiquent aux clients tous les renseignements dont ils ont besoin pour suivre leur pharmacothérapie de manière sûre et efficace.

2. **Obligation de diriger le client vers un autre professionnel**
   Les membres sont tenus de diriger un client vers un autre professionnel compétent exerçant une profession de la santé réglementée dans les cas suivants :

   a) les soins ou le traitement dont le client a besoin ne relèvent pas de leur champ d’exercice ou dépassent leurs compétences;

   b) les services offerts dans le cadre de l’exercice de la pharmacie ne conviennent pas en vue du traitement efficace du trouble du client;

   c) la pharmacothérapie ou le traitement offert n’a pas été efficace.

3. **Collaboration**
   Les membres sont tenus de travailler en collaboration avec les autres personnes qui dispensent des soins aux clients, notamment les autres professionnels de la santé, afin d’offrir des services coordonnés et d’éviter le double emploi.

   Les membres qui offrent leurs services de concert avec d’autres personnes doivent respecter les consignes suivantes :

   a) traiter ces autres personnes avec respect;
(b) recognize the skills, knowledge, competencies and roles of the other provider, and communicate effectively and appropriately with them; and

(c) explain to the patient the member’s role and responsibility.

4. **Prescribing and dispensing drugs**
   A member who prescribes a drug must provide a written prescription to the patient and advise the patient that he or she may choose to have the prescription dispensed at another pharmacy or by the prescribing member.

5. **Administration of drugs**
   A member who administers a drug to a patient must
   
   (a) do so only with the patient’s authorization;

   (b) have policies and procedures in place respecting the administration of drugs and be prepared to immediately respond in emergencies, like anaphylaxis; and

   (c) only administer a drug if the pharmacy has facilities that are appropriate for the administration.

6. **Drug distribution**
   A member must comply with the conditions of sale for all prescription and non-prescription drugs, in accordance with applicable legislation, to ensure the safety and quality of drugs being distributed.

7. **Test interpretation**
   A member must interpret a patient-administered automated test in a competent and accurate manner.

8. **Extemporaneous compounding**
   A member must ensure that extemporaneous compounding is done in a manner that ensures the preparation is safe and of an appropriate consistency and quality.

b) reconnaître les compétences et les connaissances de ces personnes, comprendre leur rôle et communiquer de manière efficace et appropriée avec eux;

c) expliquer aux clients en quoi consiste leurs propres responsabilités et rôle.

4. **Prescription et fourniture de médicaments**
   Les membres qui prescrivent un médicament à un client doivent lui remettre une ordonnance écrite et lui indiquer qu’il peut, s’il le désire, faire exécuter l’ordonnance dans une autre pharmacie.

5. **Administration de médicaments**
   Les membres peuvent administrer un médicament à un client seulement si les conditions suivantes sont réunies :

   a) le client a accordé son consentement;

   b) ils ont adopté des lignes directrices régissant cette activité et sont en mesure de faire face sur-le-champ aux urgences, notamment les cas d’anaphylaxie;

   c) la pharmacie dispose des installations nécessaires à cette fin.

6. **Distribution de médicaments**
   Les membres doivent se conformer aux dispositions législatives régissant la vente de médicaments, délivrés sur ordonnance ou non, de manière à ce que seuls des médicaments sûrs et de qualité soient offerts.

7. **Interprétation des résultats d’épreuves**
   Les membres sont tenus d’analyser avec rigueur et compétence les résultats des épreuves que les clients s’auto-administent.

8. **Médicaments préparés extemporanément**
   Les membres veillent à ce que les médicaments qu’ils préparent extemporanément soient sûrs, de qualité et aient la consistance voulue.
9. Incidents and discrepancies
A member must expeditiously address, document and report incidents, discrepancies and adverse events in dispensing drugs and in providing patient care.

10. Transfer of patient care
If a patient or his or her authorized representative requests that the patient’s care be transferred to another member or to another health care professional, the member must ensure that a copy of the information specified by the patient is provided to the pharmacy or health professional specified by the patient as promptly as the circumstances require.

11. Termination of relationship with patient
A member who terminates a relationship with a patient must have reasonable grounds for doing so and document those reasons on the patient record.

The member must give the patient notice of the intention to terminate care and provide such notice as is commensurate with the continuing care needs of the patient. However, advance notice is not required if

(a) the patient poses a risk to the member or to others at the practice site or if the patient has failed to respect professional boundaries; and

(b) the member provides for continuity of care by offering to provide information to another member.

12. Records and information
An owner must not request or require a member to use, disclose or otherwise deal with a record containing the personal health information of a patient in a way that is not consistent with the obligations that a member has under the Act, this regulation. The Personal Health Information Act or under any other law.

9. Incidents et erreurs
Les membres prennent rapidement les mesures qui s'imposent en cas d'incidents, d'erreurs ou d'événements indésirables lors de la fourniture de médicaments ou de la prestation de soins. Ils doivent en outre consigner par écrit les faits propres à ces situations et signaler celles-ci.

10. Prise en charge par une autre personne
Si un client ou son mandataire demande d'obtenir dorénavant les services d'un autre membre ou d'un autre professionnel de la santé, le membre concerné fait en sorte que les renseignements dont la communication est autorisée soient transmis dans les délais qui s'imposent à la pharmacie ou au professionnel de la santé qui prendra en charge les soins.

11. Fin de la relation professionnelle
Toute membre qui met fin à une relation professionnelle doit avoir des motifs raisonnables pour agir ainsi et les consigner dans les documents concernant le client.

Le membre est tenu de donner un préavis suffisant au client pour lui permettre de continuer à recevoir les soins dont il a besoin. L'obligation en matière de préavis ne s'applique toutefois pas dans le cas suivant :

a) le client a commis des actes compromettant les liens professionnels que le membre entretient avec lui ou présente un risque pour ce dernier ou les autres personnes se trouvant dans le lieu d'exercice de la profession;

b) le membre assure la continuité des soins en offrant au client de communiquer à un de ses collègues les renseignements pertinents.

12. Documents et renseignements
Il est interdit aux propriétaires de demander ou d'imposer à un membre de traiter, d'utiliser ou de communiquer des documents comportant des renseignements médicaux personnels au sujet d'un client de manière qui contreviendrait à ses obligations au titre de la Loi, du présent règlement, de la Loi sur les renseignements médicaux personnels ou de toute autre loi.
A member and an owner must create, maintain and retain records as required under the Act and this regulation and in a form and manner that allows them to be accessed as promptly as needed in order to provide patient care and to otherwise comply with the requirements of the Act, this regulation, The Personal Health Information Act and any other law.

A pharmacy manager and an owner must ensure that the policies and procedures of the pharmacy are consistent with the obligations that members have under The Personal Health Information Act and any other law.

13. **Policies and procedures** re safe practice

A pharmacy manager must establish, implement and maintain written policies and procedures to

(a) identify, mitigate and avoid situations that expose patients and staff to inappropriate risk;

(b) ensure safe and effective pharmacy practice; and

(c) set out the role of staff in the pharmacy with respect to the matters set out in clauses (a) and (b).

14. **Pharmacist to staff ratio**

A member and an owner must ensure that a pharmacy is operated with a ratio of members to pharmacy technicians, interns, students and other staff or workers that ensures safe and effective pharmacy practice.

15. **Pharmacy facilities**

A pharmacy manager and an owner must ensure that the facilities in the pharmacy are safe, sanitary, appropriate and accessible for the professional practice conducted in the pharmacy.

Les membres et les propriétaires sont tenus d'établir, de tenir et de conserver les documents exigés au titre de la Loi et du présent règlement. Ils doivent pouvoir consulter ces documents rapidement dans l'exercice de leurs fonctions pour s'acquitter des obligations qui leur incombent selon les textes indiqués au paragraphe précédent.

Les gérants et les propriétaires de pharmacie veillent à ce que les lignes directrices de leurs établissements soient conformes aux dispositions des lois régissant les activités des membres, notamment la Loi sur les renseignements médicaux personnels.

13. **Lignes directrices sur l'exercice sécuritaire de la profession**

Les gérants de pharmacie sont tenus d'établir, de mettre en œuvre et de garder à jour des lignes directrices écrites ayant pour but:

a) de définir, d'atténuer et de prévenir les situations qui pourraient entraîner des risques indus pour les clients et le personnel;

b) de permettre l'exercice sûr et efficace de la profession;

c) de préciser le rôle du personnel en ce qui a trait aux questions visées aux alinéas a) et b).

14. **Ratio entre les pharmaciens et les autres membres du personnel**

Les propriétaires et les membres veillent à ce que le ratio entre ces derniers et les préparateurs, les stagiaires, les étudiants et les autres employés permette l'exercice sûr et efficace de la profession.

15. **Installations**

Les gérants et les propriétaires de pharmacie veillent à ce que les installations soient sûres, propres, convenables et d'accès facile en vue de l'exercice des activités professionnelles au sein de l'établissement.
16. Technology
A pharmacy manager and an owner must establish, implement and maintain written policies for the assessment and use of technology that ensures safe and effective pharmacy practice.

17. Drug product acquisition and handling
A member is responsible for ensuring the safety, accuracy and quality of the products and services that the member acquires or supplies.

56(2) The standards of practice are subject to any practice directions.

16. Moyens technologiques
Les gérants et les propriétaires de pharmacie sont tenus d’établir, de mettre en œuvre et de garder à jour des lignes directrices écrites qui portent sur la vérification et l’utilisation des moyens technologiques permettant l’exercice sûr et efficace de la profession.

17. Acquisitions et manipulation de médicaments
Les membres sont tenus de s’assurer que leurs produits et services sont offerts avec exactitude et de manière sûre et efficace.

56(2) Les normes d’exercice sont subordonnées aux directives professionnelles, le cas échéant.
Practice Direction
Standard of Practice # 15: Pharmacy Facilities

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning the requirement to provide appropriate and accessible pharmacy facilities.

1.2 Document Jurisdiction (Area of Practice)

All licensed pharmacies must comply with this practice direction.

1.3 Regulatory Authority Reference

Section 56(1) of the Pharmaceutical Regulations to the Pharmaceutical Act empowers Council to create this practice direction.

2.0 Practice Direction

2.1 The Premises, with the exception of the Dispensary, shall:

2.1.1 with the exception of hospital practice, be accessible to the public in person, by telephone, and by facsimile machine;

2.1.2 with the exception of hospital practice, have a patient counseling and consultation area suitable to the College of Pharmacists of Manitoba, which shall:

2.1.2.1 contain no items for sale other than articles needed for counseling sessions; and

2.1.2.2 provide a setting for confidential discussion between the patient and the pharmacist.
2.1.2.3 display the required College of Pharmacists of Manitoba signs in view of the public:
   2.1.2.3.1 “Accepting Drugs for Return to Inventory”;  
   2.1.2.3.2 “Proof of Identity”;  
   2.1.2.3.3 “It's Your Right to Know”; and  
   2.1.2.3.4 “Updated Personal Health Information”

2.1.3 be well ventilated and sufficiently lit and of cleanliness suitable to the College of Pharmacists of Manitoba;

2.2 The Dispensary must:
   2.2.1 be well ventilated and sufficiently lit and of cleanliness suitable to the College of Pharmacists of Manitoba;
   2.2.2 be at least 150 square feet in size in addition to space allocated for the patient counseling area;
   2.2.3 be accessible to authorized personnel only;
   2.2.4 contain no products inappropriate to the practice of pharmacy;
   2.2.5 have a facsimile machine only accessible to authorized personnel;
   2.2.6 have Internet access for the purposes of email, electronic fan out, and information research;
   2.2.7 have a prescription counter area that provides for 12 square feet of free working space dedicated to the preparation of medication and compounding medication, pursuant to a prescription;
   2.2.8 have secure drug storage;
2.2.9 have a refrigerator that is:
2.2.9.1 clean and in good working order;
2.2.9.2 dedicated to the storage of pharmaceuticals and related products;
2.2.9.3 maintains the temperature defined by the manufacturer of product stored in the refrigerator; and
2.2.9.4 regularly monitored for temperature.

2.2.10 have a sanitary sink that is:
2.2.10.1 kept in a clean condition
2.2.10.2 easily accessible to the prescription preparation area; and
2.2.10.3 supplied with hot and cold water.

2.2.11 Have a waste container of either plastic, metal or similar material.

2.2.12 Provide a setting to protect the patient’s right to privacy by:
2.2.12.1 Providing security of information in compliance with federal and provincial privacy legislation and any additional security measures approved by Council. As part of a patient counseling session, patient information displayed on computer screens must not be visible to any person in the public area of a pharmacy. The information displayed must relate to the patient being counseled and it may only be viewed by the patient being counseled, their delegate or other authorized members of the inter-professional team.
2.2.12.2 Using a sound dulling assembly and visual barriers where appropriate
2.2.12.3 Effective January 1, 2019, for all new community pharmacies and community pharmacy relocations, having a private patient counselling room.

2.3 Compounding and Dispensing equipment required to meet compounding standards, based on the type of compounding performed at the pharmacy (non-sterile, sterile, hazardous compounding).

2.4 The minimum Library Requirements available to all authorized personnel are:
2.4.1 The College Manual (*) containing current Federal and Provincial pharmacy related statutes and information;
2.4.2 Policy and Procedures Manual (*) that includes minimum content as required by Council;
2.4.3 References for drugs, interactions, herbs, nutraceuticals and food (*);
2.4.4 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, etcetera) (*)

(*) Indicates that library requirements may be in hardcopy or electronic format

3.0 Compliance Adjudication

3.1 The Pharmacy site must be readily accessible and open to regulatory review.
3.2 Application May be made to Council for Exceptions or Waivers to the Requirements of this Document.

4.0 Appendices

Not applicable

A Practice Direction is a written statement of a regulatory position made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations.

A Practice Direction carries similar legal weight to a Regulation under the Act and compliance by all Manitoba pharmacists and pharmacy license holders is expected.

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

Development Source: Standards of Practice Committee
Regulatory Reference: Sec 56(1), The Pharmaceutical Regulations
Consultation Close: October 31, 2013
Authorized by Council: November 15, 2013
Effective Date: January 1, 2014
Review Date: April 7, 2016
Consultation Close: May 19, 2017
Approved Revisions: February 12, 2018
Practice Direction
Standard of Practice # 12 – Records and Information

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning documentation and records 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 licensed pharmacists in Manitoba practice.

1.3 Regulatory Authority Reference

Section 56 of The Pharmaceutical Regulations to the Pharmaceutical Act empowers the Council to create a practice direction for documentation and information.

2.0 Practice Direction

2.1 Documentation:

2.1.1 A licensed pharmacist shall document and keep all required records according to the legislation and any other applicable practice directions.

2.1.2 All documentation shall be in a clear, concise and easy to read format that facilitates sharing, ease of use and retrieval of information.

2.1.3 All records maintained by the pharmacy shall be current and accurate with respect to the pharmacist’s or pharmacy’s activities.

2.1.4 In hospital practice, documentation unique to the pharmacy standards shall be maintained; however, information already appearing in the patient’s chart need not be duplicated.

2.2 Amending a Record:

When a record under section 79 of the Regulations is amended to correct an error after the fact the following must be identifiable:

2.2.1 the original entry,

2.2.2 the identity of the pharmacist or other staff member who amended the record,

2.2.3 the date on which the record was amended.
2.3 Electronic Records:

2.3.1 A pharmacy license holder must ensure that the pharmacy’s computer equipment, system and software has the ability to:

2.3.1.1 Store and report the information required in a patient record and prescription transaction;

2.3.1.2 Identify each user who is granted access, control the access granted to the users and create an accurate audit trail of access;

2.3.1.3 Generate reports of prescription information chronologically and by drug name and strength, patient name and prescriber name;

2.3.1.4 Store and report the information required for the time required by the appropriate legislation and standards.

2.3.2 A pharmacy license holder must ensure that the pharmacy’s computer equipment, system and software:

2.3.2.1 Facilitates the sharing, ease of use and retrieval of necessary data to facilitate continuity of patient care;

2.3.2.2 Have sufficient security to ensure that only authorized users have access to the system;

2.3.2.3 Requires a deliberate and auditable procedure to be carried out by the pharmacy license holder or their delegate prior to purging any information from the system;

2.3.2.4 Has adequate backup and recovery systems.

2.3.3 A pharmacy license holder must ensure that the back up of electronic records:

2.3.3.1 occurs once daily;

2.3.3.2 is tested for recovery on a regular basis;

2.3.3.3 is retrievable in the event the system malfunctions or is destroyed.

2.4 Security of Records:

2.4.1 Pharmacy records, including back-ups, stored either on- or off-site must have adequate security to protect the records from unauthorized access, theft, use, or loss.

2.4.1.1 Security measures include appropriate physical, administrative and technical safeguards.

2.5 Access to Records:

2.5.1 If a patient or their agent requests access to their records, the pharmacy license holder must provide a response as soon as reasonably practical, but no longer than 30 days from the date the record was requested.

2.5.1.1 In responding the pharmacy must either:
2.5.1.1.1 Make the record (or a copy) available to the individual
2.5.1.1.2 Indicate that no record exists (if a record is found later, then the individual must be notified)
2.5.1.1.3 Indicate that access is denied pursuant to a specific section of the Personal Health Information Act (PHIA).

2.6 Destruction of Records:
2.6.1 A licensed pharmacist must ensure the appropriate destruction of records in one or more of the following manners:
2.6.1.1 Physical destruction using a shredder or complete incineration;
2.6.1.2 Erasure or destruction of electronic records in such a manner that the information cannot be reconstructed.

2.7 Remedying a Security Breach:
2.7.1 A pharmacy license holder must take appropriate measures to remedy a security breach as soon as reasonably possible after discovery of unauthorized access, use, disclosure, or disposal of personal patient information. These measures include:
2.7.1.1 Recovering personal information or ensuring disposal of such information if it cannot be recovered;
2.7.1.2 Ensuring the security of remaining personal information;
2.7.1.3 Notification of affected persons, the College, and legal authorities (if breach is a result of a criminal activity);
2.7.1.4 Modifying security measures to prevent a re-occurrence.

2.8 Transfer of Patient Records:
2.8.1 The pharmacy manager is responsible for patient records until such time as the records are transferred to another trustee.
2.8.2 The pharmacy must make reasonable efforts to notify the patients whose records are being transferred and must make those records available to the patients during the transfer.
2.8.2.1 Where it is not reasonable to notify patients individually, pharmacies shall use a minimum of 2 methods of providing notice including but not limited to: notice on pharmacy website, posting of notice in/on pharmacy, message on pharmacy answering machine.
2.8.3 In the event of a permanent store closure, where no other party takes ownership, patients must still have access to their records for the time specified in any applicable regulations and:
2.8.3.1 The pharmacy is responsible for ensuring the secure storage or transfer of patient records.
2.8.3.2 The College of Pharmacists of Manitoba must be notified in writing of the disposition of such records.

2.9 Delegation to external document storage or destruction companies:
   2.9.1 The pharmacy license holder must ensure the company is bonded and the service arrangement is compliant with PHIA.
   2.9.2 The pharmacy retains responsibility for the safety and security of patient records even if the storage or destruction is contracted out to a third party.

3.0 Compliance Adjudication

3.1 All records must be readily accessible and open to regulatory review.

4.0 Appendices

4.1 Not applicable

A Practice Direction is a written statement of a regulatory position made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations.

A Practice Direction carries similar legal weight to a Regulation under the Act and compliance by all Manitoba pharmacists and pharmacy license holders is expected.

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

Development Source: Standards of Practice Committee
Regulatory Reference: Part 9, The Pharmaceutical Regulations
Consultation Close: October 31, 2013
Authorized by Council: November 15, 2013
Effective Date: January 1, 2014
Revised:
Review Due:
Minimum Pharmacy Policy and Procedures Manual Content
(Effective July 1, 2004 for new stores; January 1, 2005 for pharmacies licenced prior to January 1, 2005)

The Pharmaceutical Regulations to the Pharmaceutical Act provides for the establishment of minimum library contents for the pharmacy library. One of the library requirements is a Policy and Procedures Manual for the pharmacy. The purpose of this document is to describe the minimum content of the manual and to provide a tool that a pharmacy may use in the development of the manual specific to that pharmacy. The expectation is that the manual with 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.

Pharmacy Policy and Procedure Manual

Mandatory Content:

Table of Contents;

General Practice:
Pharmacy Name/Address/Telephone/Hours of Operation;
Manager/Pharmacists;
Technicians/Other Pharmacy Staff & Positions;
Position Descriptions (General);
Manager, Pharmacists, Technicians, Clerks etc.;
Security; Policy & Procedures; Dispensary & Balance of Facility;
Security; Opening & Closing; Keys, Opening, Closing, Lock & Leave, Alarm Company Contacts;
Security; Storage of email & Electronic Records Compliant with The Personal Health Information Act for 7 Years;
Security; Storage of Prescription Hard Copies for 2 Years Consistent with The Manitoba Pharmaceutical Act;
Non-Prescription Medication; Stock Layout, Sales, Exempted Codeine, NAPRA Schedule II & III;
Delivery/Mail; Policy & Procedure;

Dispensary:
Computer; PSV Supplier, Repair Contact, Supplies;
Dispensary Software; Counselling, Reference etc.;
Stock Layout; Diagram & Text;
Reference Library;
Work Flow Schematic (Text);
Work Flow Schematic (Diagrammatic);
Narcotics; Policies & Procedures; Reports, Inventory Management;
Outdated Stock; Policies & Procedures;
Child Resistant Container Policy; Policies & Procedures;
Suppliers; Policies & Procedures; Principle & Contacts;
Ordering; Policy & Procedures;
Inventory Receiving; Policy & Procedures;
Client Complaints; Policies & Procedures;
Counselling; Error Standard; Policies & Procedures showing an audit trail;
Confidentiality Agreements; Policy, Procedures & Sample Document;
Fax Standard Compliance; Policies & Procedures;
Documentation Guideline Compliance (eg DPIN access, MY/MZ codes); Policies & Procedures;

**International Practice (if applicable):**

Physician Licensure Confirmation; Policy & Procedures, Sample Document with Name & Address;
Intent to Honour Standards of Practice (eg SOP Internet Pharmacy #6);
Counselling; Policy, Procedures & Audit Trail;
Website & Affiliate Websites Disclosed to the Association;

**Additional Recommended Content:**

Charge Accounts; Policy & Procedure;
Cheques; Policy & Procedure;
Staff Purchases; Policy & Procedure;
Telephones; Policy & Procedures;
Accounts Receivable; Policy & Procedures;
Accounts Payable; Policy & Procedures;
Policies & Procedures showing counselling audit trail;
Banking; Policies & Procedures;
APPLICATION FOR DPIN REGISTRATION

Please Print Clearly

DPIN REQUIRES 4-6 WEEKS NOTICE

1) Pharmacy Information
Change of information - Please indicate effective date
New application - Please indicate opening date

<table>
<thead>
<tr>
<th>Trade Name of Pharmacy/Dispensary</th>
<th>Pharmacy License No. (as shown on M.Ph.A. License certificate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal Name of Pharmacy/Dispensary</td>
<td></td>
</tr>
<tr>
<td>Site Address (Location of Pharmacy/Dispensary)</td>
<td>Mailing Address (different)</td>
</tr>
<tr>
<td>City</td>
<td>Postal Code</td>
</tr>
<tr>
<td>Telephone No. (Pharmacy)</td>
<td>Fax No. (Pharmacy)</td>
</tr>
</tbody>
</table>

2) Ownership
Legal Name of Head Office
Mailing Address
MH Use Only

<table>
<thead>
<tr>
<th>City</th>
<th>Postal Code</th>
<th>Telephone No.</th>
<th>Fax No.</th>
<th>Name of Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>( )</td>
<td>( )</td>
<td></td>
</tr>
</tbody>
</table>

3) Type of Pharmacy

<table>
<thead>
<tr>
<th>Organization Type</th>
<th>Independent</th>
<th>Chain – Operator Owned</th>
<th>Chain – Centrally Owned</th>
<th>Trade Name of Chain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( )</td>
<td>( )</td>
<td>( )</td>
<td></td>
</tr>
</tbody>
</table>

Dispensing Physician ➔ Distance to nearest Community Pharmacy km.

4) Software Vendor Information

<table>
<thead>
<tr>
<th>Mailing Address</th>
<th>City</th>
<th>Postal Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5) Banking Data for electronic funds transfer - Attach a blank cheque marked "VOID" or a fully encoded deposit slip for the account, and complete the following:

<table>
<thead>
<tr>
<th>Institution / Bank Name</th>
<th>Institution No.</th>
<th>Account Holder Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Branch Name</td>
<td>Branch No.</td>
<td>Bank Account Number</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fax No.</td>
</tr>
<tr>
<td>Branch Mailing Address</td>
<td>Postal Code</td>
<td>Telephone No.</td>
</tr>
</tbody>
</table>

6) Please provide the name(s) and address(s) of owner(s) and partner(s)

<table>
<thead>
<tr>
<th>Name(s)</th>
<th>Address(s)</th>
</tr>
</thead>
</table>

Note: Additional names and address may be listed on a separate sheet.

I request and authorize that a copy of my Remittance Advice be forwarded to my Pharmacy Chain Head Office.

Manager Signature | Date | Owner Signature | Date |

MH Use Only

<table>
<thead>
<tr>
<th>New Pharmacy No.</th>
<th>Approval Date Year</th>
<th>Month</th>
<th>Day</th>
<th>Network Processing Effective Date Year</th>
<th>Month</th>
<th>Day</th>
</tr>
</thead>
</table>
TO: COLLEGE OF PHARMACISTS OF MANITOBA
AND TO: COMPANIES OFFICE (MANITOBA)
FROM: ____________________________________________
RE: APPROVAL OF CORPORATION AND/OR BUSINESS (PHARMACY) NAME

WHEREAS ______________________________ is a licensed pharmacist within Manitoba; AND intends to be the pharmacy manager of a:

pharmacy called ______________________________ (Business Name).

AND/OR a Corporation called _______________________________________.

AND WHEREAS the name of the pharmacy and/or the name of the corporation has been approved by the Manitoba Companies Office, subject to the College of Pharmacists of Manitoba (the “College”) giving its consent to the use of such name(s);

______________________________ wishes to confirm the following to the College;

(Pharmacy Manager)

1. I am in the process of preparing an application to have the business licensed as a pharmacy pursuant to *The Pharmaceutical Act* (Manitoba); and/or the Corporation registered.

2. the pharmacy will not commence doing business until such license is obtained.

DATED this ________ day of ____________, 20____  __________________________________ Signature of Pharmacist

The College hereby acknowledges the foregoing, and gives its consent for the business to use the name of ________________________________ as a licensed pharmacy and/or consent to use the name ________________________________ as a Corporation.

DATED this __________ day of ____________, 20____

PER: ____________________________________________

Susan Lessard-Friesen, Registrar
College of Pharmacists of Manitoba