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# NEW PHARMACY APPLICATION PACKAGE

Every pharmacy in Manitoba must be registered with the College of Pharmacists of Manitoba. Before opening a pharmacy, it is your responsibility to be aware of the regulations, guidelines, standards of practice, etc. Below are the references and materials you need in order to start the application process. Click on each link below and read them diligently. If you have any questions or concerns, please contact registration@cphm.ca.

- √ The Pharmaceutical Act: Part 7 "Pharmacies"
- ✓ *The Pharmaceutical Regulations*: Part 6 "Pharmacy Licences"
- ✓ The Pharmaceutical Regulations: Part 7 "Standards of Practice"
- ✓ <u>Standard 15: Pharmacy Facilities Practice Directions that includes</u> <u>pharmacy minimum standards</u>
- ✓ Standard 12: Records and Information Practice Directions
- ✓ Minimum Pharmacy Policy and Procedure Manual Content
- ✓ Safety IQ Implementation New Pharmacy Opening Notice
- ✓ New Pharmacy Applications
  - > Requirements
  - > Application Form
  - > Floor Plan Checklist
- ✓ Frequently Asked Questions

## PART 7

## **PHARMACIES**

## Pharmacy licence

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

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

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

- 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

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**

If the registrar refuses to issue or renew a pharmacy licence, or issues or renews 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

- 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

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

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

## PARTIE 6

## LICENCES DE PHARMACIE

DEMANDES DE LICENCE PHARMACIE

## 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:

## 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.
- $\begin{array}{lll} \textbf{31(2)} & \text{Le paragraphe (1) ne s'applique pas aux} \\ \text{pharmacies} & \text{qui} & \text{se} & \text{trouvent} & \text{dans} & \text{plusieurs} \\ \text{bâtiments non contigus dans les cas suivants} : \end{array}$ 
  - 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 registraire.

## 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 convaincant 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.

- b) que l'établissement se conformera aux directives professionnelles pertinentes;
- 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 fonctionnement.

## 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

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

Postes de pharmacie

## 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.

## 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

## 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

## 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

## 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

## 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

## 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

## 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

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;

## Renouvellement de la licence de pharmacie

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

- 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;

- f) au moins 30 jours avant de cesser leurs activités, s'il leur est possible de respecter ce délai, aviser les clients de la fermeture conformément aux directives professionnelles et prendre les mesures suivantes :
  - (i) leur communiquer le nom de la pharmacie où les documents concernant les ordonnances seront transférés ainsi que la façon de communiquer avec elle, s'ils ne s'opposent pas à ce transfert,
  - (ii) leur indiquer que les documents seront acheminés à la pharmacie de leur choix s'ils s'opposent au transfert en question;
- g) fournir au registraire une copie de l'avis mentionné à l'alinéa f).
- **45(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.

b) si une société en nom collectif est propriétaire de la pharmacie, ses associés 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*.

## 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.

### Accurate disclosure

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

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

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

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

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;

PHARMACIES P60 — R.M. 185/2013

(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-administrent.

## 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.

PHARMACEUTICAL P60 — M.R. 185/2013

## 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.

### 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.

PHARMACIES P60 — R.M. 185/2013

### 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.

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.

## 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 d'une 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.

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. PHARMACEUTICAL P60 — M.R. 185/2013

## 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.

## 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.

## 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. 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.



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## 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 Definitions

A narcotic drug is defined as any substance set out in the Schedule to the Federal Narcotic Control Regulations or anything that contains any substance set out in that Schedule.

A controlled drug is defined as any drug set out in the Schedule to Part G of the Federal Food and Drug Regulations or anything that contains any substance set out in that Schedule.

## 1.4 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:



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- 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;
- 2.1.4 have the hours of operation posted at the principle entrance, along with call-back information where available, for all community pharmacies;
- 2.1.5 With the exception of hospital pharmacy facilities, display Council approved time delayed safe signage at all public entrances and near the dispensary in view of the public.

## 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 provide the maximum possible hours of on-site pharmacist services based on the needs of the institution or community, and the availability of pharmacist staff;
- 2.2.10 provide hours of operation offering the availability of pharmacist services for at least 25 hours over a minimum of four days per week, unless a



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written appeal is received two weeks prior to a council meeting and council reviews and approves the lesser number of hours;

- 2.2.11 have a refrigerator that is:
  - 2.2.11.1 clean and in good working order;
  - 2.2.11.2 dedicated to the storage of pharmaceuticals and related products;
  - 2.2.11.3 maintains the temperature defined by the manufacturer of product stored in the refrigerator; and
  - 2.2.11.4 regularly monitored for temperature.
- 2.2.12 have a sanitary sink that is:
  - 2.2.12.1 kept in a clean condition
  - 2.2.12.2 easily accessible to the prescription preparation area; and
  - 2.2.12.3 supplied with hot and cold water.
- 2.2.13 Have a waste container of either plastic, metal or similar material.
- 2.2.14 Provide a setting to protect the patient's right to privacy by:
  - 2.2.14.1 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.
  - 2.2.14.2 Using a sound dulling assembly and visual barriers where appropriate
  - 2.2.14.3 Effective January 1, 2019, for all new community pharmacies and community pharmacy relocations, having a private patient counselling room.
- 2.2.15 Have an appropriate secure narcotic safe to store all narcotic and controlled drug inventory.
  - 2.2.15.1 With the exception of hospital pharmacy facilities, the narcotic safe must have a time- delay lock set to a minimum of 5 minutes.
- 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).



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- 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, pediatric, 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 published on the College website.

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

Approved Revisions:

Standards of Practice Committee Sec 56(1), *The Pharmaceutical Regulations* October 31, 2013 November 15, 2013 January 1, 2014 May 1, 2023

June 16, 2023 June 26, 2023



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## 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.



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## 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:

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## **College of Pharmacists of Manitoba**

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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.



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

Review Due:

Standards of Practice Committee
Part 9, The Pharmaceutical Regulations
October 31, 2013
November 15, 2013
January 1, 2014



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## Guideline on Minimum Pharmacy Policy and Procedures Manual

Standard of Practice #13 of the Regulations to the *Pharmaceutical Act* requires the pharmacy manager to establish, implement and maintain written policies and procedures. A policy and procedure manual will provide pharmacy staff with clear direction on the scope and limitations of their functions and responsibilities. The manual will help ensure safe and effective pharmacy practice and will help identify, mitigate and avoid situations that expose patients and staff to inappropriate risks. The purpose of this guideline is to describe the minimum required content of the Policy and Procedures manual and to provide a template a pharmacy may use in the development of their individual manual. The manual must be updated as circumstances in the pharmacy change (e.g. change of ownership, change of manager, etc.) or at a minimum of every three years, and dated to indicate the most recent revision. The pharmacy manager must ensure all pharmacy staff are familiar with the manual. Policies and procedures are important for new staff orientation and crucial to staff development and continued competence.

Please note: If a pharmacy has received approval for another pharmacy component, each component must have a policy and procedure manual specific to that pharmacy component.

## **Mandatory Content:**

- A. Table of Contents
- **B.** Introduction

## C. General Practice

- Pharmacy information: Pharmacy name, address, telephone, fax, email, hours of operation
- Staff information: Pharmacy manager, pharmacists, technicians, other staff and contact information
- Position descriptions: Manager, pharmacists, technicians, assistants, clerks, etc.
- Security: Opening and closing procedure, keys, lock & leave (if applicable), alarm
- Non-prescription medication: Stock layout, NAPRA Schedule II & III drugs
- Delivery/mail
- Dress code
- Excused absences: Sick leave, vacation requests, leaves of absence

### D. Dispensary

 Dispensary software (or Pharmacy Practice Management System - PPMS) and computer: PSV supplier, repair contact, computer suppliesordering, data backup

### E. Reference library

- Federal/provincial legislation, compendium, drug interaction text, therapeutic text, dispensatory/foreign drug text, medical dictionary, OTC reference, natural health products and alternative therapies text, other references specific to thepharmacy's area of practice
- Counselling area
- Stock layout
- Workflow schematic (include a diagram and text to illustrate workflow)
- Narcotics: Storage area, inventory management, outdated stock, destructed or returned narcotics
- Regular inventory management: Maintenance, outdated stock
- Stock ordering: Principle supplier and contact, ordering procedure, inventory receiving protocol
- Child Resistant Container Policy
- Prescription balances or owing
- Policy on prescriptions not picked up
- Cold chain management and refrigerator temperature log

### F. Pharmacy Practice

- Patient counselling: Counselling record, counselling for delivered prescriptions
- Administration of drugs including vaccines: procedure, informed consent (include sample form), anaphylaxis kit
- Pharmacist prescribing: continued care, OTC, minor ailments, uncomplicated cystitis, prescription adaptation(informed consent, adaptation notification form, documentation and rationale)
- DPIN documentation compliance: DPIN access, MY/MZ codes
- Lab test orders
- Compounding:
  - Non-sterile products: Compounding area, equipment (use and maintenance), compound formulas, compounding procedure, documentation (lot number, expiry date, quantity of each ingredient), product assessment, product packaging and labelling
  - Sterile products: Aseptic area, equipment, protective gear, hand washing procedure, WHIMIS training and MSDS location, compounding procedure, product assessment, product packaging and labeling
- Methadone and Suboxone: patient agreement (include sample document), patient verification procedure, witnessed dosing, missed dose, lost/stolen dose, vomited dose, carries
- Opioids, benzodiazepines/z-Drugs, and other sedatives (managing prescriptions that fall outside clinical guidelines, early refill requests, alternative care plans with prescribers, documentation of communication)
- Exempted Codeine Prescribing Procedures

- Client complaints against pharmacist or pharmacy
- Confidentiality: Confidentiality agreement (attach sample agreement), media calls
- Facsimile communication procedure
- Return policies for prescription, non-prescription and other health care products
- Privacy policy: Storage of email and electronic records (compliant with *ThePersonal Health Information Act* for 7 Years), storage and destruction of prescription hard copies (for 5 years compliant with the Regulations to *the Pharmaceutical Act*), storage and destruction of material with personal healthinformation during the dispensing and counselling process
- Waste management: Sharps disposal, needlestick injury (prevention, managing injuries)
- Loss or theft: Procedure, documentation (including reporting to the CPhM), prevention measures
- Prescription forgeries: Procedure, documentation (including reporting to the CPhM)

### **G. Medication Incidents and Near Miss Events**

### Staff Training

- Medication Incidents and Near Miss Events
- Communication
- Safety IQ
- Pharmacy Online Incident Reporting Platform/Program

### • Discovery and Disclosure

- Procedure when incident is discovered
- Disclosure Process and Apology
- Communication and documentation with Patient/Prescriber/Staff

### Report

- Name of Pharmacy Online Incident Reporting Platform/Program:
- Process for Reporting Incidents
- Process for Reporting Near Miss Events
- Documentation of Incidents and Near Miss Events

### • Investigation and Analysis

- Communication of Incident/Near Miss with Staff
- Process for investigating and analyzing incident/near miss
- Process for developing, documenting and monitoring action plans
- Communication of action plans with patients and staff

### Safety Self-Assessment

- Name of Safety Self-Assessment Tool used by Pharmacy
- Procedure for completing Safety Self-Assessment
- Development and Monitoring of actions related to Safety Self-Assessment
- Date of last Safety-Self Assessment

### CQI Meetings

- Date of Last Meeting
- Minutes of Meetings

### **H. Contacts**

- Manager
- Staff

- Alarm company
- Wholesaler(s)
- Supplier(s)
- Local Physicians
- Third party
- Emergency services (police, fire/ambulance)

### I. Additional Recommended Content

- Charge accounts: Accounts receivable, accounts payable, banking
- Cheques
- Staff Purchases
- Telephones

### J. Distance Care Component (International Practice) (if applicable)

- Physician licensure confirmation (sample document with name and address)
- Counselling record
- Website and affiliate websites disclosed to the College

### K. Residential Care Home (if applicable)

• Services provided to residential care homes

### L. Emergency Preparedness

• <u>See the Emergency Preparedness Resource Kit for Pharmacists</u> for a complete explanation and information you should include in your Policy and Procedure Manual



# SAFETY IQ IMPLEMENTATION **NEW PHARMACY OPENING NOTICE**



In line with its mandate to protect the health and safety of the public, the College of Pharmacists of Manitoba (College) is implementing a mandatory continuous quality improvement (CQI) program called Safety Improvement in Quality (Safety IQ) for all community pharmacies.

The College successfully piloted this program with 20 community pharmacies for one year starting in September 2017. Upon evaluation and assessment, College Council approved Safety IQ as the mandatory CQI program for community pharmacies.

Currently, all community pharmacies are required to document medication incidents and ensure patient safety. Safety IQ improves current practice by ensuring that pharmacy professionals across the province share lessons about medication incidents using standardized CQI practices. Safety IQ enables community pharmacies to

- anonymously report medication incidents and near-miss events to the National Incident Data Repository (NIDR) for Community Pharmacy an ISMP Canada-led component of the Canadian Medication Incident Reporting and Prevention System (CMIRPS);
- enhance patient safety using standardized tools and practices;
- learn from medication incidents and near-miss events in other pharmacies;
- contribute to analysis that will define and investigate the prevalence and causes of medication incidents in Canada; and
- promote a culture of safety in which all pharmacy staff feel comfortable reporting and discussing medication incidents.

As a pharmacy manager opening a new pharmacy, you are responsible for implementing Safety IQ. Within 30 days of opening, your pharmacy must be compliant with Safety IQ requirements and the Medication Incident and Near-Miss Event Practice Direction including the technical capability to report medication incidents and near-miss events to a reporting software platform that meets College Criteria.

The following resources outline the information you need and the steps you must take to implement Safety IQ into your pharmacy practice:

- Safety IQ Implementation Toolkit for New Pharmacies
- Medication Incident Reporting Platform Criteria
- Guide to Safety IQ

In addition, the Safety IQ web page holds several other resources to be reviewed by all pharmacy staff.

The College welcomes questions or comments. Please email us at safetyig@cphm.ca.



200 Taché Avenue, Winnipeg, Manitoba R2H 1A7 Phone #: 204-233-1411 | Fax #: 204-237-3468 E-Mail Address: info@cphm.ca | Website: www.cphm.ca

# NEW COMMUNITY PHARMACY



200 Taché Avenue, Winnipeg, Manitoba R2H 1A7 Phone #: 204-233-1411 | Fax #: 204-237-3468 E-Mail Address: info@cphm.ca | Website: www.cphm.ca

# **COMMUNITY/CLINICAL PHARMACY REQUIREMENTS**

### **INITIAL REQUIREMENTS:**

- 1. Name Consent Form for New Pharmacy Application
- 2. New Pharmacy Application Form

The 'Expected Opening Date' on the form must be no less than 30 days after the College has received all required documents and must be no later than 45 days after the College has granted its approval.

- 3. <u>Manitoba Companies Office</u> supporting documents that the pharmacy owner (sole proprietor, partnership, or corporation) is in good standing under <u>The Corporation Act</u>. Please refer to <u>Section</u> 64(2)(b)(ii) of The Pharmaceutical Act.
  - ✓ File Summary

    NOTE: The "As of" date (shown on the upper right-hand corner) must be within one month from submission of documents to the College.
  - ✓ Articles of Incorporation
  - ✓ Certificate of Incorporation
  - ✓ Business Number Information
- 4. Evidence in the form of a Notarized Declaration that the corporation's officer(s) and director(s), and legal and beneficial owners have not been subject to disciplinary, criminal, or administrative sanction in any jurisdiction. Should disciplinary, criminal, or administrative sanctions exist, further description of the specific incidents must be included. Please refer to section 64(2)(e) of The Pharmaceutical Act.
- 5. A description of the pharmacy services in bulleted format
- 6. Pharmacy Floor Plan Checklist along with a detailed floorplan of the pharmacy facility
- 7. The <u>Drug Programs Information Network Registration</u> form must be filled out and submitted to Manitoba Health.

### **SUBMISSION OF DOCUMENTS:**

Before you send any physical documents to the College, please scan them first and send to <a href="mailto:registration@cphm.ca">registration@cphm.ca</a> (Subject line: **New Pharmacy Application**). A staff will review the documents and advise you if any correction is needed. If deemed complete with no errors or concerns, you will then be asked to submit physical documents to the College either by regular mail or by dropping off at our secure mailbox in front.



# **College of Pharmacists of Manitoba**

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7 Phone (204) 233-1411 | Fax: (204) 237-3468 E-mail: info@cphm.ca | Website: www.cphm.ca

# 2023 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 <i>The Pharmaceutical Act</i> in the Province of Manitoba <b>until the 31st day of December, 2023</b> .						
Pharmacy Business Name(s)						
Pharmacy Address*			City	P	rovince	Postal Code
*[ ] Additional buildings, fa and description of activities		•	being used as part of this phar to this application.	macy licer	nce and details of	f the location(s)
Corporation's (9 digit) Business Nu	mber		Telephone #1	Т	elephone #2	
Primary E-Mail Address			Additional E-Mail Address		Fax Number	
Primary Website			Additional Website Business Hours of Ope		eration	
Lock and Leave	YES or	r No	If Lock and Leave, list hours	s		
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 Att	ach:					
<ol> <li>A sketch / floorplan showing the physical layout of the pharmacy</li> <li>A description of the pharmacy services to be provided</li> <li>If a Lock &amp; Leave permit is also being requested, a sketch that includes the Lock &amp; Leave area and the larger retail operation.</li> </ol>						
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):						
FOR OFFICE USE ONLY:						
Licence #		Approved By		Date App	roved	

Does this pharmacy conduct business or practice pharmacy with the following components:							
Central Fill	YES	or	No	Personal care home (long term care)	YES	or	No
*Distance care (international prescription service (IPS))	YES	or	No	Satellite pharmacy	YES	or	No
Distance care (non-international prescription service)	YES	or	No	Secondary hospital	YES	or	No
External dispensing	YES	or	No	Sterile compounding	YES	or	No
Lock and Leave	YES	or	No	Opioid Agonist Therapy (OAT)	YES	or	No

### **Sterile Compounding Licence Component Declaration**

- 1. Please indicate if your pharmacy currently provides sterile compounding care services:
  - Yes, my pharmacy provides sterile compounding services in compliance with NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations\*
  - No, my pharmacy does not provide sterile compounding services.
- \*Please note that if your pharmacy provides these services, the pharmacy manager and staff must ensure they are fully compliant with the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations including appropriate facilities, training, education, and personnel.
- 2. Do you want your pharmacy listed on the College of Pharmacists of Manitoba website so other pharmacists, healthcare providers, and the public can find sterile compounding pharmacy care services:
  - Yes, list my pharmacy on the public register.
  - o No, do not list my pharmacy on the public register.

The applicant must provide additional details with this application for any of the components listed above.

\* Please be advised, for a pharmacy that applies for a Distance Care (International Prescription Service (IPS) component of the Pharmacy licence, the 2023 Pharmacy licence will be issued with the condition the pharmacy includes the Council-approved disclaimer that will advise their clients, and potential clients, that 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
	please print and include licence number	
Licensed Pharmacists		

Pharmacy Students & Interns						
Pharmacy Technicians (qualified and listed by						
the College)						
and rules related to the and <i>Controlled Drugs an</i> owner (legal and benefic have been subject to dis	The pharmacy, above, will be conducted in accordance with the provisions of <i>The Pharmaceutical Act</i> , other legislation and rules related to the practice of pharmacy and the provisions of and regulations made under the <i>Food and Drugs Act</i> and <i>Controlled Drugs and Substances Act of Canada</i> . 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.					
Safety IQ Quality Assurant within an incident report exported to the National The pharmacy will comp	ill act in compliance of the Medicationce Program (effective June 1, 2021 ting platform that satisfies the Count Incident Data Repository housed bullete a Safety Self-Assessment and	). The pharm icil-approved y ISMP Canada a formal Cor	acy will document all medication criteria. All incident/near miss dada.  da.  atinuous Quality Improvement st	incidents ata will then be aff meeting in		
compliance with Section	ns, 3.2.5.3 and 3.2.5.4 of the Medic	ation Incider	nts and Near-Miss Events Practic	e Direction.		
I grant permission for th	e College of Pharmacists of Manito	ba to access	drug wholesale records for this	pharmacy.		
Signature of Pharmacy	Manager					
Signature of CEO or Pha	rmacy Owner					
Print Name of CEO or Ph	narmacy Owner					
Date of Application						
FEES & PAYMENT	FEES & PAYMENT					
Select all applicable fees	:: ::			Total Amount		
		-				

FEES	FEES & PAYMENT						
Select all applicable fees:							
	Pre-Opening Inspection Fee	\$886.89 + GST \$44.34 =	\$931.23				
	Pharmacy Licence Fee Licence effective January 1st to December 31st	\$1,743.40 + GST \$87.17 =	\$1,830.57				

Pharmacy Licence Fee Licence effective July 1st to December 31st	\$1,046.04 + GST \$52.30 =	\$1,098.34
Additional Fees		
Central Fill (non-"patient contact" pharmacy) component	\$591.26 + GST \$29.56 =	\$620.83
Distance Care (IPS) Component: effective Jan 1 <sup>st</sup> – Dec 31 <sup>st</sup>	\$7,822.41 + GST \$391.12 =	\$8,213.53
Distance Care (IPS) Component: effective Jul 1 <sup>st</sup> – Dec 31 <sup>st</sup>	\$4,693.45 + GST \$234.67 =	\$4,928.12
Distance Care (Non-IPS) Component	\$754.29 + GST \$37.71 =	\$792.00

When your application, and all supporting documents are received and approved at the College Office, you will be notified by email that an invoice has been generated and is ready for payment.

Payments are accepted by:

### 1. Visa or MasterCard

If you choose to pay by credit card, you will be advised to pay online through your registrant portal.

### 2. Cheque

If you choose to pay by cheque, print a copy of the invoice and mail both the invoice and cheque to the College Office. Cheque made payable to the College of Pharmacists of Manitoba

Please Note: All Fees are NON-REFUNDABLE

### 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 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 *				
Name	Address			
Name	Address			

** If any of the Shareholders of the applicant are corporations, then also provide all of the information above for any such corporate Shareholders.				
· · · · · · · · · · · · · · · · ·	r director or legal or beneficial owner of shares of the corporation any other pharmacy in Canada, disclosure of the name(s) and address(es)			
Name	Address			
Name	Address			
Section 2 – Partnerships and Sole	Proprietorships			
• •	siness under a name other than its own name, a copy of the Business Name Tertificate of Search (under <i>The Business Names Registration Act</i> ) for each			
Identify by name and addresses all of the	partners*** of the partnership*			
Name	Address			
Name	Address			
*** 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 *				
Name	Address			
Name	Address			
Please Attach Documents and Lists as No	ecessary			



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# NEW CLINICAL PHARMACY



200 Taché Avenue, Winnipeg, Manitoba R2H 1A7 Phone #: 204-233-1411 | Fax #: 204-237-3468 E-Mail Address: info@cphm.ca | Website: www.cphm.ca

# **COMMUNITY/CLINICAL PHARMACY REQUIREMENTS**

### **INITIAL REQUIREMENTS:**

- 1. Name Consent Form for New Pharmacy Application
- 2. New Pharmacy Application Form

The 'Expected Opening Date' on the form must be no less than 30 days after the College has received all required documents and must be no later than 45 days after the College has granted its approval.

- 3. <u>Manitoba Companies Office</u> supporting documents that the pharmacy owner (sole proprietor, partnership, or corporation) is in good standing under <u>The Corporation Act</u>. Please refer to <u>Section</u> 64(2)(b)(ii) of The Pharmaceutical Act.
  - ✓ File Summary

    NOTE: The "As of" date (shown on the upper right-hand corner) must be within one month from submission of documents to the College.
  - ✓ Articles of Incorporation
  - ✓ Certificate of Incorporation
  - ✓ Business Number Information
- 4. Evidence in the form of a Notarized Declaration that the corporation's officer(s) and director(s), and legal and beneficial owners have not been subject to disciplinary, criminal, or administrative sanction in any jurisdiction. Should disciplinary, criminal, or administrative sanctions exist, further description of the specific incidents must be included. Please refer to section 64(2)(e) of The Pharmaceutical Act.
- 5. A description of the pharmacy services in bulleted format
- 6. Pharmacy Floor Plan Checklist along with a detailed floorplan of the pharmacy facility
- 7. The <u>Drug Programs Information Network Registration</u> form must be filled out and submitted to Manitoba Health.

### **SUBMISSION OF DOCUMENTS:**

Before you send any physical documents to the College, please scan them first and send to <a href="mailto:registration@cphm.ca">registration@cphm.ca</a> (Subject line: **New Pharmacy Application**). A staff will review the documents and advise you if any correction is needed. If deemed complete with no errors or concerns, you will then be asked to submit physical documents to the College either by regular mail or by dropping off at our secure mailbox in front.



# **College of Pharmacists of Manitoba**

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7 Phone (204) 233-1411 | Fax: (204) 237-3468 E-mail: info@cphm.ca | Website: www.cphm.ca

# 2023 APPLICATION FOR PHARMACY LICENCE FOR A CLINICAL PRACTICE PHARMACY

			FOR A CLI	NICA	L PRACTICE	PHARMACY	
I (We),	• • •		•	nduct a			
Pharmacy Business Name(s)							
Pharmacy Address*			City		Province	Postal Code	
*[ ] Additional buildings, fand description of activities	es at each location	-		his phar	macy licence and detail	s of the location(s)	
Corporation's (9 digit) Business N	lumber		Telephone #1		Telephone #2		
Primary E-Mail Address			Additional E-Mail Address		Fax Number	Fax Number	
Primary Website			Additional Website		Business Hours of	Business Hours of Operation	
This pharmacy meets th through the following in insurance broker or the	surance comp	any (and evi	dence will be provide	ed to th	e College such as a le	• •	
Pharmacy Manager	please print						
	please print and in	nclude licence nu	ımber				
Licensed Pharmacists							
FOR OFFICE USE ONLY:							
Licence #		Approved By			Date Approved		

Pharmacy Students & Interns			
Pharmacy Technicians (qualified and listed by the College)			
The above pharmacy will be con other provincial legislation and r made under the <i>Food and Drugs</i>	ules related to the practic	e of pharmacy ar	nd the provisions of and regulations
I grant permission for the Colleg	e of Pharmacists of Manito	ba to access dru	g wholesale records for this pharmacy.
Signature of Pharmacy Manage	r		
Signature of CEO or Pharmacy Owner			
Print Name of CEO or Pharmacy Owner			
Date of Application			

FEES & PAYMENT					
Selec	t all applicable fees:		Total Amount		
	Pre-Opening Inspection Fee	\$886.89 + GST \$44.34 =	\$931.23		
	For licence effective January 1st to December 31st				
	Pharmacy Licence Fee	\$1,743.40 + GST \$87.17 =	\$1,830.57		
	For licence effective July 1st to December 31st				
	Pharmacy Licence Fee	\$1,046.04 + GST \$52.30 =	\$1,098.34		

When your application, and all supporting documents are received and approved at the College office, you will be notified by email that an invoice has been generated and is ready for payment.

Payments are accepted by:

### 1. Visa or MasterCard

If you choose to pay by credit card, you will be advised to pay online through your registrant portal.

### 2. Cheque

If you choose to pay by cheque, print a copy of the invoice and mail both the invoice and cheque to the College Office. Cheque made payable to the **College of Pharmacists of Manitoba** 

Please Note: All Fees are NON-REFUNDABLE

### Section 1 – Must be Completed by Corporations

(Partnerships and Sole Proprietorships, please see Section 2 below.)

### Renewal of Pharmacy Licence Holders by a Corporation:

- 1. A copy of the last Annual Return for the applicant and any changes since filing this last annual return with the companies office.
- 2. If applicable, copies of any amendments to the Articles of Incorporation (or equivalent, if any extra-provincial corporation) for the applicant.
- 3. Where the applicant conducts business under a name **other than** its own name, copies of any Renewal of Business Name, or a search (uncertified) or Certificate of Search (under *The Business Names Registration Act*) for each business name confirming registration/renewal. (*This is only required if the business name was renewed during the previous year, and a copy of the Renewal has not previously been provided.*)
- 4. If there have been any changes in the legal or beneficial ownership of the applicant from what was shown on the 2022 application, please provide details of such changes on an attached list.

**NOTE - Annual returns** must comply with s.8 of *The Corporations Act* regulations which requires listing of:

- 1. The names and addresses of all the directors of the corporation;
- 2. The names and addresses of the president, secretary, treasurer, and manager of the corporation (for each office which is occupied); and
- 3. The names and addresses of each shareholder holding 10% or more of the voting shares of the corporation.

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 \*

Name	Address
Name	Address
Name	Address
Nume	Addiess

### Section 2 – Must be Completed by Partnerships and Sole Proprietorships

### Renewal of Pharmacy Licence Holders by Partnerships and Sole Proprietorships

Where the applicant conducts business under a name, **other than** its own name, copies of any Renewal of Business Name, or a search (uncertified) or Certificate of Search (under *The Business Names Registration Act*) for each business name confirming registration/renewal. (*This is only required if the business name was renewed during the previous year, and a copy of the Renewal has not been previously provided.*)

	ollowing item below is to be completed ONLY formation given on the 2022 Application:	Y if there
Identify by names and addres	ses, all partners*** of the partnership*	
Name	Address	
Name	Address	
Name	Address	
*** For Partnerships, if any of t provided for any such corporate	ne Partners are corporations, all the information about Partners.	ove regarding Corporations must also be
	n owner, or director or legal or beneficial owner or y other pharmacy in Canada, disclosure of the nan	
Name	Address	
Name	Address	
Name	Address	
Please Attach Documents a	d Lists as Necessary	



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# NEW HOSPITAL PHARMACY



200 Taché Avenue, Winnipeg, Manitoba R2H 1A7 Phone #: 204-233-1411 | Fax #: 204-237-3468 E-Mail Address: info@cphm.ca | Website: www.cphm.ca

## **HOSPITAL PHARMACY REQUIREMENTS**

### **INITIAL REQUIREMENTS:**

- 1. Approval of Business Name Form
- 2. New Hospital Pharmacy Application Form

The 'Expected Opening Date' on the form must be no less than 30 days after the College received all required documents and must be no later than 45 days after the College has granted its approval.

- 3. List of Board of Directors and Officers for the hospital
- 4. Evidence in the form of a Notarized Declaration that the hospital's officer(s) and director(s), and legal and beneficial owners have not been subject to disciplinary, criminal, or administrative sanction in any jurisdiction. Should disciplinary, criminal, or administrative sanctions exist, further description of the specific incidents must be included. Please refer to section 64(2)(e) of *The Pharmaceutical Act*.
- 8. A description of the pharmacy services in bulleted format
- 5. Pharmacy Floor Plan Checklist along with a detailed floorplan of the pharmacy facility
- 6. The <u>Drug Programs Information Network Registration</u> form must be filled out and submitted to Manitoba Health.

### **SUBMISSION OF DOCUMENTS:**

Before you send any physical documents to the College, please scan them first and send to <a href="mailto:registration@cphm.ca">registration@cphm.ca</a> (Subject line: *New Pharmacy Application*). A staff will review the documents and advise you if any correction is needed. If deemed complete with no errors or concerns, you will then be asked to submit physical documents to the College either by regular mail or by dropping off at our secure mailbox in front.



# **College of Pharmacists of Manitoba**

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7 Phone (204) 233-1411 | Fax: (204) 237-3468 E-mail: info@cphm.ca | Website: www.cphm.ca

# 2023 APPLICATION FOR PHARMACY LICENCE FOR A NEW HOSPITAL 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 <i>The Pharmaceutical Act</i> in the Province of Manitoba <b>until the 31st day of December, 2023</b> .					
Pharmacy Business Name(s)					
Pharmacy Address*			City	Province	Postal Code
*[ ] Additional buildings, fa and description of activities		-	being used as part of this phar to this application.	macy licence and details or	f the location(s)
Corporation's (9 digit) Business Nu	ımber		Telephone #1	Telephone #2	
Primary E-Mail Address			Additional E-Mail Address	Fax Number	
Primary Website Add		Additional Website	Business Hours of Ope	eration	
Expected Date of Opening	all supporting documents, or at such other time as may be acceptable to the				
All Applications Must Att	ach:				
<ol> <li>A sketch / floorplan showing the physical layout of the pharmacy</li> <li>A description of the pharmacy services to be provided</li> </ol>					
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):					
FOR OFFICE USE ONLY:					
Licence # Approved By		Approved By		Date Approved	

Does this pharmacy conduct business or practice pharmacy with the following components:							
Central Fill	YES	or	No	Personal care home (long term care)	YES	or	No
*Distance care (international prescription service (IPS))	YES	or	No	Satellite pharmacy	YES	or	No
Distance care (non-international prescription service)	YES	or	No	Secondary hospital	YES	or	No
External dispensing	YES	or	No	Sterile compounding	YES	or	No
Lock and Leave	YES	or	No	Opioid Agonist Therapy (OAT) for Out-Patients	YES	or	No

### **Sterile Compounding Licence Component Declaration**

- 1. Please indicate if your pharmacy currently provides sterile compounding care services:
  - Yes, my pharmacy provides sterile compounding services in compliance with NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations\*
  - No, my pharmacy does not provide sterile compounding services.
- \*Please note that if your pharmacy provides these services, the pharmacy manager and staff must ensure they are fully compliant with the NAPRA Model Standards for Pharmacy Compounding of Hazardous and Non-Hazardous Sterile Preparations including appropriate facilities, training, education, and personnel.
- 2. Do you want your pharmacy listed on the College of Pharmacists of Manitoba website so other pharmacists, healthcare providers, and the public can find sterile compounding pharmacy care services:
  - Yes, list my pharmacy on the public register.
  - o No, do not list my pharmacy on the public register.

The applicant must provide additional details with this application for any of the components listed above.

\* Please be advised for a pharmacy that applies for a Distance Care (International Prescription Service (IPS)) component of the Pharmacy licence, the 2023 Pharmacy licence will be issued with the condition the pharmacy includes the Council-approved disclaimer that will advise their clients, and potential clients, that 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	
	please print and include licence number		
Licensed Pharmacists			

Pharmacy Students & Interns				
Pharmacy Technicians (qualified and listed by the College)				
The pharmacy, above, 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 th	e College of Pharmacists of Manito	ba to access	s 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				

FEES & PAYMENT				
Select all applicable fees:		Total Amount		
Pre-Opening Inspection Fee	\$931.23			
Pharmacy Licence Fee Licence effective January 1st to December 31st	\$1,743.40 + GST \$87.17 =	\$1,830.57		
Pharmacy Licence Fee Licence effective July 1st to December 31st	\$1,098.34			
Additional Fees				
Central Fill (non-"patient contact" pharmacy) component	\$591.26 + GST \$29.56 =	\$620.83		
Distance Care (IPS) Component: effective Jan 1 <sup>st</sup> – Dec 31 <sup>st</sup>	\$7,822.41 + GST \$391.12 =	\$8,213.53		
Distance Care (IPS) Component: effective Jul 1 <sup>st</sup> – Dec 31 <sup>st</sup>	\$4,693.45 + GST \$234.67 =	\$4,928.12		
Distance Care (Non-IPS) Component	\$754.29 + GST \$37.71 =	\$792.00		

When your application, and all supporting documents are received and approved at the College office, you will be notified by email that an invoice has been generated and is ready for payment.

Payments are accepted by:

### 1. Visa or MasterCard

If you choose to pay by credit card, you will be advised to pay online through your registrant portal.

### 2. Cheque

If you choose to pay by cheque, print a copy of the invoice and mail both the invoice and cheque to the College Office. Cheque made payable to the **College of Pharmacists of Manitoba** 

Please Note: All Fees are NON-REFUNDABLE

Hospitals: Name and Address of Officers and Directors *				
Name	Address			
Name	Address			
Name	Address			
Please Attach Documents and Lists as Necessary				



Registrar, College of Pharmacists of Manitoba

## **COLLEGE OF PHARMACIST OF MANITOBA**

200 Taché Avenue, Winnipeg, Manitoba R2H 1A7 Phone #: 204-233-1411 | Fax #: 204-237-3468 E-Mail Address: info@cphm.ca | Website: www.cphm.ca

### NAME CONSENT FORM FOR NEW PHARMACY APPLICATION

то:	College of Pharmacist of Mani	toba
We at		ng with our designated licenced pharmacy manager
	, would like t	to confirm to the College that we are in the process o
•	, ,	nd that the pharmacy will not commence doing business
preparing an ap	pheation to have our business nechecu ar	that the pharmacy will not commence doing business.
until such licens	e is obtained. Therefore, pursuant to <u>Sect</u>	ion 4(2) of The Pharmaceutical Act, we hereby seek the
College's conser	nt to use the pharmacy/business name of	
J		(Pharmacy/Business Name)
DATED this	day of, 20	
Pharmacy Mana	nger (Signature Over Printed Name)	Pharmacy Owner (Signature Over Printed Name)
The College her	reby acknowledges the foregoing, and ${\mathfrak g}$	gives its consent for the business to use the name o
	as a	licensed pharmacy and this shall <u>not</u> be use to amend the
company name.	This name consent is only valid within 3 m	onths from the approval date below.
PER:		
	vin Hamilton	Date of Approval



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### Floor Plan Checklist

Pharmacy Name (Please include licence # if applicable)	Address
Pharmacy Manager Name and License Number	Type of Floor Plan (New opening, Relocation or Renovation)
Anticipated Construction Start Date	Anticipated Construction End Date

The Pharmaceutical Regulation requires an applicant for a new pharmacy licence to provide a floor plan to the College of Pharmacists of Manitoba (College). The College also requests a floor plan be submitted prior to a pharmacy relocation or renovation.

A College Field Officer will review the floor plan for compliance with the <u>Pharmacy Facilities Practice Direction</u>. When preparing your floor plan please use this checklist to ensure it contains all necessary details.

AREA/CATEGORY	$\checkmark$	REQUIREMENT(S)	COMMENT(S)
		Size of Dispensary (sq feet)	
		Size of Counterspace (sq feet)	
		Dispensary Access Points	
		Outline security against unauthorized entry	
		Location of the Narcotic Safe and how it will be Secured	
DISPENSARY		Location of the Fridge and Temperature  Monitoring Equipment	
Please ensure the pharmacy floor plan		Location of the Sink	
includes these items		Compounding Area: Include size, location and intended level of compounding (Nonsterile A, B or C, Nonhazardous Sterile and/or Hazardous Sterile)	
		Location of Prescription Pick-up and Drop-off	
		Location of Privacy Barriers	
		Location of schedule 1 drug Storage	
		Location of Schedule 2 Drug Storage	



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AREA/CATEGORY	$\checkmark$	REQUIREMENTS	COMMENT(S)
COUNSELING		Size of Counseling Room (sq feet)	
ROOM Please ensure the		Location of Counseling Room	
pharmacy floor plan includes these items		Counseling Room Access Points	
SIGNAGE Applicable to new pharmacy openings		Provide a description and mockup of external pharmacy signage	
and relocations only		Provide a description of any internal pharmacy signage (Rx drop-off and pick-up, counseling room, pharmacy bulkhead etc.)	
LOCK & LEAVE Only applicable to a pharmacy with or applying for a Lock and Leave Component		Outline of the larger retail operation, including a depiction of the area within which the pharmacy is to be located	
RENOVATION Only appliable to pharmacy renovations		Outline proposed changes from the original layout	
		FOR OFFICE USE ONLY	
CPhM Staff Reviewer			
Date of Review			
Approved (Yes or No)			
CPhM Comments			

For new pharmacies, a copy of this form and the floor plan should be included with the new pharmacy application. For pharmacy renovations or relocations please submit the form and floor plan by email to <a href="mailto:fieldops@cphm.ca">fieldops@cphm.ca</a> or by fax to 204.237.3468.



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# **FREQUENTLY ASKED QUESTIONS (FAQs)**

- 1. How do I pay the fees for the application?
  - Once you've been issued a pharmacy licence number, the College will provide you with login credentials for your pharmacy profile. This is where you will modify pharmacy information and access the invoices created by the College. Our preferred mode of payment is either by Visa or MasterCard which can be done online. However, you may also opt to issue a cheque payable to the College of Pharmacists of Manitoba.
- 2. When do I get a pharmacy licence number?
  - After you have registered the pharmacy/business name with Manitoba Companies Office, the College will send you an email containing your assigned pharmacy licence number along with other important reminders such as how to access your pharmacy profile and pay fee(s) online.

    Please take note that issuance of a pharmacy licence number does not mean you've been approved by the Registrar.
- 3. How long does it take for my application to be approved?
  - The turnaround time depends on factors such as your ability to complete the requirements being asked from you, Manitoba Companies Office application, pharmacy construction, scheduling inspection, and the number of requests/applications the Registrar must review along with yours. An applicant who diligently complied and adhered to our process have been granted to operate as a pharmacy after 3 months from initial application.
- 4. How can I apply for Pharmacare number?
  - Manitoba Health is responsible for assigning a Pharmacare number thus it is your responsibility to fill out and timely submit the <u>DPIN application form</u>. Please note that they will only finalize your application once they received an email from the College confirming that the Registrar has granted you the licence to operate a pharmacy. Concerns about your DPIN/Pharmacare application must be directed to MB Health and **not** to the College.
- 5. Can I apply for new accounts from third party organizations?
  - Third party organizations require that you are fully licenced with the College before they can process your application with them. Once you are granted approval by the College to operate as a pharmacy, an email will be shared with you at the end of the application which you can forward to these third parties as proof.

If you have questions or concerns, please contact <a href="mailto:registration@cphm.ca">registration@cphm.ca</a>. CPhM Version 09.05.2023