

Regulation Policy Document: October 8th, 2010

THE PHARMACEUTICAL ACT
(C.C.S.M. c. P60)

2010 Pharmaceutical Regulations Policy Document

TABLE OF CONTENTS

Section

- 1 Definitions

PART 1- REGISTERS

- 2 Registers

PART 2- REGISTRATION

- 3 Registration
4 Conditional Register
5 Temporary Registration
6 Rights and Limitation for Temporary and Conditional
7 Extended Practice Pharmacist Register
8 Student Registration
9 Intern Registration
10 Accurate Disclosure of Information

PART 3 - LICENSING OF PHARMACISTS

- 11 Application for pharmacist licence
12 Practicing Licence
13 Place holder
14 Restriction on practicing licence
15 Absence from Practice
16 Renewal of Pharmacist Licence
17 Accurate Disclosure of Information

PART 4 - PHARMACIST PROFILE

- 18-28 Pharmacist Profiles

PART 5 - PHARMACY LICENCES

- 29 Application for pharmacy licence
30 Pre-opening Inspection
31 Community Pharmacy licence
32 Lock and Leave Component
33 Distance Care Component
34 Long Term Care Component
35 Hospital Pharmacy Licence
36 Central Fill Component
37 External Dispensing Component
38 Clinical Practice Pharmacy Licence
39 Pharmacy manager qualifications
40 Corporate Owner Change
41 Other Changes to Pharmacy Licence
42 Change of Pharmacy Hours
43 Converting Pharmacy Licence
44 Accurate Disclosure of Information

October 8th, 2010

- 45 Business Names
- 46 Display Licence
- 47 Closure of Pharmacy
- 48 Renewals of Licence

PART 6 - STANDARDS

- 49 Standards to be followed

PART 7 – DUTIES AND DELEGATION

- 50 Duties of pharmacists
- 51 Duties of Interns
- 52 Pharmacy technicians
- 53 Students
- 54 Other persons
- 55 Supervision
- 56 General

PART 8 – PRESCRIPTION & RECORDS

- 57 Records Required
- 58 Description of Records
- 59 Medication labels
- 60 Patient Profiles
- 61 Central-fill Records
- 62 Acquisition Records
- 63
- 64 €
- 65 Manitoba Prescribing Practices Program
- 66 Patient access to records
- 67 Retention of records

PART 9 – DISPENSING OF DRUGS

- 68 Drug Substitution and Questionable Prescriptions
- 69 Approved Drugs and DPIN record
- 70 Child Resistant Containers
- 71 Sale of Expired Drugs Prohibited
- 72 Limitation on sale of drugs
- 73 Inducements

**PART 10 – DISPENSING BY PERSONS
WHO ARE NOT MEMBERS**

- 74 Dispensing Practitioners Committee
- 75 Application and Conditions
- 76 Dispensing Practitioners
- 77 Obligations of Dispensing Practitioner
- 78 Veterinarians
- 79 Revocation and Appeal

PART 11 – EXTENDED PRACTICE

October 8th, 2010

PHARMACISTS & SPECIALITY PRACTICE

- 80 Extended Practice Pharmacists
- 81 Registration
- 82 Speciality Practice
- 83 "place holder"
- 84 Specialty Practice Qualifications
- 85 Advisory Committee

PART 12 – PRESCRIBING BY MEMBERS

- 86 Prescribing by members
- 87 Criteria for prescribing
- 88 Controlled substances
- 89 Prescribing Record
- 90 Continued Care prescriptions

PART 13- ADMINISTRATION OF DRUGS

- 91 Administration of drugs by members
- 92 Drug Administration record

PART 14 – TEST INTERPRETATION

- 93 Interpretation of tests by members
- 94 Test Interpretation Records

PART 15 – ORDERING AND RECEIPT OF REPORTS

- 95 Ordering tests by members
- 96 Test ordering and results record

PART 16 – INSURANCE

- 97 Pharmacist and pharmacy insurance

PART 17 – PUBLICATION

- 98 Newsletter
- 99 Decisions of Discipline Committee, Complaints Committee & Registrar
- 100 Notice through newsletter

PART 18- COMING INTO FORCE

- 101 Coming into force

SCHEDULE A - STANDARDS

October 8th, 2010

Definitions

1(1) In this regulation,

"Act" means *The Pharmaceutical Act*;

"adaptation of a prescription" means altering the dosage strength, dosing interval or formulation of a prescribed drug;

"authorized practitioner" means a practitioner authorized to prescribe drugs under the *Controlled Drugs and Substances Act* (Canada);

"child resistant container" means a container that meets the Canadian Standards Association standards for child resistant containers;

"extended practice pharmacist" means a person whose name is entered on the register of extended practice pharmacists;

"collaborative practice" means a practice setting in which a member delivers patient centred care and works closely and cooperatively with other health care professions;

"DPIN" means the Drug Programs Information Network system maintained by or on behalf of the Minister;

"dispensary" means the area of a pharmacy where drugs listed on schedule 1 and 2 of the manual are stored for sale and/or prepared for dispensing;

"electronic" means the same as under *The Electronic Commerce and Information Act*;

"electronic signature" means the same as under *The Electronic Commerce and Information Act*;

"hospital" means an institution or facility under *The Health Services Insurances Act*

"manual" means the Manual for Canada's National Drug Scheduling System published by the National Association of Pharmacy Regulatory Authorities, as amended from time to time;

"medical device" means any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in human beings for :

1. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, but not including orthotics or prosthetics,
2. the diagnosis of pregnancy, or
3. a contraceptive device but does not include a drug.

"M3P" means the Manitoba Prescribing Practices Program, as adopted by council, as amended from time to time;

"M3P schedule" means a schedule of certain drugs set under M3P which require surveillance and monitoring, as amended from time to time;

October 8th, 2010

"patient centred care" means health care practitioners listen to and respect the patient's opinions.

"personal care homes" means a premises listed in the schedule of the regulations to *The Health Services Insurances Act*;

"pharmacist profile" or "profile" means a record about a pharmacist that includes personal, professional and other information about him or her, compiled for the purpose of being made available to the public;

"pharmacy manager" means a member designated by an owner to manage a pharmacy under s.64 of the Act;

"PHIN" means a personal health information number, as defined in *The Personal Health Information Act*;

"prescription drug" means a drug designated by the minister pursuant to s.73(2) of the Act that can only be sold to a practitioner or pursuant to a prescription;

"prescription number" means a unique identification number or code used to identify or locate a particular prescription;

"preparing a drug for dispensing" means to count, measure, or pour the amount of a drug designated in a prescription into a container and label the container for the purposes of dispensing, and includes pre-packaging of drugs prior to receipt of a prescription;

"prescribe" means to authorize the dispensing of a specified drug in a specified amount for use by a named individual;

1(2) In this regulation, words defined in the Act have the same meaning as in the Act.

PART 1 – REGISTERS

All registers

2(1) In addition to the information required by s.9(2) of the Act, all registers must contain:

- (a) a notation of every voluntary surrender or cancellation of a registration, the date of the surrender or cancellation; and
- (b) a notation of every reinstatement and the date of reinstatement.

Mailing and street addresses

2(2) On any register where the mailing address is other than the street address, the register must contain both the mailing and street address.

Register of pharmacists

2(3) In addition to the information required by s.9(2) of the Act, the register of pharmacists must contain the following information:

- a) a notation and date of the retirement from practice or death of a pharmacist;

and

b) the type of pharmacist licence issued to the member.

Public information

2(4) In addition to the information set out at s.9(3) of the Act, the information noted in this part must be available to the public except the home address of the member.

PART 2 – REGISTRATION

Registration of pharmacists

3 In addition to the requirements set out in s.11(1) of the Act, an applicant for registration as a pharmacist must, prior to registration:

- (a) complete an application in the form prescribed in the by-laws;
- (b) satisfy the board that the applicant does not suffer from a physical or mental condition, disorder or addiction to alcohol or drugs that makes it desirable in the public interest that he or she not practice pharmacy
- (c) satisfy the board that the applicant has not been convicted of an offence or been subject to professional discipline which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;
- (d) where the applicant's first language is not English or French, be able to speak and write either English or French in accordance with the language fluency criteria established by the council ;
- (e) demonstrate, to the satisfaction of the board, knowledge of the Act, Regulations, by-laws, code of ethics, standards of practice and practice directions applicable to the practice of pharmacy in Manitoba;
- (f) where the applicant is licenced as a pharmacist in another jurisdiction, provide a letter of standing from that jurisdiction satisfactory to the board;
- (g) serve a period of internship as determined by the board; and
- (h) provide a recent passport size image of the applicant in a manner approved by the board.

Conditional register

4(1) Where an applicant for registration as a pharmacist does not yet meet all the requirements for registration, the board may direct the registrar to place the applicant on the conditional register, if in addition to the requirements of s.12(1) of the Act, the applicant:

- (a) completes an application in the form prescribed in the by-laws;
- (b) satisfy the board that the applicant does not suffer from a physical or mental condition, disorder or addiction to alcohol or drugs that make it desirable in the public interest that he or she not practice pharmacy ;
- (c) satisfies the board that the applicant has not been convicted of an offence or been subject to professional discipline which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a

October 8th, 2010

pharmacist;

- (d) where the applicant's first language is not English or French, be able to speak and write either English or French in accordance with the language fluency criteria established by the council';
- (e) demonstrates, to the satisfaction of the board, knowledge of the Act, Regulations, , by-laws, code of ethics, standards of practice and practice directions applicable to the practice of pharmacy in Manitoba;
- (f) where the applicant is licensed as a pharmacist in another jurisdiction, provides a letter of standing from that jurisdiction satisfactory to the board;
- (g) serves a period of internship as determined by the board; and
- (h) provides a recent passport size image of the applicant in a manner approved by the board.

Completion date

4(2) Where a person is registered on the conditional register pursuant to s.12(1) of the Act, the board must specify a date before which the remaining requirements for registration under s.11(1) of the Act must be completed.

Extension

4(3) The board may modify or extend the date in s.4(2) upon request by the applicant.

Duration of conditional registration

4(4) Where a person is registered on the conditional register pursuant to s.12(1) of the Act, the registration must be cancelled by the registrar:

- (a) upon the person completing the remaining requirements for registration as a pharmacist within the time required by the board and being entered on the register of pharmacists;
- (b) upon the person failing to complete the remaining requirements for registration as a pharmacist within the time required by the board; or
- (c) upon the registration being cancelled under s.23 or part 6 of the Act.

Temporary Certificate of Registration

5 In addition to the requirements of s.18(1) of the Act, an applicant for a temporary certificate of registration must:

- (a) provide evidence satisfactory to council that the applicant is licensed to practice pharmacy and actively practices in another jurisdiction approved by council;
- (b) advise council as to all the jurisdictions in which the applicant is licensed to practice pharmacy;
- (c) provide a letter of standing, satisfactory to council, from the jurisdiction in which the applicant is currently licensed and actively practicing pharmacy;
- (d) complete the application forms specified in the by-laws;

October 8th, 2010

- (e) provide evidence satisfactory to the council that the applicant has engaged in the practice of pharmacy for a minimum of 400 hours in the two year period immediately before the date of application ;
- (f) provide an undertaking that the temporary practice will be conducted in accordance with the Act, by-laws, code of ethics, standards of practice, and all relevant practice directions; and
- (g) pay any fee specified in the by-laws.

Rights of conditional registration

6(1) Where a person is registered on the conditional register, he or she may:

- (a) apply for a pharmacist licence, which will expire after a period of time determined by the council, but in any event no later than the date the conditional registration expires;
- (b) conduct the practice of pharmacy only in accordance with any conditions imposed under s.12(3) or 18(2) of the Act; and
- (c) except as set out in subsection (2), exercise all the other rights and privileges of a member.

Limitations on conditional registration

6(2) Where a person is registered on the conditional register, he or she:

- (a) may not act as a preceptor;
- (b) may not apply as a specialist, as described under sections 16(2) and 16 (3) of the act, or as an extended practice pharmacist, unless under a temporary certificate of registration; and
- (c) may not act as a pharmacy manager, unless under a temporary certificate of registration and specifically permitted by council.

Extended practice pharmacist register

7(1) An applicant is entitled to be registered on the register of extended practice pharmacists if the applicant meets the requirements of Part 11 of these regulations.

Contents of extended practice pharmacist register

7(2) In addition to the information required by s.9(2) of the Act, the register of extended practice pharmacists must contain a notation of each specialty held under s.16 of the Act and Part 11 of these regulations and the date of qualification and any cancellation.

Registration of students

8(1) In addition to the requirements of s.19 of the Act, an applicant for registration as a student must:

- (a) provide evidence satisfactory to the registrar that the applicant is registered as a student in a pharmacy education program approved by the council;
- (b) submit an application to the registrar:
 - (i) where the applicant is registered in the Faculty of Pharmacy at

October 8th, 2010

the University of Manitoba, by December 31, in the year the applicant enters the Faculty or such other date as the registrar will permit; or

- (ii) where the applicant is registered in any other pharmacy education program, at least 30 days prior to the intended date to commence working as a student;
- (c) refrain from working as a student in a pharmacy until registered, which registration can be delayed by failure to comply with (b);
- (d) pay any late filing fee provided for in the by-laws if the applicant fails to comply with (b);
- (e) satisfy the registrar that the applicant does not suffer from a physical or mental condition, disorder or addiction to alcohol or drugs that makes it desirable in the public interest that he or she not register as a student ;
- (f) satisfy the registrar that the applicant has not been convicted of an offence which makes the applicant unsuitable for registration as a student;
- (g) provide to the registrar a recent passport size image of the applicant; and
- (h) where the applicant's first language is not English or French, be able to speak and write either English or French in accordance with the language fluency criteria established by the council ; and
- (i) provide an undertaking that his or her practice as a student will be conducted in accordance with the Act, Regulations, by-laws, code of ethics, standards of practice and all relevant practice directions.

Duration of registration of students

8(2) The registration of a student must be cancelled by the registrar:

- (a) upon the student being registered on another register;
- (b) upon the student ceasing to be enrolled in a pharmacy education program approved by the council; or
- (c) upon the registration being cancelled under s.23 or part 6 of the Act.

Notification of Employer

8(3) In addition to the reporting requirements under section 10, the student must notify the pharmacy manager where the student is employed and working as a student should he or she cease to be enrolled in the pharmacy education program under 8(2)b.

Registration of interns

9(1) In addition to the requirements of s.20 of the Act, an applicant for registration as an intern must:

- (a) provide evidence satisfactory to the registrar that the applicant
 - (i) has completed or will complete within 12 months a pharmacy education program approved by the council;
 - (ii) intends to intern for an educational purpose of a type approved by the council; or

October 8th, 2010

- (iii) is serving an internship as required by the Board under section 3.
- (b) satisfy the registrar that the applicant does not suffer from a physical or mental condition, disorder or addiction to alcohol or drugs that makes it desirable in the public interest that he or she not register as an intern;
- (c) satisfy the registrar that the applicant has not been convicted of an offence which makes the applicant unsuitable for registration as an intern;
- (d) provide to the registrar a recent passport size image of the applicant; and
- (e) provide an undertaking that his or her practice as an intern will be conducted in accordance with the Act, Regulations, by-laws, code of ethics, standards of practice and all relevant practice directions.

Duration of registration of interns

9(2) The registration of an intern must be cancelled by the registrar upon:

- (a) the intern being registered on another register;
- (b) the intern ceasing to participate in an internship; or
- (c) the registration being cancelled under s.23 or part 6 of the Act.

Accurate disclosure

10 All applicants for registration must provide information which is truthful and accurate, to the best of the applicant's knowledge, and update the information if it changes during the duration of the registration.

PART 3 – LICENSING OF PHARMACISTS

Application for pharmacist licence

11(1) In addition to the requirements of s.15(1) of the Act, an applicant for a pharmacist licence must:

- (a) disclose whether the applicant is under suspension or investigation by a professional regulatory body governing the practice of pharmacy in any jurisdiction;
- (b) satisfy the registrar that the applicant does not suffer from a physical or mental condition, disorder or addiction to alcohol or drugs that makes it desirable in the public interest that he or she not practice pharmacy;
- (c) provide evidence of insurance, if required by part 16 of these regulations;
- (d) satisfy the registrar that the applicant has not been convicted of an offence or been subject to professional discipline which, in the opinion of the registrar, makes the applicant unsuitable to practice as a pharmacist;
- (e) advise as to the intended scope of the applicant's practice; and

- (f) disclose whether he or she has a licence to practice pharmacy in another jurisdiction.

Requirements for practicing licence

12(2) In addition to the requirements of s.15(1) of the Act and s.11 of these regulations, an applicant for a practicing licence must provide evidence satisfactory to the registrar that, in the two year period immediately before the date of application the applicant:

- (a) engaged in the practice of pharmacy for a minimum of 400 hours ;
- (b) successfully served a period of internship required by council; or
- (c) obtained a degree in pharmacy from a program approved by council which includes a training program that is equivalent to an internship.

13 Placeholder

Restrictions on practicing licence

14 A pharmacist issued a licence under this part is responsible for assessing his or her ability to perform competently and ethically when engaging in any aspect of the practice of pharmacy.

Short absence from practice

15 (1) Should an applicant not qualify under this part due to an absence from practice of 24 months or less and the applicant has maintained a learning portfolio documenting the applicant's professional development during the absence from practice, the registrar may issue a pharmacist licence with or without conditions.

Long absence from practice

15 (2) If an applicant is returning to practice after an absence of more than 24 months, the applicant must, in addition to the requirements of section 11(1), :

- (a) serve an internship, to the satisfaction of the board;
- (b) provide evidence, acceptable to the board, of participation in the Continuing Professional Development program of the College that requires a minimum number of professional development learning hours and the maintenance of a portfolio documenting learning and the application to practice; and
- (c) successfully complete any other requirements specified by the board.

Renewal of pharmacist licence

16 A pharmacist is entitled to have his or her pharmacist licence renewed upon:

- (a) providing evidence satisfactory to the registrar that, in the two year period immediately before the date of application, he or she engaged in the practice of pharmacy for 400 hours;
- (b) meeting all the same requirements of s.15 of the Act and s.11, of these regulations for an application for a pharmacist licence, and
- (c) providing evidence to the registrar that, in the preceding 12-month period,

October 8th, 2010

the applicant has participated in the Continuing Professional Development program of the College that requires a minimum number of professional development learning hours and the maintenance of a portfolio documenting learning and the application to practice.

Accurate disclosure

17 Applicants for a pharmacist licence must provide information which is truthful and accurate to the best of the applicant's knowledge, and update the information if it changes during the duration of the licence.

PART 4 - PHARMACIST PROFILE

Council must make pharmacist profiles available

18(1) Beginning January 1, 2012, the council must make available to the public a profile of each member who:

- (a) is registered on either the register of pharmacists or the conditional register;
and
- (b) holds a current pharmacist licence of any category.

Provided however if the council reasonably believes that a licensed member is not currently practicing in Manitoba, it need not make available a profile of that member.

Profile to be maintained while licence suspended

18(2) Notwithstanding subsection (1), the council must make available the profile of a pharmacist whose licence to practice is suspended and, in such a case, the profile must be revised to note the suspension and the date on which it began.

How profiles are to be made available

19(1) A pharmacist profile must be made available to the public through:

- (a) the college website;
- (b) orally in response to a telephone inquiry; or
- (c) in writing in response to a written request or telephone inquiry.

College may enter into agreement for assistance

19(2) The College may enter into an agreement with the government or any person, organization or entity, including a public or private sector organization or entity, for assistance in making pharmacist profiles available.

Profile content

20(1) Each profile must contain the following information about the member and his or her practice in Manitoba and elsewhere:

- (a) the member's current name as shown on the applicable register;
- (b) subject to subsection (2), the member's gender;
- (c) the current address at which the member primarily carries on practice;

October 8th, 2010

- (d) the name of the pharmacy education program from which the member graduated, and the year of his or her graduation;
- (f) the date of the member's initial registration in Manitoba;
- (g) the member's current category of pharmacist licence;
- (h) subject to subsections (3) and (4), the date and a brief description of any final disciplinary action taken against the member within the past ten years by the body named in the profile as regulating the profession that the member is or has been licensed to practice, whether in Manitoba or elsewhere, and if the member has initiated an appeal respecting the disciplinary action;
- (i) any current restrictions, terms or conditions on the member's registration or licence, including any geographic or practice restrictions pending qualification for full registration, but not including information respecting restrictions, terms or conditions imposed as part of final disciplinary action that is already included in the profile under clause (h);
- (j) the commencement date of any current interim suspension from the practice of pharmacy imposed on the member;
- (k) any current certification of the member as a specialist or an extended practice pharmacist;
- (l) subject to subsection (6), the date of any malpractice court judgment against the member by a court in any jurisdiction within the past 10 years the name of the court that issued it, and if the member has initiated an appeal respecting the malpractice judgment;
- (m) a description of any offence under
 - (i) the *Criminal Code* (Canada),
 - (ii) the *Controlled Drugs and Substances Act* (Canada), or
 - (i) *the Food and Drugs Act* (Canada),

of which the member has been convicted within the past 10 years, if the council determines that the conviction is reasonably relevant to the member's competence or to the safe practice of pharmacy. The description must include the date of the conviction and the name of the court imposing the conviction, and if the member has initiated an appeal respecting the conviction.

Information re member's gender not to be included on request

20(2) The council must not include a member's gender in his or her profile under clause (1)(b) if the member requests, in writing, that this information not be included.

Limits on including information re disciplinary action

20(3) The council must not include in a member's profile information about:

- (a) any final disciplinary action taken against the member before January 1, 2007;

October 8th, 2010

- (b) any final disciplinary action taken against him or her on or after January 1, 2007, and before January 1, 2010, if the tribunal issuing it ordered that the member's name not be published for any reason; and
- (c) any final disciplinary action against the member on or after January 1, 2010, if the tribunal issuing it ordered that the member's name not be published.

Limit on including information re disciplinary action under appeal

20(4) Where the council includes information in a member's profile about a final disciplinary action taken against him or her, it must not do so before the earliest of the following dates:

- (a) the date on which any right the member has to appeal the disciplinary action expires;
- (b) the date on which the member initiates an appeal respecting the disciplinary action;
- (c) the date on which the member waives his or her right to appeal the disciplinary action.

Provided however, if, before any of those dates has passed, information about the final disciplinary action has been published by the council under section 58 of the Act, or has been made available to the public by another tribunal which took the final disciplinary action, the published or publicly available information must be included in the pharmacist profile.

Malpractice judgment information not to be included until appeal period expires

20(5) The council must not include any information about a malpractice court judgment in a member's profile under clause 20(1)(l) until any period available to the member to appeal the judgment has expired.

Voluntary information

21 A member may provide information to the council about any or all of the following matters, for inclusion in his or her profile:

- (a) telephone number of his or her place of practice; and,
- (b) languages spoken (including American Sign Language).

Explanatory Information

22 The council may include in pharmacist profiles any explanatory information about pharmacist profiles and the categories of information specified in subsection 20(1) that it considers appropriate.

Required information

23 A member must provide to the registrar complete and accurate information relating to each category of information specified in subsection 20(1), at the time required by the registrar and in a form satisfactory to the registrar.

Change in information in a required category

24(1) Where, for any reason, information in a member's profile in a category specified in subsection 20(1) becomes inaccurate or incomplete, the member must, within 30 days, provide accurate and complete information to the

registrar in a form satisfactory to the registrar.

Change in information provided voluntarily

24(2) A member may, at any time, provide to the registrar updates to the information provided voluntarily under section 21.

Registrar to revise pharmacist profile

24(3) Within 30 days after receiving information under subsection (1) or (2), the registrar must revise the member's profile if the registrar reasonably believes that the information is accurate.

Registrar must notify the member of the change

24(4) Where the registrar receives information about a member relating to a category of information under subsection 20(1) or information provided voluntarily under section 21 from a source other than the member, and takes reasonable steps to insure the information is accurate, the registrar must notify the member of the changes therein 60 days prior to posting.

Profile provided to member before publication

25(1) Each member must have an opportunity to review his or her profile before it is made available to the public. The registrar may satisfy this requirement by providing an electronic version of the profile.

Member may dispute information

25(2) Within 60 days after receiving a copy of his or her profile under subsection (1), the member may dispute the factual accuracy of any information in it by submitting to the registrar:

- (a) a written statement detailing the basis of the dispute; and
- (b) any other information that the member considers relevant to the dispute.

The onus of proving that the information is factually inaccurate is on the member.

Registrar may make profile available despite dispute

25(3) Notwithstanding subsection (2), receipt of a written statement disputing the factual accuracy of information does not affect the registrar's ability to make a pharmacist profile available. However, until a final determination is made under subsection (4), the profile

- (a) must not include the disputed information; and
- (b) must include a statement in the relevant category that information in the category is under dispute and is not currently available.

Determination of dispute

25(4) Upon receipt of a written statement of dispute under subsection (2), the council must review the statement and any other information provided by the member that is relevant to the dispute and

- (a) revise the information in the profile, if the council determines that the member's position on the dispute is correct; or
- (b) where the council determines that the member's position on the dispute is incorrect, include the information in the relevant category of information in the profile with a statement that the member disputes the information.

October 8th, 2010

If member fails to provide information

26 Where a member fails to provide information as required under this part the registrar may note the failure on the member's profile.

If member provides false, inaccurate or incomplete information

27 A member must not willfully provide false, inaccurate or incomplete information under this part.

Review of regulation

28 Not later than January 1, 2016, the minister and the council must review the effectiveness of this part, and, in the course of the review, consult with any persons affected by this regulation that the minister or the council considers appropriate. On completion of the review, the minister may, if he or she considers it advisable, recommend to the Lieutenant Governor in Council that this part be amended or repealed.

PART 5 – PHARMACY LICENCES

Pharmacy licence application

29(1) In addition to the requirements of s.64(2) of the Act, an applicant for a pharmacy licence must provide to the registrar:

- (a) confirmation that the pharmacy is located in Manitoba and subject to 29(6) of these regulations, 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 for the pharmacy, including hours for each facility covered by the pharmacy licence;
- (c) evidence of insurance, if required by Part 16 of these regulations;
- (d) evidence satisfactory to the registrar that the owner, if required by law, is registered to conduct business in Manitoba; and
- (e) the main Uniform Resource Locator (URL) of any websites used by or affiliated with the pharmacy.

Application for category of licence

29(2) An applicant must specify on the application for a pharmacy licence that the applicant is applying for one or more of the following categories of pharmacy licence:

- (a) community pharmacy;
- (b) hospital pharmacy; or
- (c) clinical practice pharmacy.

Application for components

29(3) Where an applicant applies for a community pharmacy or hospital pharmacy licence, the applicant must indicate whether it is applying for one or more of the following additional components to the requested licence:

October 8th, 2010

- (a) central-fill component described under section 36;
- (b) secondary hospital component described under section 35(1.1);
- (c) personal care home component described under section 34;
- (d) distance care component described under section 33;
- (e) external dispensing component described under section 37(1) and 37(2);
or
- (f) intermittent satellite pharmacy described under section 37(3).

Application for Lock and Leave component

29(4) Where an applicant qualifies for a community pharmacy licence, the applicant may apply for a lock and leave component.

Application for multiple categories

29(5) Where an applicant applies for multiple categories or components of pharmacy licence, the applicant must meet the requirements of each category or component.

Separate applications

29(6) An applicant must make application for separate pharmacy licences where the facility used as a pharmacy is not in the same or adjoining building.

Exceptions to separate applications

29(7) Notwithstanding subsection (6), and s.37, a separate application is not required for a facility which is not in the same or adjoining buildings, if it is:

- (a) used only for the purpose of storing drugs;
- (b) used only for the purpose of storing records; or
- (c) a home office;

in which case that facility may be included on the same licence as the primary pharmacy.

Mobile pharmacy prohibited

29(8) A facility to be included under a pharmacy licence must be located at a fixed location, and may not be mobile or transportable except as approved by Council.

Restriction on operation

29(9) 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.

Urgent need

29(9.1) Nothing in this part prevents a member from providing care inconsistent with their pharmacy component licence where:

- a) there is an urgent and life threatening patient care need;
- b) the service will be provided for a period of no longer than 72 hours; and,
- c) written notification has been given to the registrar.

October 8th, 2010

Pre-opening inspection

30 In addition to the other requirements of this section, where the application for a pharmacy licence is for a location that is not currently licenced the registrar may cause the pharmacy to be inspected prior to receiving a pharmacy licence by an inspector appointed under Part 10 of the Act, and the applicant shall provide to the inspector

- (a) evidence satisfactory to the registrar that the pharmacy has the facilities, equipment, and staff required to operate in a safe and legal manner;
- (b) a description of the pharmacy services to be provided by the proposed pharmacy;
- (c) a sketch of the physical layout of the proposed pharmacy; and
- (d) where the application is for a lock and leave pharmacy licence, a sketch of the larger retail operation including a depiction of the area within which the pharmacy is to be located,

and the inspector shall report his or her findings to the registrar and the applicant.

Community pharmacy licence

31(1) An applicant must specify that 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; and

therefore section 33(1) does not apply.

Requirements for community pharmacy

31(2) In addition to the requirements of s.64(2) of the Act and s.29(1) of these regulations, an applicant for a community pharmacy licence must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for a community pharmacy;
- (b) the facility will be staffed and managed by members capable of operating a community pharmacy;
- (c) the hours of operation will meet the needs of the community served by the pharmacy; and
- (d) the facility will be accessible to the public.

Lock and leave component

32(1) An applicant for a community pharmacy licence must specify that the applicant is applying for a lock and leave component if:

- (a) the pharmacy will operate as a community pharmacy;
- (b) the pharmacy is located within a larger operation; and

October 8th, 2010

- (c) the applicant intends to close off the dispensary and the public access to drugs listed on schedule 3 of the manual during times when the larger retail operation remains open.

Requirements for lock and leave component

32(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 facility will comply with the Standards of Practice for a lock and leave component;
- (b) the lock and leave component will be open a minimum of 25 hours spread over a minimum of four days per week, unless the applicant can demonstrate to Council that a lesser amount of hours will still meet the needs of the community, and that a member will be available to respond to patients a minimum of 37.5 hours per week; and
- (c) the lock and leave component will be secure when not in operation, including:
 - (i) the dispensary and drugs listed on schedule 3 of the manual will be secured and not available for sale;
 - (ii) except as permitted under section 52(4)(g), non-pharmacist staff will not be able to enter the dispensary or access drugs listed on schedule 3 of the manual; and
 - (iii) non-pharmacist staff will not perform any tasks which are restricted by the Act or these regulations.

Distance Care Component

33(1) An applicant for a community pharmacy or hospital pharmacy licence must specify that the applicant is applying for a distance care component if:

- (a) the pharmacy will operate as a community pharmacy or hospital pharmacy; and
- (b) it is intended that the pharmacy will also serve patients who will not attend the pharmacy in person and do not reside in Manitoba

Requirements for distance care component

33(2) In addition to the requirements for a community pharmacy licence or hospital pharmacy license, an applicant for a distance care component must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for a distance care pharmacy;
- (b) the pharmacy can be contacted by distant patients with reasonable ease and without charge;
- (c) the pharmacy will be open a minimum of 25 hours spread over a minimum of four days per week, and

October 8th, 2010

- (d) a member will be available to respond to contacts from distant patients a minimum of 37.5 hours per week.
- (e) where the patient described in section 1 resides outside Canada and subject to section 73(2) of the Act, the pharmacy must post at the home page of its website, and include in any patient care agreement or bulletin for the solicitation of business, a disclaimer as approved by the council.

Personal care home component

34(1) An applicant for a community pharmacy licence or hospital pharmacy licence must specify that the applicant is applying for a personal care home component if the pharmacy will operate to serve patients residing in a personal care homes licensed under *The Health Services Insurance Act*.

Requirements for personal care home component

34(2) In addition to the requirements of the pharmacy licence, an applicant for a personal care home component must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for servicing a personal care home facility;
- (b) the facility will be staffed and managed by members capable of serving personal care home facilities; and
- (c) the hours of operation will meet the needs of the community and facilities served by the pharmacy.

Hospital pharmacy licence

35(1) An applicant must specify that the applicant is applying for a hospital pharmacy licence if the pharmacy will be located within a hospital and operate to serve in-patients and out-patients at a hospital designated under *The Health Services Insurance Act*.

Secondary Hospital Services Component

35(1.1) An applicant for a community pharmacy or hospital pharmacy licence must specify that the applicant is applying for a secondary hospital services component if:

- (a) the facility will be capable of providing services to a hospital;
- (b) the pharmacy services are for the patients of the hospital; and
- (c) the hours of operation will meet the needs of the hospital or hospitals served by the pharmacy.

Requirements for hospital pharmacy

35(2) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for a hospital pharmacy licence must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for a hospital pharmacy;

October 8th, 2010

- (b) the facility will be staffed and managed by members capable of operating a hospital pharmacy; and
- (c) the hours of operation will meet the needs of the hospital or hospitals served by the pharmacy.

Central-fill component

36(1) An applicant for a community pharmacy or hospital pharmacy licence must specify that the applicant is applying for a central-fill component if:

- (a) the pharmacy will provide services to other pharmacies; and
- (b) the nature of the services will be storing and preparing drugs for dispensing.

Requirements for central-fill component

36(2) In addition to the requirements of s.64(2) of the Act, and s. 29 of these regulations, an applicant for a central-fill component must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for a central-fill pharmacy;
- (b) the hours of operation will meet the needs of the pharmacies served by the central-fill pharmacy;
- (c) reasonable arrangements have been made to protect personal information and personal health information;
- (d) the central-fill pharmacy will not interact directly with the patient for whom the prescription services are provided;
- (e) records are being kept in compliance with sections 58 and 61 of these regulations; and
- (f) the central-fill pharmacy has a quality assurance program relating to work performed at the facility, and the pharmacies to which it provides services.

Requirements for pharmacies using central-fill services

36(3) Except for drugs being dispensed for a hospital, a pharmacy which uses the services of another pharmacy with a central-fill component, must disclose to a patient, prior to drugs being dispensed, that:

- (a) the drugs will be prepared for dispensing at another facility; and
- (b) the name of the central-fill pharmacy.

External Dispensing component

37(1) An applicant for a community pharmacy or hospital pharmacy licence must comply with the application process and specify that the applicant is applying for an external dispensing component if:

- (a) the pharmacy will include at least one external facility in a location that complies with section 37(2) and be used for dispensing or selling drugs, or for preparing drugs for dispensing; and

October 8th, 2010

- (b) the facility will not regularly be staffed by a member.

Requirements for external dispensing component

37(2) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for an external dispensing component must provide evidence satisfactory to the registrar that:

- (a) the external facility will be located in a Manitoba community that does not have reasonable access to pharmacy services, and will comply with section 55(1.1) of these regulations;
- (b) the technology and equipment used for the facility will comply with the Standards of Practice for external dispensing and the hours of operation will meet the needs of the community wherein it is located;
- (c) reasonable arrangements have been made to protect personal and personal health information;
- (d) supervision of technician(s) or technology at the external facility will be provided by a member, in part by a live two-way video telecommunication link;
- (e) a member will conduct an on site inspection of the external facility a minimum of every two months and in compliance with the practice direction established by Council;
- (f) patients and/or health care professionals will be able to communicate with a supervising member by way of a live two-way video telecommunication link;
- (g) the external facility will not be open when the primary pharmacy is not;
- (h) the primary pharmacy must be accessible to the patients, serviced by the external facility, a minimum of 37.5 hours per week and must ensure the contact information is well publicized and the patient can contact the primary pharmacy without charge; and,
- (i) each external facility and the primary pharmacy must have a policy and procedure manual available outlining:
 - (i) the records which must be kept;
 - (ii) compliance with relevant standards of practice and practice directions regarding the patient counselling;
 - (iii) the procedure for performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling, prior to dispensing; and
 - (iv) the requirement of a pharmacist's involvement in the sale of non-prescription scheduled drugs.

Requirements for Intermittent Satellite Pharmacy component

37(3) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for an intermittent satellite pharmacy component must provide evidence satisfactory to the registrar that:

October 8th, 2010

- (a) the satellite facility will be located in a Manitoba community that does not have reasonable access to pharmacy services;
- (b) describes the needs of the community and the collaborative practice that will occur;
- (c) describes the location, suitability for the practice of pharmacy and hours of operations;
- (d) the satellite facility and equipment will be suitable to meet the needs of the care provided;
- (e) non-medicinal products or non-medical devices will not be sold;
- (f) the satellite pharmacy computer will be linked to the primary pharmacy computer that has access to the DPIN database;
- (g) a member will be onsite during all hours of operation;
- (h) drugs will not be left onsite when the satellite is not open;
- (i) the telephone number and address of the primary pharmacy will be identified on all printed materials and prescription labels; and
- (j) all drugs dispensed from the satellite pharmacy would be labelled to indicate as such.

Clinical practice pharmacy licence

38(1) An applicant must specify that the applicant is applying for a clinical practice pharmacy licence if:

- (a) the pharmacist or pharmacy will not dispense or sell drugs, or, a product not listed in the Manual, but has been issued a drug identification number or natural health product number under the Food and Drugs Act (Canada), or prepare drugs for dispensing; and
- (b) the pharmacist will provide care to patients and advise health care professionals to enhance patient care; or,
- (c) the use of the pharmacy is for the sole purpose of training and education of pharmacy personnel.

Requirements for clinical practice pharmacy

38(2) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for a clinical practice pharmacy licence must provide evidence satisfactory to the registrar that:

- (a) the facility will comply with the Standards of Practice for a clinical practice pharmacy;
- (b) the facility will be staffed and managed by members capable of operating a clinical practice pharmacy; and
- (c) the hours of operation will meet the needs of the persons served by the pharmacy.

Pharmacy manager qualifications

39 In addition to the requirements of s.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 council; and
- (c) demonstrate to the satisfaction of the registrar that he or she will personally and adequately supervise the operation of the pharmacy.

Corporate owner change

40(1) Where the owner is a corporation, and:

- (a) there is a change of ownership of 50% or more of the voting shares of the corporation; or
- (b) there is a change in the directors of the corporation,

during the term of the pharmacy licence, the owner must advise the registrar of the changes and, provided the owner continues to meet all the requirements under section 64 and 65 of the Act and this part, the licence will continue.

Partnership change

41(1) Where the owner is a partnership, and:

- (a) there is any change in the members of the partnership ;
- (b) there is a change of a general or limited partner; or
- (c) there is a change of managing partner;

during the term of the pharmacy licence, the owner must advise the registrar of the changes and provided the owner continues to meet all the requirements under section 64 and 65 of the act and this part, the licence will continue.

Change of pharmacy manager

41(2) Where a change of a pharmacy manager occurs during the term of the pharmacy licence, the owner must advise the registrar of the change and surrender the pharmacy licence to the registrar, and upon payment of the fees prescribed in the by-laws, the registrar must issue a new licence to the owner, unless the owner no longer meets the requirements of s.64 and 65 of the Act and this part.

Change of name

41(3) Where the name of the pharmacy owner changes, or the name(s) under which the pharmacy conducts business change during the term of the pharmacy licence, the owner must advise the registrar of the changes and surrender the pharmacy licence to the registrar, and upon payment of the fees prescribed in the by-laws, the registrar must issue a new licence to the owner, unless the owner no longer meets the requirements of s.64 and 65 of the Act and this part.

Change of premises

41(4) Where the pharmacy moves, or the premises from which the pharmacy operates are renovated or changed in any substantial way, the owner must advise the registrar of the changes and may be required to surrender the pharmacy licence to the registrar, and upon payment of the fees prescribed in the by-laws and a pre-opening inspection under s.30, the registrar may issue a new licence to the owner, unless the owner no longer meets the requirements of s.61 and 62 of the Act and this part.

Notification

41(5) The owner must cause notice of any changes set out in this section to be provided to the registrar within seven days of the change, with the exception of 41(4) where 30 days notice is required.

Change of hours

42 Where the pharmacy changes its hours of operation, the pharmacy manager or owner must, on the next business day, advise the registrar of the changes, and the registrar must note the change on the record maintained at the College.

Converting licence

43(1) Where, during the duration of a pharmacy licence, an owner intends to change the operation in a manner which would make a licence of a different or additional category or component more appropriate, the owner must, at least 30 days in advance of the anticipated conversion:

- (a) surrender the pharmacy licence to the registrar;
- (b) meet all of the requirements for the issuance of licence of each requested category or component;
- (c) pay the fee specified in the by-laws; and

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

Temporary conversion

43(2) Where, during the duration of a pharmacy licence, an owner intends to operate temporarily in a manner which would make a pharmacy licence of a different category or component more appropriate, the owner must:

- (a) complete the application form prescribed in the by-laws;
- (b) pay the fee specified in the by-laws;
- (c) advise the registrar of the nature of the operation intended to be conducted;
- (d) provide evidence satisfactory to the registrar that the owner's temporary operation will not place patient safety at risk; and
- (e) operate in the temporary manner for a period of not more than 3 months.

Accurate disclosure

44 Applicants for a pharmacy licence must provide information which is truthful and accurate, to the best of the applicant's knowledge, and update the information if it changes during the duration of the licence.

Business names

45 A pharmacy must conduct business:

- (a) under a single business name, unless otherwise approved by the council; and
- (b) only under business names registered to the owner for use in Manitoba pursuant to *The Business Names Registration Act*, or pursuant to a valid franchise or use agreement.

Display licence

46 A pharmacy must display its pharmacy licence in a location visible to the public at each facility included under the pharmacy licence.

Closure of pharmacy

47(1) Where a pharmacy ceases to operate or carry on business for any reason, on a permanent or temporary basis, it is the joint responsibility of the owner and the pharmacy manager to take reasonable steps to:

- (a) advise the registrar as to where the records required to be maintained under the Act and these regulations will be located;
- (b) arrange for the records to be maintained for the required period of time;
- (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 from the subject location; and
- (f) take reasonable steps to inform patients that the pharmacy has ceased to operate and how their records may be accessed.

Closure notification

47(2) The owner or pharmacy manager must attend to the matters set out in subsections (1)(a), (b), (c) and (e) within seven days of the cessation of business or operation.

Renewal of pharmacy licence

48 A pharmacy licence may be renewed upon the applicant meeting all the same requirements of s.64 of the Act and this part for an initial application for a pharmacy licence.

PART 6 - STANDARDS

Standards to be followed

49 The standards set out in Schedule A, and applicable practice directions issued by council from time to time, under s.6(3)(c) of the Act, must be followed by:

- (a) members in practicing their profession, directly or through delegation;
- (b) owners in operating the pharmacies for which they are responsible;
- (c) pharmacy managers in supervising the staff of the pharmacies for which

October 8th, 2010

they are responsible;

- (d) students, interns, pharmacy technicians and other persons ; and
- (e) persons operating under the authority of Part 10 of these regulations.

PART 7 – DUTIES AND DELEGATION

Duties of pharmacists

50(1) Except as permitted by s.3(2) of the Act, no person except a member must:

- (a) sell a drug by retail;
- (b) engage in any included practice;
- (c) prepare written copies of a prescription and, provide or receive verbal copies of a prescription;
- (d) assess and approve a prescription for filling or refilling;
- (e) receive and record a verbal prescription from a practitioner or extended practice pharmacist; or
- (f) educate a person or health care professional about a drug or drug therapy.

Additional Duties of pharmacists

50(2) Members may perform, or supervise, the additional duties described in sections 52(4), 53(1), 53(2) and 54(2).

Duties of interns

51 Subject to section 50, an intern may be delegated and engage in the practice of pharmacy or any other task supporting the practice of pharmacy, under the supervision of a member.

Delegation to pharmacy technicians

52(1) A member must not delegate any task to a person under this section unless the person is qualified as a pharmacy technician.

Qualification of pharmacy technicians

52(2) A person is qualified as a pharmacy technician if the person is at least 18 years of age and:

- (a) has graduated from a program of pharmacy technician training as approved by council or successfully completed a bridging educational program as approved by council;
- (b) has passed any examinations approved by the council; and
- (c) has successfully completed a structured practical training program approved by council .

Continuing qualification of pharmacy technicians

October 8th, 2010

52(2.1) A person qualifying under section 52(2) is entitled to have his or her qualification continue upon:

- (a) continued work in a pharmacy under the supervision of a member; or failing that, a period of work under direct supervision and reassessment by a member, and
- (b) participation in the Pharmacy Technicians Continuing Professional Development and Quality Assurance program of the College that requires a minimum number of professional development learning hours .

Pharmacy Technician Liability Insurance

52(2.2) Every Pharmacy Technician must be covered by liability insurance as required by the council. **Limits on delegation to pharmacy technicians**

52(3) A pharmacy technician may engage in the following aspects of the practice of pharmacy, under the supervision of a member:

- (a) dispensing, subject to approval by a member under s.50(1d) and any standards related to a member counselling the patient;
- (b) operating an external dispensing site; and
- (c) identifying and assessing when drug-related problems require referral to the member.

Duties of pharmacy technicians

52(4) In addition to the delegated duties described in 54(2), the following duties supporting the practice of pharmacy may be performed by a pharmacy technician, under supervision of a member and in accordance with applicable practice directions:

- (a) reviewing the information on the prescription for compliance with federal and provincial regulations;
- (b) replenishing drug storage containers and dispensing machines;
- (c) performing a final check when the process of preparing a drug for dispensing was performed by another technician, student or intern, prior to dispensing providing that, prior thereto, an application setting out drug packaging preparation processes consistent with the standards of practice and patient safety have been approved by Council;
- (d) providing instruction to a person on how to operate a medical device but not provide any explanation involving the interpretation of the results or value of the device;
- (e) inquiring of the practitioner or extended practice pharmacist, and receiving the instruction, of whether an existing prescription can be refilled as previously prescribed and without any changes to the prescription; and,
- (f) entering the pharmacy when it is closed and, with the exception of (d) and (e) perform the duties listed under this section.

Pharmacy technicians in training

October 8th, 2010

52(5) Notwithstanding anything in this section and subject to section 55, a pharmacy technician in training may perform the duties under subsection 3 and 4 under the direct supervision of a member or a pharmacy technician.

Delegation to students

53(1) The following aspects of the practice of pharmacy may be delegated to a student, under the direct supervision of a member:

- (a) compounding;
- (b) dispensing, subject to approval by a member under s.50(1d) and any standards related to a member counselling the patient;
- (c) advising on the contents, therapeutic values and hazards of drugs;
- (d) advising on the use, calibration, effectiveness and hazards of devices; and
- (e) identifying and assessing drug-related problems and making recommendations to prevent or resolve them.

Duties of students

53(2) In addition to the duties described in 52(4) and 54(2), the following duties supporting the practice of pharmacy may be performed by a pharmacy student, under direct supervision of a member and in accordance with applicable practice directions:

- (a) educating a patient about their drug or drug therapy;
- (b) receiving and recording verbal prescriptions;

Policies regarding students

53(3) Notwithstanding anything else in this section, a pharmacy manager must take reasonable steps to ensure that:

- (a) the pharmacy under his or her supervision has developed policies regarding the appropriate delegation of tasks to students with regard to their skill level and professional development; and
- (b) the members under the manager's supervision only delegate tasks to students in accordance with the policy.

Duties of other persons

54(1) A person other than a member, intern, pharmacy technician, or student must not engage in or be delegated any aspects of the practice of pharmacy.

Limits on duties of other persons

54(2) A member may permit a person other than a member, intern, pharmacy technician or student, to do the following duties provided they are performed under supervision of a member and in accordance with applicable practice directions;

- (a) preparing and pre-packaging a drug for dispensing;
- (b) selecting an appropriate container;
- (c) attaching the prescription label to the container;

- (d) recording and retrieving data regarding a patient or a prescription;
- (e) compounding to the extent approved by a member;
- (f) entering prescription information into a database;
- (g) collecting information from a patient for a patient profile; and
- (h) managing drug inventory.

Dispensing by health professionals

54(3) Notwithstanding subsection (2), a member may delegate the dispensing of drugs to a person practicing as a health professional under an Act of the Legislature, subject to approval under s.50(1(d)) and any standards related to counselling the patient.

Pharmacy manager to arrange supervision

55(1) A pharmacy manager must take reasonable steps to ensure that supervision is provided to interns, pharmacy technicians, students and other persons in accordance with this part, the standards of practice and any relevant practice directions.

Safe use of automation

55(1.1) A pharmacy manager must take reasonable steps to insure that automated or computerized systems used in prescription filling processes in the pharmacy, or any components thereof, are in good working order and perform their intended tasks in a safe, secure and appropriate manner.

Member to supervise

55(2) A member must take reasonable steps to ensure that his or her supervision of interns, pharmacy technicians, students and other persons is provided in accordance with this part, the standards of practice and any relevant practice directions.

Delegation to qualified persons

55(3) A member must not delegate a task to any person, unless that person is reasonably qualified and competent to engage in the specified task.

Oversight of delegations

55(4) A pharmacy manager must take reasonable steps to ensure that members under his or her supervision are competent in the practice of pharmacy being performed and members do not delegate tasks to any person or require a person to do a task, unless that person is reasonably qualified and competent to engage in the specified task.

Delegation is not required

55(5) An owner or pharmacy manager must not require a member to delegate a task to an intern, pharmacy technician, student or other person if the member is uncertain the person is reasonably qualified and competent to engage in the intended task.

General operation

56 Notwithstanding anything else in this part, a member or owner may delegate a task to any person, without providing supervision, to the extent that the task is related primarily to the general operation of the business or institution, and

not to the care of patients;

PART 8 – PRESCRIPTIONS & RECORDS

Records required

57 The records set out in this part are required to be made and kept by a member as it applies to the member's practice.

Authorization Requirement

58(1) No drug may be released to the patient, pursuant to a prescription, unless an authorization is received and recorded pursuant to:

- (a) section 86(1), or 68(1.1) 86 (4) or 90 of these regulations; or
- (b) a prescription, or refill thereof, indicating:
 - (i) where the prescription is a written prescription, by the signature of the practitioner or extended practice pharmacist; or
 - (ii) where the prescription is a verbal prescription, the name of the practitioner or extended practice pharmacist issuing the verbal order and the signature or initials of the person receiving the prescription; and
 - (iii) the number of refills authorized by the practitioner or extended practice pharmacist issuing the prescription.

Approval Record

58(2) Where the final check of the packaged and labelled drug, pursuant to a prescription, is performed by a person other than a member or intern, no drug may be released to the patient unless an approval record of the prescription number and the signature or initials of the member approving the prescription for filling or refilling, as required under section 50(1(d)), is made and retained.

Counselling Record

58(2.1) Except for inpatients of a hospital, no drug may be released for the patient, pursuant to a prescription unless a counselling record of the following is made and retained:

- (a) the applicable standards of practice and practice directions related to the counselling of the patient, or their agent, have been met, as indicated by:
 - (i) the signature or initials of the member or intern providing the counselling; and
 - (ii) where the person counselling is a student, the signature or initials of the member supervising the student.
- (b) or where the counselling has been refused by the patient or their agent, the name of the person refusing counselling and the signature or initials of the member being advised of the refusal.

Additional Counselling Record

58(2.2) Notwithstanding section 58(2.1), and in the following situations where a pharmacist cannot counsel the patient directly, the counselling record for:

October 8th, 2010

- (a) an inpatient of a personal care home;
- (b) a resident of a group home; or
- (c) a person who is not capable of comprehending the information and making a decision regarding their care

must be made and retained indicating the name(s) of the caregiver being provided the information.

Hospital Counselling Record

58(2.3) Where the pharmacist does counsel an inpatient of a hospital, the same documentation requirements described in 58(2.1) apply.

Prescription record

58(3) In addition to the approval and counselling record, no drug may be dispensed unless a prescription record of the following is made and retained:

- (a) the date the prescription and each refill of the prescription was dispensed;
- (b) the name of the patient for whom the drug is prescribed;
- (c) the address of the patient for whom the drug is prescribed;
- (d) the name of the drug, as prescribed;
- (e) the manufacturer of the drug, as dispensed;
- (f) strength (where applicable) and quantity of the prescribed drug;
- (g) the directions for use, as prescribed;
- (h) the price charged;
- (i) the name and address of the practitioner, extended practice pharmacist or the member described under 58(1a) authorizing the prescription; and
- (j) the signature or initials of the person preparing the drug for dispensing or of the member, intern, student or pharmacy technician doing the final check where the person who prepared the drug for dispensing was not a member or intern.

Method of keeping records

58(4) The information required by subsections (1), (2), and (3) may be recorded and retained electronically or in written form, except:

- (a) where a signature is required, it must be an original signature or an electronic signature; and
- (b) where initials are required, it must be original initials or electronic initials.

Hospital records

58(5) Section 58(3) does not apply to the prescription record for a drug prescribed to an in-patient in a hospital under *The Health Services Insurance Act*, except a record must show the:

- (a) name and location of the patient;
- (c) the name of the person authorizing the prescription as described under

October 8th, 2010

section 58(1);

- (d) the name of the persons who prepared the medication for dispensing and performed the final check
- (d) the date the drug was prepared for dispensing; and
- (e) the drug name, strength and identification of the manufacturer.

Food and Drugs Act applies

58(6) This section is subject to the requirements of the *Food and Drugs Act* (Canada) and regulations regarding the retention of written records.

Medication label

59(1) No drug may be dispensed pursuant to a prescription unless the container in which a drug is dispensed is marked with the following information:

- (a) the name of the patient for whom the drug is prescribed;
- (b) the prescription number;
- (c) the business name of the pharmacy;
- (d) the address and telephone number of the pharmacy, or where applicable, the external dispensing site or intermittent satellite;
- (e) the name of the drug:
 - (i) where a single entity drug, by its generic name and manufacturer;
or
 - (ii) where a multiple entity drug, by its trade name;
- (f) the strength (where applicable) and quantity of the drug;
- (g) the name or initials of the person preparing the drug for dispensing and of the member, intern, student or pharmacy technician doing the final check where the person who prepared the drug for dispensing was not a member or intern;
- (h) the date the drug is dispensed;
- (i) the name of the person authorizing the prescription under section 58(1);
- (j) the directions for use, as prescribed;
- (k) the price charged; and
- (l) the number of refills, part-fills or doses remaining.

Method of keeping prescription label record

59(2) The record required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.

59(3) Hospital in-patient records exempt

October 8th, 2010

Section 59(1) does not apply to drug dispensed for an inpatient of a hospital or resident of a personal care home under *The Health Services Insurance Act*.

Hospital and personal care home medication labels

59(4) No drug may be dispensed pursuant to a prescription for an in-patient of a hospital or resident of a personal care home, under *The Health Services Insurance Act* unless the container in which a drug is dispensed is marked in accordance with any pertinent Standards of Practice or practice direction.

Patient profile

60(1) No drug may be dispensed pursuant to a prescription, unless a patient profile of the following is made and retained:

- (a) the name of the patient;
- (b) the address of the patient;
- (c) a reference to the prescription number for each prescription filled for the patient;
- (d) any written medical history or information collected regarding the patient;
- (e) any declaration waiving of the use of a child resistant container, and the name of the person waiving its use; and
- (f) the notation of any written authorization forms, order forms, terms of purchase and sale, or other agreements between the pharmacy and the patient.

Method of keeping patient profile

60(2) The records required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.

Central-fill pharmacy records

61 Where the pharmacy from which the drug is dispensed to a patient is other than the pharmacy in which the drug was prepared for dispensing:

- (a) the pharmacy dispensing to the patient must retain a copy of the prescription record, prescription label record, and patient profile required under this part;
- (b) the pharmacy preparing the drug for dispensing must retain the original prescription record and the prescription label record required under this part;
- (c) the prescription label must, in addition to the requirements of s.59.(1), be marked with the name of the pharmacy in which the medication was prepared for dispensing;
- (d) the prescription record must, in addition to the requirements of s.58(3), contain the name of the pharmacy in which the medication was prepared for dispensing;
- (e) the patient profile must, in addition to the requirements of s.60(1), include documented authority from the patient, or their agent, to share the patient's personal and personal health information with the pharmacy in which the medication is to be prepared for dispensing; and

October 8th, 2010

- (f) pharmacies must meet any other requirements of the standards of practice and applicable practice directions.

Acquisition and sales records

62(1) In addition to section 58(3), every pharmacy manager shall keep a record of all acquisitions and sales of drugs for a period of five years.

Return to inventory

62(2) A drug must not be accepted for return to inventory if it has been previously dispensed.

Exceptions on returns

62(3) Notwithstanding subsection (2), a drug may be accepted for return to inventory if:

- (a) the lot numbers and expiry dates of the drug, where applicable, are directly attached to the dispensed container;
- (b) the drug has not expired;
- (c) where each dose of the drug or the container of the drug is sealed and the seal is intact at the time of the return to the pharmacy;
- (d) the patient, or agent, has not been in possession of the dispensed drug ;
- (e) the conditions under which the drug has been stored between the time of dispensing and the time of return are known and appropriate; and
- (f) it is reasonably safe to do so.

62(4) Where a drug is returned to inventory, the acquisition record must include;

- (a) the name of the drug returned;
- (b) the drug identification number or name of the manufacturer of the drug returned;
- (c) the strength (where applicable) and quantity of the drug returned;
- (d) the date of the return; and
- (e) the prescription number of each drug returned where applicable.

Method of keeping acquisition records

62(5) The records required by this section may be recorded and retained in a readily retrievable manner electronically or on paper.

63 “numbering system Place holder”

64 “numbering system Place holder”

Manitoba Prescribing Practices Program (M3P) Schedule

65(1) The council may create the M3P Schedule of drugs.

M3P Prescription requirements

65(1.1) A prescription for a drug listed on the M3P schedule must:

- (a) be dated and signed by the authorized practitioner on a form specified in the by-laws;
- (b) contain only one drug product prescribed on the form; and
- (c) contain all of the other information required under s.58(3).

Limits on dispensing

65(2) A drug listed in the M3P schedule must not be dispensed unless:

- (a) the person dispensing the drug has taken reasonable steps to determine that there are no questions or issues as described in s.68(4) of these regulations;
- (b) the prescription meets all the requirements of subsection (1.1);and
- (c) the prescription is dated by the authorized practitioner within three days of the date it is presented at the pharmacy for filling.

65(3) Subject to subsection (4), before dispensing a drug on the M3P schedule, prescription and patient information must be entered into DPIN in accordance with any applicable practice directions.

65(4) Where the requirements of subsection (2) are not met, the person requested to dispense must:

- (a) refuse to fill the prescription and advise the patient or his or her designate and the authorized practitioner or other person who issued the prescription, of the refusal;
- (b) record the refusal to fill the prescription
 - (i) on the prescription form, and
 - (ii) in DPIN, in accordance with any applicable practice directions;
- (c) retain the prescription form, unless the patient or that patient's designate requests the prescription be returned, in which case a copy of the prescription form must be retained.

65(5) This section does not apply to a prescription for a drug that is listed on the M3P schedule, if it is, subject to section (6), prescribed by a practitioner not licensed in Manitoba or the drug will be administered to:

- (a) a patient in a hospital; or
- (b) a resident in a personal care home;

if the facility is designated under *The Health Services Insurance Act*.

Out of Province practitioners

65(6) This section does not apply to prescriptions issued by practitioners licensed

October 8th, 2010

in provinces other than Manitoba, with the exception of 65(1.1c), 65(2a), 65(3) and 65(4bii)

Patient access to records

66 Upon request by a patient, a member must provide a copy of the information on:

- (a) the prescription record;
- (b) the prescription label record;
- (c) the patient profile; and
- (d) any other record maintained by the pharmacy;

relating to the patient making the request and is consistent with the requirements under the *Personal Health Information Act*.

Retention of records

67(1) Subject to sections 58(5) and 59(3), a member or owner must retain the following records for a period of not less than five years after the circumstances giving rise to the creation of the record:

- (a) approval record
- (b) counselling record
- (c) prescription record;
- (d) prescription label;
- (e) patient profile;
- (f) acquisition and sales record;
- (g) prescriptions, or copies thereof, which were refused to be filled, under s.68(4);
- (h) prescribing record;
- (i) drug administration record;
- (j) test interpretation record; and
- (k) test ordering and results record.

Access to retained records

67(2) A member or owner must make all records required to be retained available within a reasonable time during an investigation under Part 6 or an inspection under Part 10 of the Act.

Location of records

67(3) The records required to be retained by a pharmacy need not be stored in the pharmacy, as long as the location of the records is reported under section 29, the records are secure, and access is available pursuant to subsection (2).

PART 9 – DISPENSING OF DRUGS

Substitution

68(1) When dispensing a drug pursuant to a prescription, one drug may not be substituted for another, or one brand of drug for another, without the consent of the practitioner, or extended practice pharmacist who issued the prescription, or in accordance with Part 9 of the Act.

Substitution by members in hospital

68(1.1) Any member working in a hospital pharmacy may, upon receipt of a prescription to be dispensed to an in-patient of a hospital:

- (a) issue a new prescription for a drug deemed equivalent by the facility formulary to the one specified in the original prescription; or
- (b) issue a new prescription for a different dosage or dosage form deemed equivalent by the facility formulary to the one specified in the original prescription.

Recording substitutions

68(2) Any substitution under subsection (1) or (1.1) must be recorded and form part of the prescription record.

Changing prescriptions

68(3) Except as permitted by any applicable practice directions describing the adaptation of a prescription, no change must be made to a prescription without the consent of the practitioner or extended practice pharmacist issuing the prescription, in which case:

- (a) a revised written prescription must be issued by the practitioner or extended practice pharmacist; or
- (b) a verbal prescription recorded.

Questionable prescriptions

68(4) A drug must not be approved for dispensing pursuant to a prescription if there is reason to believe:

- (a) the practitioner or the extended practice pharmacist issuing the prescription is not authorized by law to have his or her orders filled;
- (b) the practitioner or the extended practice pharmacist issued the prescription outside his or her usual scope of practice;
- (c) the prescription contains an error;
- (d) the patient's safety may be at risk, or
- (e) the drug lacks therapeutic value for the patient.

Approved drugs

69(1) Only Health Canada approved drugs may be sold, dispensed or used in compounded preparations.

Approved Substances

69 (1.1) Only substances meeting the standards listed in schedule B to the Food and Drugs Act may be sold, dispensed or used in compounding preparations.

Child resistant containers

70(1) A drug must, subject to subsection (2), be dispensed in a child resistant container.

Child resistant containers not required

70(2) Subsection (1) does not apply to an inpatient of a hospital, resident of personal care home or if the use of a child resistant container is waived:

(a) by the patient (or agent):

(i) declaring that the patient does not want a child resistant container for their prescriptions and the declaration is documented;

and

(ii) the declaration is reasonable in the circumstances of the patient.

(b) by the member:

(i) declaring that, in the member's professional judgment, the use of a child resistant container should be waived with regard to any prescription for a patient ;

(ii) the declaration is documented on the prescription record or on the patient profile; and

(iii) the member has assessed that the declaration under subsection (a) is reasonable in the circumstances of the patient, or that a child resistant container is not suitable because of the physical nature of the drug.

Sale of expired drugs prohibited

71(1) No person may sell any drug in a pharmacy if:

(a) its use is limited to a prescribed period of time, if that time has expired;

(b) it has an expiry date, if that date has expired, or

(c) it is unlikely the drug would be fully consumed before its expiry date.

Removal of expired drugs

71(2) A product described in subsection (1) must be removed from any public or selling area of the pharmacy and disposed of in accordance with the law.

Limitations on sale of particular drugs

72(1) The following drugs may only be sold by retail from a dispensary to a patient (or agent), and only after complying with any applicable standards of practice or practice directions and assessing that the drugs are appropriate in the circumstances of the patient:

(a) any drug listed in Schedule 2 of the manual; or

- (b) a drug with pseudoephedrine as the single active ingredient.

Maximum quantity

72(2) A drug referred to in subsection (1)(b) must not be sold in a quantity that results in the purchaser receiving, at the time of purchase, more than 3,600 mg of pseudoephedrine.

Schedule 3 drugs

72(3) A drug listed in Schedule 3 of the manual must only be displayed for retail sale in an area immediately adjacent to the dispensary and as permitted by any applicable practice direction.

Sale of Schedule 1 drugs without a prescription

72(4) A drug listed in Schedule 1 of the manual, subject to the Controlled Drugs and Substances Act, may be sold without a prescription to:

- (a) a practitioner; or
- (b) a member.

Inducements

73 With the exception of the retail sale of a drug not pursuant to a prescription, a member or owner must not offer or provide any promotion or event that would provide a patient, or his or her agent, increase in the usual amount of points, loyalty points or rewards in the course of performing any activity described under section 2(1) of the Act.

PART 10 - DISPENSING BY PERSONS WHO ARE
NOT MEMBERS

Dispensing practitioners' committee

74(1) There is hereby established a dispensing practitioners' committee composed of:

- (a) two members appointed by the council, one of which shall be chair,;
- (b) one representative appointed by the College of Physicians and Surgeons of Manitoba; and
- (c) one representative appointed by the College of Registered Nurses of Manitoba.

Term on committee

74(2) Each member of the committee must be appointed for a term of two years, and may be reappointed to additional terms at the discretion of the appointing body.

Vacancies

74(3) Should a member of the committee be unable or unwilling to complete his or her term, a vacancy may be filled by the appropriate appointing body.

Quorum

74(4) A quorum of the committee is two members, and must include representatives from at least two of the appointing bodies, including one member appointed by council.

Committee may consult

74(5) The Committee may consult with other health care professions and individuals as it may deem appropriate.

Application for dispensing practitioner

75(1) A practitioner may apply to the dispensing practitioners' committee to be designated as a dispensing practitioner, if:

- (a) the applicant practices in a remote community that does not have reasonable access to pharmacy services; and
- (b) pays to the College the fees provided in the by-laws.

Approval of application

75(2) The dispensing practitioners' committee must grant a practitioner approval to practice as a dispensing practitioner if the committee is satisfied that:

- (a) the subject community reasonably requires better access to pharmacy services;
- (b) the applicant is reasonably competent to undertake the duties of a dispensing practitioner; and
- (c) the applicant is unlikely to abuse the authority of the designation as a dispensing practitioner.

Conditions on designation

75(3) The dispensing practitioners' committee may grant a designation as a dispensing practitioner on such conditions as it considers appropriate.

Appeal

75(4) A decision of the Dispensing Practitioners' Committee may be appealed to council, but there is no further appeal under these regulations.

Authority of dispensing practitioner

76(1) A dispensing practitioner may conduct the practice of pharmacy, except any included practice.

Delegation to qualified persons

76(2) A dispensing practitioner must not delegate a task to any person, unless that person is reasonably qualified and competent to engage in the specified task.

Duties of dispensing practitioner

76(3) Notwithstanding s.76(2), a dispensing practitioner must not delegate the following tasks :

- (a) sell a drug by retail;
- (b) provide copies of a prescription to a patient; or
- (c) assess and approve a prescription for filling or refilling.

Pharmacy

77(1) A dispensing practitioner's place of business or operation is deemed a pharmacy for the purposes of:

- (a) the obligations of pharmacies under the Act regarding conduct of their operation;
- (b) allowing inspections under Part 10 of the Act,

but is not required to obtain a pharmacy licence under Part 7 of the Act.

Requirements of dispensing

77(2) A dispensing practitioner must practice under this designation in accordance with the obligation of members under the Act, including the regulations and any applicable practice directions.

Scope of practice

77(3) A dispensing practitioner must use his or her designation only for a purpose which is reasonably within his or her scope of practice.

Veterinarians

78 Subject to s.98, a person licensed in Manitoba to practice veterinary medicine, veterinary surgery or veterinary dentistry is, without the need to apply under Part 10, automatically designated as a dispensing practitioner for the purpose of treating animals.

Revoking designation

79(1) Upon receipt of information from any person relevant to the conduct of a dispensing practitioner, the dispensing practitioners' committee may, as it deems fit:

- (a) impose conditions on the dispensing practitioner's designation; or
- (b) revoke the dispensing practitioner's designation.

Automatic revocation

79(2) The designation of a dispensing practitioner is automatically revoked :

- (a) upon the practitioner ceasing to practice his or her own profession,
- (b) upon the practitioner ceasing to practice at the site designated in his or her application, or,
- (c) after 30 days upon the community obtaining reasonable access to pharmacy services.

Interim suspension

79(3) Upon receipt of information from any person relevant to the conduct of a dispensing practitioner, the registrar may temporarily suspend the practitioner's designation at any time, until the matter is considered by the dispensing practitioners' committee under subsection (1).

Appeal

79(4) A decision under this section may be appealed to the council, but there is no further appeal under these regulations.

Application of Prescribing Members

79.1(1) An extended practice pharmacist wanting to prescribe and

October 8th, 2010

then dispense the drug pursuant to that prescription, must receive prior approval for this practice through the Committee described in this section.

All other parts are applicable

79.1(2) All provisions of this part apply to prescribing members with necessary modifications as though the prescribing member was the dispensing practitioner.

Restriction of this section for prescribing members

79.1(3) This section does not apply to prescribing members where the member is issuing the prescription in a hospital, under section 86(1) or under section 90(1).

PART 11-EXTENDED PRACTICE PHARMACISTS & SPECIALTY PRACTICE

Extended practice pharmacist

80(1) A member must not engage in any included practice unless he or she is registered as an extended practice pharmacist, or as otherwise permitted by these regulations.

Use of title

80(2) No person except an extended practice pharmacist may use the designation "extended practice pharmacist", a variation of such title or an equivalent in another language.

Pharmacist licence

80(3) The pharmacist licence of an extended practice pharmacist must note this designation and any specialty or specialties of the member.

Requirements of registration

81(1) An applicant for registration as an extended practice pharmacist must:

- (a) be a member ;
- (b) submit an application to the board in the form specified in the by-laws;
- (c) practice in a collaborative practice ;
- (d) be qualified as a specialist in one or more areas under this part; and
- (e) pay the fee provided for in the by-laws.

Registration

81(2) Where an applicant meets the requirements of subsection (1), the board must approve the application and direct the registrar to enter the name of the applicant on the register of extended practice pharmacists.

Conditions

81(3) An approval under subsection (2) may be made subject to any conditions that the board considers appropriate.

Application not approved

81(4) Where the board does not approve an application or approves an

October 8th, 2010

application subject to conditions, it must give notice to the applicant in writing, with reasons for its decision, and advise the applicant of his or her right to appeal the decision to council, in which case s.21 of the Act shall apply, with necessary modifications.

Duration of registration

81(5) The registration of a extended practice pharmacist continues until the earlier of:

- (a) the member's registration as a pharmacist or pharmacist licence is cancelled;
- (b) the member ceases to practice in the area or areas of specialty for a period of more than 24 months; or
- (c) the member ceases to practice in a collaborative practice for a period of more than 24 months.

Specialty Practice

82 A member may request that his or her pharmacist licence list the member as a specialist, as permitted under sections 16(2) and 16(3) of the act, in the areas listed under section 84(1).

Speciality Practice Qualifications

84(1) A member is qualified as a specialist in a requested area upon providing evidence satisfactory to the registrar that he or she has qualified through

(a) Board Certification from the American Board of Pharmacy Specialties in one of the following specialties and currently practices, and has practiced for at least 1000 hours in the last 2 years in a healthcare setting within one of the following specialty area:

- (i) Ambulatory Care
- (ii) Nuclear Medicine
- (iii) Nutrition Support
- (iv) Oncology
- (v) Pharmacotherapy
- (vi) Psychiatry

(b) Board Certification in Geriatric Medicine from The Commission for Certification in Geriatric Pharmacy; is currently practicing and has practiced for at least 1,000 hours in the last 2 years in a geriatric healthcare setting;

(c) a post graduate clinical degree of Pharmacy (Pharm D, M.Sc. or Ph.D.) from a program approved by council and currently practices, and has practiced for at least 1,000 hours in the last 2 years in a healthcare setting and in a specialty area(s):

(d) certification as an educator/provider from a specified certification body and currently practices, and has practiced for at least 5,000 hours in the last 5 years in a healthcare setting within on of the following specialty areas:

- (i) Diabetes Educator certified by the Canadian Diabetes Association
- (ii) Respiratory Educator certified by the Canadian Lung Association
- (iii) Anticoagulation Provider certified by the National Certification Board for Anticoagulation Providers

(e) certification from a program that is approved by council and equivalent to the programs described in section 84(1a), 84(1b) and 84 (1d) regarding

qualification assessment and practice experience.

Renewal of Specialty Practice Qualifications

84(2) A member who qualifies under section 84(1), is entitled to have the designation continue upon the member renewing their annual pharmacist license and providing evidence to the registrar that:

- (a) confirms the continued certification under 84(1a), 84(1b), 84(1d) and 84(1e);
- (b) in the two year period immediately before the member applies for renewal, the member engaged in the practice of pharmacy in their area of specialty for a minimum of 400 hours and
- (c) confirms participation in the Continuing Professional Development program of the College that requires a minimum number of professional development learning hours and the maintenance of a portfolio documenting learning and the application to practice in the area of specialty.

Appeal of Renewal

84(3) Where the renewal of Specialty Practice is refused under section 84(2), a member may appeal the decision under the same process as described in section 21 of the Act.

Extended practice pharmacist practice advisory committee

85(1) Council must establish an extended practice pharmacist advisory committee, consisting of:

- (a) three pharmacists who are members, appointed by the council, one of which shall be chair;
- (b) two representatives appointed by the College of Physicians and Surgeons of Manitoba;
- (c) two representatives appointed by the College of Registered Nurses of Manitoba; and
- (d) three public representatives.

Committee may consult

85(1.1) The Committee may consult with other health care professions and individuals as it may deem appropriate.

Term on committee

85(2) Each member of the committee must be appointed for a term of two years, and may be reappointed to additional terms at the discretion of the appointing body.

Vacancies

85(3) Should a member of the committee be unable or unwilling to complete his or her term, a vacancy may be filled by the appropriate appointing body.

Quorum

85(4) A quorum of the committee is five committee members, and must

October 8th, 2010

include a representative from at least two of the appointing bodies and two of the members appointed by the council.

Duties of committee

85(5) The committee must, on at least an annual basis:

- (a) review and make recommendation to this regulation as it relates to included practices;
- (b) review and make recommendations to standards of practice, practice directions, and the code of ethics as they relate to included practices;
- (c) review the outcomes of inspections and audits which relate to included practices;
- (d) formulate recommendations regarding the qualification of specialists;
- (e) formulate recommendations regarding improvements or changes which could be made to these regulations, standards of practice, practice directions and the code of ethics in regard to included practices;
- (f) formulate recommendations regarding the appropriateness of included practices being exercised outside of a collaborative practice ; and
- (g) present the recommendations to the council.

Council may decide

85(5.1) The council may decide to accept, reject or alter the recommendations made by the committee.

Sharing of inspection information

85(6) For the purposes of this section, the registrar may share with the committee the results of audits or inspections conducted under Part 10 of the Act.

PART 12 – PRESCRIBING BY MEMBERS

Prescribing by members

86(1) Subject to this part, any member may prescribe the following:

- (a) a drug listed on schedule 2 of the manual;
- (b) a drug listed on schedule 3 of the manual;
- (c) a drug which is not listed in the manual, but has been issued a drug identification number or natural health product number under the *Food and Drugs Act* (Canada);
- (d) a medical device approved by Health Canada, in accordance with any applicable practice direction.

Additional Prescribing by members

86(1.1) Subject to this part, any member who has completed a training program approved by the council may prescribe a drug included in the category

for a condition listed in schedule B;

Prescribing by extended practice pharmacists

86(2) Subject to this part, a member who is an extended practice pharmacist may prescribe a drug listed on schedule 1 of the manual, within the scope of his or her specialty in accordance with the practice direction approved by the council.

Prescribing in emergency

86(4) Notwithstanding subsection (2), where the minister gives the council written notice that a public health emergency exists in all or part of the province, council may approve members to prescribe drugs listed on schedule 1 of the manual, under any conditions deemed appropriate by council, until the state of emergency is lifted.

Criteria for prescribing

87 A member may only prescribe where:

- (a) the member has made a reasonable inquiry to assess whether the drug will be safe and effective in the circumstances of the patient, including:
 - (i) the patient's symptoms;
 - (ii) the patient's medical history or information;
 - (iii) the patient's allergies;
 - (iv) other medications the patient may be taking; and
 - (v) any other inquiries reasonably necessary in the circumstances.
- (b) the member has assessed the patient in person, in compliance with the standards of practice;
- (c) the drug is prescribed in a circumstance which is within the member's usual scope of practice or specialty;
- (d) the member has complied with any policies or rules related to prescribing at the pharmacy at which the member practices;
- (e) the member has complied with any applicable practice directions;
- (f) the member has determined that the prescription is reasonably necessary or desirable to treat the patient;
- (g) except where the prescription is being issued for an in-patient of a facility under the Health Services Insurance Act, the member has discussed with the patient, or agent, reasonable and available therapeutic options and costs.
- (h) the drug or device is needed to meet the care needs of the patient.

Controlled substances

88 This Part is subject to the restrictions set out in the *Controlled Drugs and Substances Act* (Canada) and the regulations there under.

Prescribing record

89(1) A member who issues a prescription must make and retain a record of:

- (a) the name and address of the patient;
- (b) the date of birth of the patient
- (c) the name of the drug prescribed;
- (d) the strength (where applicable) and quantity of the prescribed drug;
- (e) the directions for use;
- (f) the number of refills available to the patient;
- (g) the name of the member issuing the prescription;
- (h) the date of the prescription; and
- (i) the treatment goal, diagnosis or clinical indication when issuing the prescription.

Method of keeping prescribing records

89(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

Continued care prescriptions

90(1) Subject to this section, a member may authorize an additional refill of a prescription, beyond those authorized by the original practitioner or extended practice pharmacist issuing the prescription, if:

- (a) the patient has a continuing need or chronic condition;
- (b) the prescribing practitioner or extended practice pharmacist has:
 - i) died or retired within the previous six months; or,
 - ii) has not responded to an inquiry for refill authorization,

and it would be onerous or impossible for the patient to contact or attend the original practitioner issuing the prescription in a timely manner;

- (c) the history of the patient with the subject drug has not changed ;
- (d) the patient advises that they have not recently experienced any adverse drug reactions to the subject drug; and,
- (e) the prescription was previously filled at the same pharmacy; or
- (f) in compliance with any applicable practice directions.

Requirements for continued care prescriptions

90(2) Where a member authorizes a refill under subsection (1), the member must:

- (a) promptly notify the original practitioner who issued the prescription, unless section 90(1b(i)) is applicable;

October 8th, 2010

- (b) enter the refill into DPIN; and
- (c) keep the records noting the pharmacist that authorized the prescription and the other prescription records as required by part 8 of this regulation.

Restrictions on continued care prescriptions

90(3) A member must not authorize a refill under subsection (1):

- (a) where the refill quantity is in excess of the original prescribed refill amount;
- (b) where the drug falls under the *Controlled Drugs and Substances Act* (Canada) unless it is issued in compliance with sections 88 and 90(1) of the regulations;
- (c) where the drug is a benzodiazepine, unless:
 - (i) the drug is used to manage a convulsive disorder; or
 - (ii) there is a serious risk of seizure due to sudden withdrawal;
- (d) where the patient appears to be using continuing care refills to avoid obtaining ongoing medical care.

Prescribing record not required

90(4) A member prescribing under section 90 is not required to keep the prescribing record described in section 89(1).

PART 13 – ADMINISTRATION OF DRUGS

Administration of drugs by members

91(1) Any member or intern may administer a drug listed in the manual or has been issued a drug identification number or natural health product number under the Food and Drugs Act (Canada) to a patient:

- (a) orally, including sublingual and buccal;
- (b) topically, including ophthalmic, otic and intranasal; or
- (c) via inhalation.

Certification in drug administration

91(2) The council may approve a training program to certify members in other methods of drug administration that includes enhanced safety measures and emergency resuscitation, and specifies the frequency and criteria by which the certification must be renewed.

Use of titles

91(3) No person may represent that they are certified in drug administration unless they hold current certification under subsection (2).

Advanced drug administration

October 8th, 2010

91(4) A member who has current certification in drug administration, or under training and direct supervision as described in section 91(2), may administer a drug:

- (a) through intradermal injection;
- (b) through subcutaneous injection;
- (c) through intramuscular injection;
- (d) intravenously through an established central or peripheral venous access device; or
- (e) rectally.

Administration by clinical assistant specialist

91(5) Notwithstanding anything in this section, a member who is a clinical assistant specialist may administer a drug in accordance with the requirements of *The Medical Act* and regulations applicable to clinical assistants.

Drug administration record

92(1) A member who administers a drug to a patient must make and retain a record in the pharmacy of:

- (a) the name of the patient;
- (b) the address of the patient;
- (c) the name of the drug and total dose administered;
- (d) the identification of the manufacturer, lot number and expiry date of the drug;
- (e) the route of administration;
- (f) the name of the member administering the drug;
- (g) the date and the time of the administration;
- (h) any adverse events, and
- (i) the price, where there is a charge for administration.

Method of keeping drug administration records

92(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

PART 14 – TEST INTERPRETATION

Interpretation of tests by members

93 Any member may interpret and advise the patient of the results and implications of any patient administered automated tests.

Test interpretation record

94(1) A member who interprets and makes a recommendation to a patient regarding a patient administered test must make and retain a record of:

- (a) the name of the patient;
- (b) the address of the patient;
- (c) the nature of the test interpreted;
- (d) the results of the test;
- (e) the nature of the advice given to the patient;
- (f) the name of the member interpreting the test; and
- (g) the date of the test.

Method of keeping test interpretation records

94(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

PART 15 – ORDERING AND RECEIPT OF TEST REPORTS

Ordering tests by members

95(1) Any member may, after collaborating with, and obtaining the approval of the patient's practitioner, order and receive copies of a screening or diagnostic test and must ensure that the patient's practitioner is advised of the results.

Ordering tests by members in hospital

95(2) Any member in a pharmacy with a hospital pharmacy licence, may, in accordance with hospital policy, order and receive a screening or diagnostic test for a person who is an in-patient of a hospital designated under *The Health Services Insurance Act*.

Ordering tests by extended practice pharmacist

95(3) In addition to the tests referred to in subsections (1) and (2), a member who is an extended practice pharmacist may order and receive the results of screening and diagnostic tests which are within the scope of the member's specialty.

Results to be made available

95(4) A member who orders and receives the results of a screening or diagnostic test, under section 95(3), that;

- (a) reveals medical issues requiring attention, or,
- (b) the member is not able to interpret

must promptly forward the results to a health professional responsible for the patient's care for the interpretation of the results after which the member may advise the patient when delegated the authority by the health care professional to do so.

Test ordering and results record

96(1) A member who orders and receives the results of a screening or diagnostic test must make and retain a record of:

- (a) the name of the patient;

October 8th, 2010

- (b) the address of the patient;
- (c) the nature of the test ordered or recommended;
- (d) the health professional to whom the results were forwarded or the recommendation was made;
- (e) the name of the member requesting the test;
- (f) the date the test was ordered or recommended;
- (g) the date the results were received;
- (h) the date the results were communicated by the member to the health professionals responsible for the patient's care.

Method of keeping Test ordering and results records

96(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

PART 16 – INSURANCE

Professional liability insurance

97(1) Every member unless registered under section 14 of the Act, must be covered by professional liability insurance that provides a minimum of \$2,000,000 per claim or per occurrence and a minimum \$4,000,000 annual aggregate.

Pharmacy Insurance

97(2) Every owner must be covered by commercial general liability insurance with a minimum limit of \$5,000,000.

PART 17 – PUBLICATION

College newsletter

98(1) The council must cause a newsletter to be published and distributed to members and owners a minimum of four times each calendar year.

Distribution of newsletter

98(2) The newsletter may be distributed by way of mail, facsimile, delivery, electronic means, and through a website.

Discipline committee decisions

99(1) After service of a decision and any order of the discipline committee on the investigated person, the council must cause the next newsletter to contain an article summarizing, at a minimum:

- (a) the matters and circumstances considered by the discipline committee; and
- (b) the findings and orders of the discipline committee,

unless the investigated person obtains a stay pending an appeal under Ss. 59 and 61 of the Act.

Complaints committee decision

99(2) Except in the case of a voluntary surrender, where the licence or

October 8th, 2010

registration of an investigated person is cancelled or suspended by the complaints committee under s. 40 of the Act, the council must give immediate notice to the profession and cause the newsletter to contain an article:

- (a) where the licence or registration is suspended pending the outcome of proceedings under Part 6 of the Act, a summary of the reasons of the complaints committee; and
- (b) the name of the investigated person.

Registrar decision

99(3) Where the licence or registration of a person is cancelled or suspended by the registrar under s.23 or 24 of the Act, the council must give immediate notice to the profession and cause the newsletter to contain an article summarizing:

- (a) the registrar's reasons for the cancellation or suspension; and
- (b) publishing the name of the person whose licence or registration was cancelled or suspended.

Notice through newsletter

100 Subject to any applicable by-laws, the newsletter may be used to provide notice to members and owners of matters concerning:

- (a) annual or special general meetings;
- (b) regulations or consultation regarding regulations;
- (c) by-laws;
- (d) the code of ethics or consultation regarding the code of ethics;
- (e) practice directions;
- (f) council resolutions; and
- (g) any other matter of concern to the profession.

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PART 18 - COMING INTO FORCE

Coming into force

101 This regulation comes into force on the day *The Pharmaceutical Act*, S.M. 2006 ?, c.?, comes into force.

SCHEDULE "A" Part 6 of Regulations

STANDARDS OF PRACTICE AND OPERATION OF PHARMACIES

Standard 1 – Collaborative practice

Members, in partnership with patients and other health care providers, use their unique knowledge and skills to meet patient's drug related needs and to achieve positive patient outcomes by maintaining or improving the patient's quality of life.

Standard 2 – Dispensing and sale

Members must only dispense or sell drugs where it is therapeutically appropriate, legal and ethical to do so.

Standard 3 – Patient counselling

Members must counsel the patient, or their agent, providing specific information required for safe and effective drug therapy.

Standard 4 - Drug Information

Members must provide accurate, unbiased and pertinent drug information.

Standard 5 – Drug acquisition and handling

Members are responsible to ensure the safety, accuracy and quality of products and services they supply.

Standard 6 – Prescribing

Members must only issue prescriptions to patients where it is therapeutically appropriate, legal and ethical to do so.

Standard 7 – Administration of drugs

Members must only administer drugs to patients upon informed consent and where it is therapeutically appropriate, legal and ethical to do so.

Standard 8 – Test interpretation

Members interpreting patient-administered automated tests must do so in a competent and accurate manner.

Standard 9 – Test orders

Members may only order screening and diagnostic tests where it is appropriate, legal and ethical to do so.

Standard 10 – Incidents and Discrepancies

Members must expeditiously address, document and report incidents, discrepancies and adverse events in dispensing and provision of patient care.

Standard 11 – Scope of Practice or Operation

Members must practice or operate a pharmacy in a safe and ethical manner and within the provision of the act.

Standard 12 - Extemporaneous Compounding

Members must ensure that all extemporaneous compounding is done in a safe, legal and ethical manner.

October 8th, 2010

Standard 13 – Additional practice direction

Members must practice in compliance with practice directions drafted by other organizations when adopted by Council.

Standard 14 - Documentation

Members must ensure all documentation is clear, comprehensive and readable.

Standard 15 – Records

Members and owners must ensure records required under the act and regulations are stored in a secure and readily retrievable manner and, when it is appropriate, destroy and dispose of in a manner that would protect the confidentiality of patient information.

Standard 16 – Pharmacist to staff ratio

Members and owners must ensure that a pharmacy is operated with a ratio of members to pharmacy technicians, interns, students, and other staff or workers that insures the practice of pharmacy which is conducted in a safe, legal and ethical manner.

Standard 17 – Pharmacy hours

Members and Owners must ensure pharmacist services are available to patients during reasonable hours of operation.

Standard 18 – Policies for staff

Pharmacy managers must develop, implement and maintain current written polices and procedures for the training of pharmacy staff clearly stating the scope and limitations of their functions for the safe, legal and ethical operation of the pharmacy.

Standard 19 – Pharmacy facilities

Pharmacy managers and owners must ensure the facilities are suitable for the pharmacy practice conducted.

Standard 20 – Technology

Pharmacy managers and owners must develop, implement and maintain written policies for the assessment and incorporation of technology into the safe, legal and ethical operation of the pharmacy.

Standard 21 – High risk practices

Pharmacy managers and owners must develop, implement and maintain written policies and procedures to:

- (a) identify, mitigate and avoid situations that expose patients and staff to inappropriate risk; and,
- (b) require all staff to participate in this undertaking.

October 8th, 2010

SCHEDULE "B" Part 12 of Regulations

Conditions (ICD-10)	Prescription Drug Categories (ATC)
L20 Atopic dermatitis	D07AA: Corticosteroids, weak (group I)
L23 Allergic contact dermatitis	D07AB Corticosteroids, moderately potent (group II)
L24 Irritant contact dermatitis	
L50 Urticaria	
O91 Infections of breast associated with childbirth	D07CA: Corticosteroids, weak, combinations with antibiotics
	D07CB: Corticosteroids, moderately potent, combinations with antibiotics
L70.0 Acne vulgaris	D10AE01 Benzoyl Peroxide
	D10AF01 Clindamycin
B35.3 Tinea pedis	D01AE: Other antifungals for topical use
B37.0 Candidal stomatitis	A07AA02: Nystatin
I84.9 Unspecified haemorrhoids without complication	C05AA: Corticosteroids
J30 Vasomotor and allergic rhinitis	R01AD: Corticosteroids
	R01AX03: Ipratropium Bromide
L21 Seborrhoeic dermatitis (excluding pediatric)	D01AE: Other antifungals for topical use
K12.0 Recurrent oral aphthae	A01AC: Corticosteroids for local oral treatment
O21.9 Vomiting of pregnancy, unspecified	R06AA59: Doxylamine, Combinations
Smoking Cessation (no ICD-10 Code)	N07BA Drugs used in nicotine dependence