

Executive Summary of the Changes in the second *Regulations Discussion Document*

The following sections have been changed from the first *Regulations Discussion Document* to create the second *Regulations Discussion Document*. There may be other typos and incidents when these changes listed in this summary required slight, non-significant wording changes in other sections that are not reported below. Please refer to the second *Regulations Discussion Document* for the complete version of the changes being proposed for the consideration of the members.

1(1) Definitions

(new explanation)

1(1) Definitions – “collaborative setting”

The definition of collaborative setting does not necessarily mean the pharmacist and other health care professions are in the same building or even the same city or town. There is opportunity for flexibility. Also, the “other health care professional” is not restricted to a medical doctor.

(new)

“collaborative setting” means a practice setting in which a member works closely and cooperatively with other health care professions;

(changed- typo)

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

(changed)

“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;

(changed)

“health care practice setting” means any practice setting within a pharmacy, primary care, in-patient care, out-patient care or any other practice setting involving direct patient care; (note to council: Changing the term to practice allows for the document to read better and it is really about the practice and not the “setting”.)

(new)

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

(changed)

“supportive care practice setting” means a practice setting in which pharmaceutical skills and knowledge are used outside a health care practice setting;

(changed)

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 **but not to include the home address of the member.**

(changed)

Limitations on conditional and temporary registration

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

- (a) may not vote;
- (b) may not be a member of council
- (c) may not be a member of the board;
- (d) may not be a voting member of any committee;
- (e) may not act as a preceptor;
- (f) may not apply as a specialist or as an extended practice pharmacist, **unless a temporary registration**; *(note: This would allow a "specialist" from another province to work temporarily in Manitoba as an Extended Practice Pharmacist.)* and
- (g) may not act as a pharmacy manager, unless a temporary registration or specifically permitted by council.

(changed)

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.**

(changed)

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 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 have a physical or mental condition which, in the opinion of the registrar, makes the applicant unsuitable for registration as a student;
- (f) satisfy the registrar that the applicant does not have an addiction to alcohol, drugs or illegal substances which, in the opinion of the registrar, makes the applicant unsuitable for registration as a student;

- (g) satisfy the registrar that the applicant has not been convicted of an offence which, in the opinion of the registrar, makes the applicant unsuitable for registration as a student;
- (h) satisfy the registrar that the applicant is of good character and reputation;
- (i) provide to the registrar a recent passport size image of the applicant;
- (j) satisfy the registrar that the applicant is fluent in one of the official languages of Canada; and
- (k) provide an undertaking that his or her practice as a student will be conducted in accordance with the Act, the by-laws, the code of ethics, the standards of practice and all relevant practice directions.

(changed)

Registration of interns

9(1) In addition to the requirements of s.20 of the Act, an applicant for registration as a 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; or
 - (ii) intends to intern for an educational purpose of a type approved by council; or
 - (iii) is serving an internship as required by the Board under section 3 or the registrar under section 14(1).
- (b) satisfy the registrar that the applicant does not have a physical or mental condition which, in the opinion of the registrar, makes the applicant unsuitable for registration as an intern;
- (c)etc.

(new explanation)

11(2) Application for category of licence

After reviewing the responses to the first Regulations Discussion Document, Council wanted to address some of the concerns regarding the two types of pharmacists' licences. According to the new Pharmaceutical Act, only a member can practice pharmacy (section 4(1)a) and a member can hold a pharmacist licence in any category as permitted in section 5(4) and there is further ability to provide additional descriptors in the regulations. A category of licensure could not be "non-practicing" as this is really not a license. If someone was not practicing pharmacy, as described in the definition of the practice of pharmacy in section 2(1) of the act, then it could be determined they are not actively practicing and could not be licenced. The proposed section 13 and definition of supportive care practice allows for a member to practice pharmacy as defined in section 13(1) of this document and then be licenced as a member. If this section is not accepted, licencing may not be possible for pharmacists that supervise, provided drug information or work in academia or administrative capacities and they then may be required to take out a non-practicing membership or show that they practice as defined in the act.

(changed)

Application for category of licence

11(2) An applicant must specify on the application for a pharmacist licence that the applicant is applying under either section 12 or section 13 of the regulations, **or both**. *(note: If a pharmacist is working in both areas and as the licenses differ for the different practices, the option for both licenses is needed.)*

(changed for clarification)

Section 12 practicing licence

12(1) An applicant must specify that he or she is applying for a Section 12 practicing licence if the applicant intends to practice **in a health care practice setting in a facility licensed under the act.**

(changed-typo)

Requirements for Section 12 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 Section 12 practicing licence must provide evidence satisfactory to the registrar that, in the two year period immediately before the date of application, he or she:

- (a) practiced at least 400 hours in a health care setting, ;
- (b) successfully served a period of internship required by council; or
- (c) obtained a degree in pharmacy from an institution which includes a training program, which in the opinion of council, is equivalent to an internship.

(changed)

Short absence from practice

15 (1) ~~Should an applicant not qualify under section 12(2)a or 13(2)a due to an absence from practice of 24 months or less, Notwithstanding s.12(2)(a) and 13(2), if an applicant is returning to practice after an absence of less than 13 months,~~ if the registrar considers it advisable and the applicant has maintained a learning portfolio documenting his or her professional development during their absence from practice , a pharmacist licence may be issued with or without conditions specified by the registrar.

(changed)

Long absence from practice

15 (2) If an applicant is returning to practice after an absence of **more than 24 months 43 months or more,** he or she shall, in addition to the requirements of section 11(1), declare whether a section 12 or section 13 licence is required and:

- (a) serve, to the satisfaction of the pharmacist preceptor, an internship as determined by the board;
- (b) provide evidence, acceptable to the board, of participation in a continuing competence program and maintained a learning portfolio documenting his or her professional development; and
- (c) successfully complete any other requirements specified by the board.

(changed)

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 him or her before January 1, 2004 2004;
- (b) any final disciplinary action taken against him or her on or after January 1, 2004 2004, and before January 1, 2009, if the tribunal issuing it ordered that the member's name not be published for any reason; and
- (c) any final disciplinary action taken against him or her on or after January 1, 2009, if the tribunal issuing it ordered that the member's name not be published.

(new explanation)

Explanatory information

22 *Members are advised that section 22 only pertains to a general description of the profiles and profile categories and does not include council providing an explanation of any members specific record.*

(new explanation)

Change in information in a required category

24(1) *The information posted in 24(1) comes directly from the member and then posted in the profile. If the information comes from another source, it is provided to the member in advance of the posting and the member can agree, disagree or change.*

(changed)

Registrar may revise profile on their own initiative

24(4) If 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 reasonably believes that the information is accurate, the registrar ~~must~~ **may revise the member's profile to include that information and notify the member of the significant changes therein 60 30 days prior to posting.**

(changed)

Member may dispute information

25(2) Within **60 30** 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.

(new explanation)

29(3) Application for components

Another component needs to be added to allow the continuation of the satellite pharmacies that are now operating within the province. Please refer to the new section 37(3) for more information.

(changed)

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:

- (a) central-fill component;
- (b) secondary hospital component;
- (c) long-term care component;
- (d) tele-pharmacy component; or
- (e) intermittent satellite pharmacy.

(changed)

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 be suitable for a lock and leave pharmacy;
- (b) the pharmacy will be open a minimum of 25 hours spread over a minimum of four days per week, unless the council determines that the service may be made available for a specific lesser amount of time.
- (c) the pharmacy will be secure when not in operation, including:
 - (i) that the dispensary and drugs listed on schedule 3 of the manual will be secured and not available for sale;
 - (ii) that non-pharmacist staff will not be able to enter the dispensary or access drugs listed on schedule 3 of the manual;
 - (iii) that non-pharmacist staff will not perform any tasks which are prohibited by the Act or this regulation.
- d) notwithstanding section b, a member with a Section 12 practicing licence will be available to respond to patients a minimum of 37.5 40 hours per week.

(changed)

Distance care component

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

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

(changed)

Requirements for distance care component

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

- (a) the facility will be suitable 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
- (d) a member with a Section 12 practicing licence will be available to respond to contacts from distant patients a minimum of **37.5 40**-hours per week.

(new explanation)

33(3) Restriction on distance care

Council reviewed the many submissions regarding this section. As described in the earlier boxed section, MPhA has had difficulty in agreeing the co-signed prescriptions are valid and the public can be protected through the regulatory authority of MPhA over the IPS Pharmacy business as it now operates. The concepts of agreements were suggested in order to ensure valid prescriptions are being filled and the MPhA has the necessary regulatory authority to investigate and insure public safety. Upon doing some research into the possibility that American State Boards of Pharmacy could enter into an agreement with MPhA, it is clear any agreement would contravene American federal law and the Boards are hesitant to enter into an agreement that would contravene federal law. Notwithstanding Nevada has licensed pharmacies located in Canada, few states would be willing or able to do so. MPhA is at the juncture knowing the regulatory authority over the IPS Pharmacies is questionable due to the inability to exchange prescribing information with other jurisdictions and the limited investigative ability outside the province of Manitoba. The Council will be engaging the government of Manitoba in some meaningful discussion as to the possible next steps to resolve this matter. In the meantime, the sections remain in the Regulations Discussion Document to facilitate further response and discussion.

(changed)

Requirements for tele-pharmacy component

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

- (a) the remote facility will be located in a community that does not have reasonable access to pharmacy services;
- ~~(a)~~(b) the facility and equipment will be suitable for tele-pharmacy;
- ~~(b)~~(c) reasonable arrangements have been made to protect personal and personal health information;
- ~~(c)~~(d) supervision of technician(s) staff at the remote satellite facility will be provided by a member, in part by a live two-way video telecommunication link;
- ~~(d)~~(e) a member must provide an on site inspection of the remote satellite facility a minimum of every two months;

- | (e)(f) patients and health care professionals will be able to communicate with a supervising member by way of a live two-way video telecommunication link;
- | (f)(g) the remotesatellite facility will not be open when the primary pharmacy is not; and
- | (g)(h) the satellite facility and the primary pharmacy each 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; and
 - (iii) the procedure for performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling, prior to dispensing.

Requirements for Intermittent Satellite Pharmacy component

37(3) *The MPhA presently allows for “satellite pharmacies” where a pharmacist from a licensed pharmacy can travel to a location where there is no pharmacy and a practitioner will also travel to provide care. The satellite pharmacy in this case would only be operational when a practitioner is onsite providing care and the satellite is staffed by a licensed pharmacist. Section 37(3) would continue this option that presently exists. The addition of this section will allow for three ways to provide pharmacy services in an under serviced area:*

- i) through section 35(1.1) as a secondary hospital services component where a local community pharmacy or another hospital pharmacy would provided medication management services in the secondary hospital and a pharmacist can attend and/or provide professional services.*
- ii) through section 37(2) as a tele-pharmacy site where the primary pharmacy is in one location, a remote facility in another location that is linked for interactive communication and the remote site is staffed by a technician*
- iii) through section 37(3) as a intermittent satellite pharmacy where the pharmacy located in one area will send a pharmacist along with the anticipated medication supply to fill prescriptions at the satellite and provide care in conjunction with a practitioner that is also temporarily located on site.*

(new)

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 a intermittent satellite pharmacy component must provide evidence satisfactory to the registrar that:

- | (a)(b) the satellite facility will be located in a community that does not have reasonable access to pharmacy services;
- (c) describes the needs of the community and the collaborative practice that will occur;
- (d) describes the location, suitability for the practice of pharmacy and hours of operations;
- (e) the satellite facility and equipment will be suitable to meet the needs of the care provided;
- (f) non-medicinal products or non medical devices will not be sold;

(b)(g) the satellite pharmacy computer will be linked to the primary pharmacy computer, and therefore, have access to the DPIN database;

(e)(h) a member licensed under section 12 will be onsite during all hours of operation;

(i) drugs will not be left onsite when the satellite is not open;

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

(k) all prescriptions dispensed from the satellite pharmacy would indicate as such.

Clinical practice pharmacy licence

38(1) An applicant must specify that he or she 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 pharmacy will provide care professional advice to patients and advise health care professionals to enhance patient care, including the safe and effective use of drugs; or,

(c) the use of the pharmacy is for the sole purpose of training and education of pharmacy personnel.

(new explanation)

39 Pharmacy manager qualifications

Council reviewed the responses regarding this section and reduced the hours from 4000 to 2000 and added the concept the training or professional development programs would need to meet learning objectives as established by Council. Some of the Pharmacy manager training programs already established by certain pharmacy owners would likely qualify. Council reminds members that this requirement is an "or". That being, the training programs or 2000 hours practice (one year) experience is required.

(changed)

Pharmacy manager qualifications

39 In addition to the requirements of s.64(3) of the Act, a pharmacy manager must:

(a) hold a licence under section 12 or section 13 ;

(b) have received training or completed a professional development program that meets the learning objective established by Council or, in the alternative, have at least 2,000 practice hours as a pharmacist at least 4,000 hours of experience as a pharmacist, in any Canadian jurisdiction, in a similar practice setting, or equivalent training or experience satisfactory to council ;

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

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

(changed)

Change of hours

42 If 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.

(change)

Duties of pharmacist

50 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) provide copies of a prescription to a patient;
- (d) assess and approve a prescription for filling or refilling;
- (e) receive and record a verbal prescription from a practitioner or pharmacist extended practice; or
- (f) educate a patient about a drug and their drug therapy.

new explanation

52(2) Qualification of pharmacy technicians

section 52(2) would include a fluency requirement in a, b and c through the establishment of national competencies and educational outcomes.

(changed)

Qualification of pharmacy technicians

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

- (a) has graduated from a program of pharmacy technician training approved by council;
- (b) has passed any examinations approved by council; or
- (c) has work experience and passed a competency assessment acceptable to council.

(changed)

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 with a section 12 pharmacist licence:

- (a) compounding;
- (b) dispensing, subject to approval under s.50(d) and any standards related to counselling the patient;
- (c) operating a tele-pharmacy site; and

~~(e)(d)~~ identifying and assessing when drug-related problems require referral to the member.

(changed)

Duties of pharmacy technicians

52(4) In addition to the duties described in 54(2), the following duties ~~tasks~~ supporting the practice of pharmacy may be performed by ~~delegated to~~ a pharmacy technician, under supervision of a member with a section 12 pharmacist license and in accordance with applicable practice directions:

- (a) reviewing the information on the prescription for legibility and compliance with federal and provincial regulations;
- (b) replenishing drug storage containers and dispensing machines;

new explanation

Council acknowledges many of the responses that expressed concern that technicians would not be able to perform this function safely or this role might be exploited by unscrupulous employers wanting to decrease the role of the pharmacist. However, Council felt that technicians doing this check is not a requirement under these proposed regulations, but it is an option that enables the practice site to use qualified technicians to perform the final check of this technical function and free-up the pharmacist to perform the professional task of ensuring patients are receiving the right medication and therapy.

- (c) performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling performed by another technician, student or intern, prior to dispensing;
- (d) entering prescription information into a pharmacy database ;
- (e) ~~attaching a prescription label to a drug container;~~
- ~~(f) recording and retrieving data regarding a patient or prescription;~~
- (e) providing instruction to a person on how to operate a medical device but not provide any explanation involving the interpretation of results or value of the device;
- (f) inquiring of the practitioner, and receiving the instruction, of whether an existing prescription can be refilled as previously prescribed and without any changes to the prescription;
- (g) collecting information from a patient for a patient profile; and
- (h) entering pharmacy when it is closed and, with the exception of (e), (f) and (g), perform the duties listed under this section.

(new)

Pharmacy technicians in training

52(5) Notwithstanding anything in this section and subject to section 55, a pharmacy technician in training can perform the duties under subsection 3 and 4 under the direct supervision of a member licensed under section 12 or a pharmacy technician.

(changed)

Duties of students

53(2) In addition to the duties described in 52(4) and 54(2), the following duties ~~tasks~~ supporting the practice of pharmacy may be performed ~~delegated~~ to a pharmacy student, under supervision of a member with a Section 12 licence and in accordance with applicable practice directions:

- (a) ~~interpreting the contents of a prescription—educating a patient about their drug or drug therapy; and~~
- (b) receiving and recording verbal prescriptions.
- (c) ~~selecting an appropriate drug container;~~
- (d) ~~preparing a drug for dispensing;~~
- (e) ~~pre-packaging drugs for the purpose of dispensing;~~
- (f) ~~replenishing drug storage containers and dispensing machines;~~
- (g) ~~managing drug inventory;~~
- (h) ~~performing a final check on the packaging or pre-packaging of drugs, container selection, and labelling performed by another technician, student or intern, prior to dispensing;~~
- (i) ~~entering prescription information into a pharmacy database;~~
- (j) ~~attaching a prescription label to a drug container;~~
- (k) ~~recording and retrieving data regarding a patient or prescription; and~~
- (l) ~~collecting information from a patient for a patient profile.~~

(changed)

Limits on duties of other persons

54(2) A member may permit ~~delegate to~~ a person other than a member, intern, pharmacy technician or student, ~~to do the following duties tasks~~ provided they are performed under supervision 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 prescription;
- (e) collecting demographic information from a patient; and
- (f) managing drug inventory.

(changed)

Dispensing by health professionals

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

New explanation

The records that must be kept under section 58 with filling a prescription would be:

- 1) the signature of the section 12 that approved the prescription for filling;
- 2) the signature or initials of the person that prepared the drug for dispensing (if it was not a section 12 member or an intern);
- 3) the signature or initials of the section 12 pharmacist, intern, student or technician that did the final check; and
- 4) the signature or initial of the pharmacist or intern that did the patient counseling.

If that person was the same pharmacist for all the steps (approval, preparation, checking and counseling) once signature would suffice. If the prescription filling process in the pharmacy involved others, then the record would show who was involved and what they did.

(changed)

Authorization Record

58(1) No drug may be authorized for dispensing unless a record of the following is made and retained:

- (a) the date and the signature of the authorizing member under section 86(1), 68(1.1) 86 (4) or 90 of these regulations; or

(changed)

Preparation Record

58(2) No drug may be prepared for dispensing unless a preparation record of the following is made and retained:

- (a) the prescription number and the signature or initials of the member approving the prescription for filling or refilling as required under section 50(d)
- (b) in regard to preparing the drug for dispensing:
 - (i) the signature or initials of the person preparing the drug for dispensing ~~doing the final check of the prepared drug~~ ; and
 - (ii) if the person in (i) is not a member or intern, the signature or initials of the member, intern, student or technician doing the final check of the prepared drug. ~~where the person doing the final check of the prepared drug is not a member or intern, the signature or initials of the member supervising the person;~~

(changed)

Counselling Record

58(2.1) ~~In addition to section 64(1)a and n~~ Not including inpatients of a hospital, no drug may be dispensed unless a counselling record of the following is made and retained:

- (a) confirmation of the drug being dispensed and that applicable standards of practice and practice directions related to the counselling of the patient, ~~or their agent~~, have been met, 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) 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.

(new)

Additional Counselling Record

58(2.2) Notwithstanding section 58(2.1), the counselling record for:

- (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 or making a decision regarding their care

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

(changed)

Prescription record

58(3) In addition to the authorization, preparation 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; and
- (i) the name and address of the practitioner or extended practice pharmacist issuing the prescription;

(change)

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 tele-pharmacy or satellite;
- (e) ...etc.
- (m) the number of refills, part-fills or doses remaining.

New explanation

62(1) Acquisition and sales record

The Council reviewed the response received regarding the record keeping required under this section. Presently in the regulations in Manitoba section 22(2) simply states that all acquisition and sales records must be kept. Council suggests that this simple statement continue in the proposed regulations discussion document and, as a result, several sections are recommended for removal. Council is also aware, according to taxation and accounting requirements and the statutes on limitations, these records need to be kept for seven years and the recommended change is consistent with that requirement.

(changed)

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 two years.

(delete)

Acquisition records

62(1) ~~Every member or owner must ensure a record is made of all drug acquisitions.~~

Purchase of drugs

62(2) ~~Where a drug is acquired by purchase, the acquisition record must include:~~

- ~~(a) the name of the drug purchased;~~
- ~~(b) the drug identification number of the drug purchased;~~
- ~~(c) the strength (where applicable) and quantity of the drug purchased;~~
- ~~(d) the date of the purchase;~~
- ~~(e) the price paid for the drug purchased;~~
- ~~(f) the name of the vendor from which the drug was purchased; and~~
- ~~(g) the address and telephone number of the vendor from which the drug was purchased.~~

(Changed – numbering)

Method of keeping acquisition records

62(56) The records required by this section may be recorded and retained in a readily retrievable manner electronically or on paper.]

63 Disposal Records

In reviewing the responses to this section, Council recommends it be removed. The section will remain that describes the record keeping requirement when drugs from the pharmacy stock are being destroyed (but not including anything that has been previously dispensed and the patient, or somebody on their behalf, has returned the drug for destruction). However, this would be a requirement for all drugs, not just drugs covered under the Controlled Drugs and Substances Act.

(delete)

Disposal records

63(1) ~~Every member or owner must make and retain a record of all disposals of drugs which are not dispensed, or sold by retail.~~

(delete)

Drugs included in this section

63(1.1) This section only pertains to drugs that are included under the federal *Controlled Drugs and Substances Act*.

(delete)

Drug sale

63(2) Where a drug is disposed of by sale that is not pursuant to a prescription or by retail sale, the disposal record must include:

- (a) the signature of the member authorizing the sale;
- (b) the name of the drug sold;
- (c) the drug identification number, lot number and expiry date of the drug sold;
- (d) the strength (where applicable) and quantity of the drug sold;
- (e) the date of the sale;
- (f) the price for which the drug was sold;
- (g) the name, address and telephone number of the purchaser of the drug; and
- (h) a notation of the reason for sale.

(changed)

Drug destroyed

63(3) Not including drugs that have been previously dispensed, where a drug is destroyed, the disposal record must include:

- (a) the signature of the member authorizing the destruction;
- (b) the lot number and the name of the manufacturer's product drug-destroyed
- (c) the reason for the destruction drug identification number of the drug destroyed;
- (d) the strength (where applicable) and quantity of the drug destroyed; and
- (e) the date and manner of the destruction; and the manner of destruction or, where the destruction was performed by a person other than the pharmacy, the name, address and telephone number of the person who destroyed the drug and the date the drug was released to the person.

(delete)

Drug returned

63(4) Where a drug is returned to the manufacturer or the person from which it was purchased, the disposal record must include:

- (a) the name of the drug returned;
- (b) the drug identification number of the drug returned;
- (c) the strength (where applicable) and quantity of the drug returned;
- (d) the date of the return; and
- (e) the name, address and telephone number of the party to which the drug was returned;

(new explanation)

In reviewing the responses, Council determined section 64(1) and 64(2) were not needed as 64(1a) is covered by section 58(2.1) and section 64(1b) is covered by section 58(1b) of this document and section 64(1c) is covered by section 82(3b) of the act. (Until the final regulations are drafted, section 64 will need a placeholder so as to not cause numbering problems in the rest of the document.)

(delete)

Communication records in health care setting

64(1) In a health care setting, every member or owner must make and retain records of the following communications:

- (a) whether patient counselling was performed or refused in regard to a prescription, the identity of the person performing the counselling or accepting the refusal, and the date;
- (b) whether the practitioner issuing a prescription was contacted or consulted in regard to the prescription, the identity of the person making the contact, the method of contact, and the date of the contact; and
- (c) all billing statements and invoices issued to the pharmacy by service providers of telephone, facsimile, cellular telephone, email, internet, voice over internet and video and teleconferencing services.

(delete)

Method of keeping communication records

64(2) The information required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.

(changed)

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
- (d) contain all of the other information required under s.61.

(changed)

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 satisfy himself or herself 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);
- (c) the prescription is entered into DPIN in accordance with any applicable practice directions; and
- (d) the prescription is dated by the **authorized** practitioner within three days of the date it is presented at the pharmacy for filling.

new explanation

Veterinary prescriptions would not be entered into DPIN and out of province patients would be entered in a pseudo-PHIN as it occurs now for M3P prescriptions.

(changed)

Patient access to records

66 Upon request by a patient, a member must provide:

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

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

new explanation

67 Retention of Records

Council is aware of other statutory obligations to keep records longer than two years. For example, prescription records need to be kept for two years as a hard copy from the last time the prescription was filled and for an additional 5 years electronically as described in the interpretation of the *Personal Health Information Act*. This proposed change would make this section consistent and with section 62(1) of this document.

(changed)

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 seven 2 years after the circumstances giving rise to the creation of the record:

- (a) authorization record
- (b) preparation record
- (c) ~~patient~~ counselling record
- (d) prescription record;
- (e) prescription label;
- (f) patient profile;
- (g) acquisition and sales record;
- (h) ~~destruction of drugs disposal~~ record;
- (i) ~~communication~~ record;
- (j) prescriptions which were refused to be filled, under s.68(4);
- (k) prescribing record;
- (l) drug administration record;
- (m) test interpretation record; and
- (n) test ordering and results record.

New explanation

Section 68(1.1) might be best located under section 68 of these regulations. If left as section 86, the recording requirement under section 87 is unrealistic in hospital practice. If the members agree this section should be relocated, Council will need to ensure there is no conflict with "interchangeability" as described under Part 9 of the act.

(moved from section 86 and changed)

Prescribing Substitution by members in hospital

~~86(1.1)~~ **68(1.1)** Any member with a Section 12 practicing licence working in a hospital pharmacy may, upon receipt of a prescription to be dispensed to an in-patient of a facility designated under *The Health Services Insurance Act*

- (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.

(changed)

Questionable prescriptions

68(4) A drug must not be dispensed 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 practitioner issued the prescription in contravention of the rules governing the practitioner's practice of his or her profession;
- (d) the prescription contains an error;
- (e) the patient's safety may be at risk, or
- (f) the drug lacks therapeutic value for the patient.

(changed)

Approved drugs

69(1) Only Health Canada approved drugs may be sold, dispensed or used in compounded preparations. ~~No drug may be compounded, sold or dispensed unless it is approved by Health Canada.~~

new explanation

69(1.1) Approved Substances

Schedule B of the Food and Drugs Act includes standards like *The British Pharmacopoeia* and the *United States Pharmacopoeia*.

(new)

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.

(changed)

Child resistant containers not required

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

(a) by the patient (or his or her designate):

(i) declaring they do not want a child resistant container for ~~their particular prescriptions~~ and the declaration is documented;

and

(iii) the declaration is reasonable in the circumstances of the patient; or

(b) by the practitioner issuing the prescription:

(i) declaring they do not want a child resistant container for ~~their particular prescriptions~~ and the declaration is documented;

(c) by the member:

(i) declaring that, in his or her professional judgment, the use of a child resistant container should be waived with regard to ~~their particular prescriptions~~;

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

(ii) the member has assessed that the declaration 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.

(changed)

Limitations on sale of particular drugs

72(1) The following drugs may only be sold by retail from a dispensary to a patient (or his or her designate) ~~attending the pharmacy in person~~, 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.

(changed)

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 only be sold:

(a) to a ~~medical practitioner, dentist, veterinary surgeon, registered nurse (extended practice) or midwife~~;

(b) to a member ~~or owner~~;

(c) ~~to a patient pursuant to a prescription~~.

New explanation

Section 73 Inducements

Council reviewed the many responses to this section and decided to leave the section as is in the document for the second round of consultation. Council did not agree with the many responses suggesting this was solely “business practice” and not an issue of patient safety or professional practice. If this section was to remain in the final draft regulations, there would still be an opportunity for businesses to provide loyalty programs for items sold without a prescription.

(changed)

Specialty Practice Qualifications

84(1) Except with regard to the clinical assistant specialty, a member is qualified as a specialist in a requested area upon providing evidence satisfactory to the registrar that:

- (a) the applicant has practiced at least 3 years, within the previous five years, in a health care setting;
- (b) the applicant has:
 - (i) obtained certification as a specialist in the requested area through an organization or agency acceptable to council;
 - (ii) passed an examination related to the requested specialty approved by council; or
 - (iii) has work experience related to the requested specialty and passed a competency assessment acceptable to council.
- (c) the applicant continues to practice in a setting consistent with the requested area of specialty; and
- (d) the applicant continues to practice in a collaborative setting **collaboratively with other health professionals working** in the requested area of specialty;

(changed)

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 qualification under section 84; and
- (b) documents professional development in the area of specialty.

(changed-typo)

Extended practice pharmacist practice advisory committee

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

- (a) two pharmacists who are members, appointed by 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.

(changed)

Prescribing by members

86(1) Subject to this part, any member with a Section 12 practicing licence may prescribe the following: **drugs:**

- (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); and
- (d) a medical device approved by Health Canada.

(changed)

Criteria for prescribing

87 A member may only prescribe **a drug** where:

- (a) the member has made a reasonable inquires to assess whether the drug will be safe and effective in the circumstances of the patient, including with regard to:
 - (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 inquires reasonably necessary in the circumstances.
- (b) the member has assessed the patient in person;
- (c) the drug is prescribed in 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 **'s symptoms;**
- (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 their agent, reasonable and available therapeutic options and costs.
- (h) **the device is needed to meet the care needs of the patient.**

(changed)

Continuing Continued care prescriptions refills

90(1) Subject to this section, a member with a Section 12 practicing licence may authorize an additional refill of a prescription, beyond those authorized by the original practitioner issuing the prescription, where:

- (a) the patient has a continuing need or chronic condition;
- (b) the prescribing practitioner or extended practice pharmacist has **died or retired within the previous six months or has not** responded to an inquiry for refill authorization and it would be

onerous or impossible for the patient to contact or attend with the original practitioner issuing the prescription in a timely manner;

(c)etc.

(changed-clarification)

Requirements for continued care prescriptions refills

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

- (a) promptly advise the original practitioner who issued the prescription;
- (b) enter the refill into DPIN; and
- (c) keep the records required by part 8 of this regulation.

(changed-clarification)

Restrictions on continued care prescriptions refills

90(3) A member may 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.

(new)

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).

(change)

Administration of drugs by members

91(1) Any member with a Section 12 practicing licence 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.

(change)

Advanced drug administration

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 subcutaneous injection; or

- (b) through intramuscular injection; or
- (c) intravenously through an established central venous or peripheral access device.

(change)

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.

94(1) Test interpretation

Council reviewed the responses to this section and made a change that recording is required when the member does an interpretation of the results and makes a recommendation.

new explanation

Test interpretation record

94(1) A member who interprets and makes a recommendation to advise a patient regarding a patient administered test must make and retain a record in the pharmacy 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.

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 in the pharmacy of:

- (a) the name of the patient;

- (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 of the test was ordered or recommended;
- (g) the date the results were received;
- (h) the date the results were communicated by the member to ~~made available to other~~ the health professional(s) responsible for the patient's care.

97(1) Professional Liability Insurance

Council would like members to be aware of the proposal in Ontario regarding liability insurance. The requirement to be implemented in Ontario in January 2008 requires "an amount of \$2,000,000 per claim or per occurrence and \$4,000,000 annual aggregate" and must exclude the erosion of the amount through the cost of legal defence. Members should take this possible change into consideration when providing feedback to this section.