

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

Pharmaceutical Regulation Second Discussion Document

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The following sections of the regulation discussion document were referred to the standing Committee or group indicated for deliberation, comments and recommendations. The Committee members were given the entire document, but asked to ensure they reviewed the assigned areas as a priority. However, the committees were also encouraged to review and make comments on the entire document should they wish to do so. The bracketed numbers refer to sections of the act that provide the authority to make regulations.

*Executive Committee (4 practicing pharmacists):*

- conditions imposed upon the dispensing of drugs or classes of drugs (73(1q))
- records to be maintained by members and owner and the length of time to be maintained (73(1t))
- qualifications of pharmacy managers (64(3))
- registers to be kept (73(1d))
- categories of pharmacy licenses (64(1))
- number and nature of pharmacy names ((64(2c) & 73(1wi))
- liability insurance (73(1z) & 73(1aa))
- loyalty programs (73(1bb))
- definition of words and phrases ((73(1cc))
- any other matters.... (73(1ff))
- recommendation on Ministerial regulations on “drugs” and “practitioners” (73(2))
- Code of Ethics review and update (76)
- By-laws review and update (75(1))
- Pharmacist profiles (27)
- Manitoba Prescribing Practices Program (7(9) & 73(1q))

*Standards of Practice Committee (12 practicing pharmacists, plus many more on the subcommittees):*

- Standards of Practice for Pharmacists and Pharmacies (not including the interpretive document)
- obligation of Pharmacy owner under 68(d) & 73(1x)
- pharmacy technicians: definition and delegated functions (73(1p))
- pharmacy students and interns: definition and delegated function (73(1p))
- prescribing and administering drugs (73(1k))
- interpretation of patient-administered automated tests (73(1l))
- ordering and receiving screening and diagnostic tests (73(1m))
- supplying of drugs by members (in addition to dispensing, retail sale and selling) (73(1o))
- conditions imposed upon the dispensing of drugs or classes of

**Discussion Document: ~~July 30~~April 16, 2007**

- *drugs (73(1q))*
- *information contained on the prescription and on the label*
- *premises are suitable for the purpose of pharmacy (64(2bii))*

*Professional Development Committee (14 practicing pharmacists):*

- *professional development (15(1c))*
- *continuing competence (15(1c))*
- *prescribing and administering drugs (73(1k))*
- *interpretation of patient-administered automated tests (73(1l))*
- *ordering and receiving screening and diagnostic tests (73(1m))*
- *pharmacy technicians: definition and delegated functions (73(1p))*
- *pharmacy students and interns: definition and delegated function (73(1p))*

*Board of Examiners (4 practicing pharmacists and one public representative)*

- *licensing and registration (Part 4)*

*Registrar, Assistant Registrars and Executive Assistant (5 staff)*

- *licensing of pharmacies and separate categories (Part 7)*
- *conditional register (73(1c))*
- *temporary practice under section 18(1)b*

*Registration Committee (5 practicing pharmacists)*

- *internship and specialization*
- *prescribing and administering drugs (73(1k))*

*Dispensing Doctors Joint Committee (2 staff from each of MPhA and CPSM)*

- *section 3(2c) regarding dispensing and compounding by practitioner*

*Complaints Committee (2 practicing pharmacists and 1 public representative)*

- *membership, proceedings and quorum of Complaints and Discipline Committees (75(1h))*
- *By-laws*

**Copies of recommendations from the above reviews are available on the Manitoba portion of the [napra.ca](http://napra.ca) website, as well as the recommendations from the Regulations Advisory Committee. These documents will be posted on or before April 27<sup>th</sup>.**

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 Practicing Licence
- 14 Conversion of Licences
- 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 Tele-Pharmacy
- 38 Clinical Practice Pharmacy Licence
- 39 Pharmacy manager qualifications
- 40 Corporate Owner Change

**Discussion Document: ~~July 30~~April 16, 2007**

- 41 Other Changes to Pharmacy Licence
- 42 Change of Pharmacy Hours
- 43 Converting Pharmacy Licence
- 44 Accurate Disclosure of Information
- 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 interns
- 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 Disposal Records
- 64 ~~Communication Records~~
- 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 under the Act
- 78 Veterinarians

**Discussion Document: ~~July 30~~April 16, 2007**

79 Revocation and Appeal

**PART 11 – EXTENDED PRACTICE  
PHARMACISTS & SPECIALITY PRACTICE**

80 Extended Practice Pharmacists

81 Registration

82 Speciality Practice

83 Clinical Assistant Specialist

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 refills

**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**

**1(1) Definitions**

*A definition for a drug is not listed anywhere and needs description beyond what is in the Food and Drugs Act and what will be defined as schedule 1, 2 or 3 under the regulations to the Pharmaceutical Act. A definition of “prescription drug” is needed to separate schedule one from 2 and 3.*

*Health care setting replaces “patient care setting” under the present act.*

*Supportive care replaces the “non-patient care” definition.*

*“Dispense” in the act means the provision of a drug pursuant to a prescription. The actual “handing over” of the medication prepared pursuant to a prescription. Technicians will have an enhanced role under the ~~the~~ new regulations and could allow technicians to “prepare a drug for dispensing” by doing the final check only after the filling of the prescription was approved by a pharmacist. Once the medication has received the final check, it can be “dispensed”.*

**Definitions**

**1(1)** In this regulation,

**"Act"** means *The Pharmaceutical Act*;

**“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;

*This is the similar term that is used in the nursing profession where individuals that have extended ability for practice due to their education and practice site. These pharmacists are defined under section 7 and part 11 and the extended practices are described under parts 12, 13 and 15.*

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.

“**collaborative practice setting**” means a practice setting in which a member 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*;

“**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;

“**hospital**” means an institution or facility under *The Health Services Insurances Act* including personal care homes

“**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;

“**M3P**” 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;

“**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*;

**Discussion Document: ~~July 30~~April 16, 2007**

“**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 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;

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

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

## PART 1 – REGISTERS

### **Part 1 - Registers**

*In addition to the registers required under section 9(1) of the act, the regulations can allow for other registers. Under section 7(1) of the regulations there will be an “Extended Practice Pharmacists” register. Apart from that, no additional registers are being considered at this time. Listing of different types of membership (non-practicing, Honorary and Honorary Life “members” will be described in the bylaws.)*

### **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, and 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, but not to include the home address of the member.

## PART 2 – REGISTRATION

### **Part 2 – Registration**

#### **3) Register of Pharmacists**

*This section lists requirements for the registration of pharmacists, in addition to the list in the Act. Registration is required before a pharmacist can be licenced. The pharmacist's name must appear on either the register or conditional register before a pharmacist licence can be issued. If a pharmacist does not renew their licence at any point in their career, it does not affect their name remaining on the register. Being on the register allows the person to use the name "pharmacist" in Manitoba, whether they have a licence or not.*

*The "board" in this section means the Board of Examiners.*

*3b) & 3c) These requirements can be fulfilled by declaration on the licence.*

*3d) Would require a criminal record check from law enforcement officials, which will include only proven matters including proven matters of "child abuse".*

*3e) Must comply with national fluency standards developed by National Association Pharmacy Regulatory Authority (NAPRA) and part of the Mutual Recognition Agreement.*

*3f) Would require the successful completion of a jurisprudence examination.*

#### **Registration of pharmacists**

**3** In addition to the requirements set out at 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 have a physical or mental condition which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;
- (c) satisfy the board that the applicant does not have an addiction to alcohol, drugs or illegal substances which, in the opinion of the board, makes the applicant unsuitable for registration as a pharmacist;
- (d) 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;
- (e) demonstrate fluency, satisfactory to the board, in one of the official languages of Canada;

**Discussion Document: ~~July 30~~April 16, 2007**

- (f) demonstrate, to the satisfaction of the board, knowledge of the Act, Regulations, by-laws, code of ethics, and practice directions applicable to the practice of pharmacy in Manitoba;
- (g) where the applicant is licenced as a pharmacist in another jurisdiction, provide a letter of standing from that jurisdiction satisfactory to the board;
- (h) serve a period of internship as determined by the board; and
- (i) provide a recent passport size image of the applicant in a manner approved by the board.

**4(1) Conditional Register**

*If the applicant does not have all requirements under 12(1) of the act, but meets all the requirements under this section, they can be placed on the Conditional Register. Typically, this register is used for Canadian graduate applicants who did not pass their Pharmacy Examining Board of Canada exams and can, after serving an additional internship, be placed on this conditional register and then licenced with conditions that will limit their practice. These licenced pharmacists would not qualify for transfer to another province under the Mutual Recognition Agreement.*

**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) satisfies the board that the applicant does not have a physical or mental condition which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a pharmacist;
- (c) satisfies the board that the applicant does not have an addiction to alcohol, drugs or illegal substances which, in the opinion of the board, makes the applicant unsuitable for conditional registration as a pharmacist;
- (d) 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 pharmacist;
- (e) demonstrates fluency, satisfactory to the board, in one of the official languages of Canada;
- (f) demonstrates, to the satisfaction of the board, knowledge of the Act, Regulations, standards of practice, by-laws, code of ethics,

**Discussion Document: ~~July 30~~April 16, 2007**

and practice directions applicable to the practice of pharmacy in Manitoba;

- (g) where the applicant is licenced as a pharmacist in another jurisdiction, provides a letter of standing from that jurisdiction satisfactory to the board;
- (h) serves a period of internship as determined by the board; and
- (i) 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.

***5 Temporary Registration***

*As described in the act, this registration is issued for a pharmacist from another jurisdiction that is urgently needed and no other licenced member is available. Their name will be placed on the Conditional Register (the requirements are listed below a) to g)) and can be issued a licence.*

**Temporary Registration**

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

- (a) provide evidence satisfactory to council that the applicant is licenced to practice pharmacy and actively practices in another jurisdiction acceptable to council;
- (b) advise council as to all the jurisdictions in which the applicant is licenced to practice pharmacy;

- (c) provide a letter of standing, satisfactory to council, from the jurisdiction in which the applicant is currently licenced and actively practicing pharmacy;
- (d) complete the application forms specified in the by-laws;
- (e) provide a work history satisfactory to council;
- (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 and temporary 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 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 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 a extended practice pharmacist, unless a temporary registration; -and
- (g) may not act as a pharmacy manager, unless a temporary registration or specifically permitted by council.

*7(1) An Extended practice Pharmacist register needs to be compiled and the qualifications are described in Part 11 of the regulations. The Extended practice register will include section 12 (see below) pharmacists that have an assessed knowledge and training level to qualify as a "specialist" or are qualified as a clinical assistant under the regulations to the Medical Act.*

### 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.

#### **8(1) Registration of students**

*As students can be delegated tasks and are subject to the Complaint and Discipline section, they need to be registered and meet the requirement in section 19 of the Act and this section. Students will qualify for registration by being enrolled in a pharmacy education program approved by Council and does not necessarily mean only the University of Manitoba. They must register by December 31 in the year they were admitted to the Faculty at U of M and would be registered as a student in the first three years of their education. (In the fourth year and upon graduation, they would be considered an intern.) If from outside MB, the student needs to apply 30 days prior to their intended starting date of work.*

### 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

**Discussion Document: ~~July 30~~April 16, 2007**

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; and

~~(j)(i)~~ satisfy the registrar that the applicant is fluent in one of the official languages of Canada; and

~~(j)(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.

**8(2)** *Should any of the events occur in section 8(2), the student would be required to report the information to the Registrar as required under section 10 of these regulations.*

**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 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 they are employed and working as a student should they cease to be enrolled in the pharmacy education program under 8(2)b.

**9(1) Registration of Interns**

*A person would qualify as an intern when they are within 12 months, before or after, graduation, is interning in the province for educational purposes or re-qualifying for a practice licence. Presently, pharmacists wanting to attend Manitoba for education purposes have no opportunity to be recognized at the practice site. This regulation would allow the College to recognize them as interns for educational purposes.*

**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

**Discussion Document: ~~July 30~~April 16, 2007**

- (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
  - ~~(ii)~~ (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) 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 an intern;
- (d) 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 pharmacist;
- (e) provide to the registrar a recent passport size image of the applicant  
.; and
- (f) provide an undertaking that his or her practice as an intern will be conducted in accordance with the Act, the by-laws, the code of ethics, the 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: \

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

*Should an intern have their registration suspended or cancelled, Council would require a notice go to all pharmacies/pharmacists as it is presently being done for pharmacists.*

**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**

***11(1) Licensing***

*Once pharmacists are registered, they now can be licenced under section 15(1) of the act and this section.*

*Under section 11(1)a, investigation would be defined, as it is in the act, as being ordered by the Complaints*

**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 he or she 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 have a physical or mental condition which, as set out by the Council, makes the applicant unsuitable for licence as a pharmacist;
- (c) satisfy the registrar that the applicant does not have an addiction to alcohol, drugs or illegal substances which, as set out by the Council, makes the applicant unsuitable for licence as a pharmacist;
- (d) provide evidence of insurance, if required by part 16 of these regulations;
- (e) 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;
- (f) advise as to the intended scope of the applicant's practice; and
- (g) disclose whether he or she has a licence to practice of pharmacy in another jurisdiction;

### **11(2) Application for Category of Licences**

Presently, pharmacists' licences are either patient care or non-patient care. There has been some uneasiness regarding pharmacists being listed using the term "non-patient care". The uneasiness is based upon the term itself and the ability to switch from non-patient care to patient care to fulfill a temporary practice role or a permanent conversion under the present regulations.

It has been difficult to set a name to aptly describe the practice area where pharmacists work in a practice setting using their knowledge to affect patient care through direct patient contact through prescription filling and assessing and counseling patients..

Clearly, there are pharmacists practicing in other important areas of "pharmacy". They still maintain their knowledge of drugs and practice pharmacy without directly interfacing with patients.. These pharmacists could be practicing in an administrative or policymaking capacity or in drug information research.

After exhaustive consideration of possible names, it was decided to include a section in the discussion document that would differentiate the type of practice.. As the act would only permit the issuing of a pharmacist licence when the pharmacist is practicing pharmacy (defined in section 2(1) and 2(2) of the Act), the proposal describes a "section 12" practicing licence and a "section 12 with conditions" practicing licence. The section 12 would be pharmacists that practice in a health care practice setting as defined in the regulations (see definition section). However, pharmacists that practice pharmacy in administration, policymaking, drug information or in supervisory capacity, to name a few examples, also need to be licenced. Under section 13 there is recognition of this type of practice that would include conditions on the license.

There will be pharmacists licenced under section 12 and section 13 of these regulations. There is no hierarchy intended,, they are just different areas of practice.

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 licence. 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, licensing 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.

### **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.

**Requirements of Section 12 practicing licence**

Qualification would include practicing in a health care practice setting (defined as any practice setting within a pharmacy, primary care, in-patient care, out-patient care or any other setting involving direct patient care)

**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.

**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) practised at least 400 hours in a health care practice 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.

**Restrictions Section 13 practicing licence**

*Pharmacists under section 13 of the regulations will have other pharmacists or health care professionals between their practice decision or recommendation and the patient. They can provide general information about medications to the public, specific information through consultation by another health care professional, do external clinical analysis with patient specific or cohort information but would not be able to be the person responsible for making the final decision regarding a particular*

**Section 13 practicing licence**

**13(1)** For an applicant under this section must specify that he or she intends to practice in a supportive care practice setting and is applying for a practice licence, the practice of pharmacy includes:

- a. the supervision of monitoring drug therapy and advising on the contents, therapeutics values and hazards of drugs; and
- b. the provision of information and training to identify and assess drug related problems, and making recommendations to prevent or resolve them.

### Requirements for Section 13 practicing licence

**13(2)** In addition to the requirements of s.15(1) of the Act and s.13 of these regulations, an applicant for a Section 13 practicing licence must provide evidence satisfactory to the registrar that, in the two year period immediately before the date of the application, he or she practised at least 400 hours in a supportive care practice setting,

### Restrictions on Section 13 practicing licence

**13(3)** The Registrar will issue a pharmacist licence under this section with the condition the member does not practice pharmacy in a manner where he or she would:

- (a) perform any of the duties described in section 50 of these regulations; or,
- (b) provide patient specific health care advice or care directly to a patient.

### Converting to Section 12 practicing licence

**14(1)** Where, during the duration of a pharmacist licence, a member intends to have the conditions described under section 13 removed, the member must:

- (a) surrender his or her pharmacist licence to the registrar;
- (b) register as an intern for educational purposes in a health care practice setting for a period of time determined by the registrar and to the satisfaction of a Section 12 member acting as the supervisor;
- (c) complete the application form prescribed in the by-laws; and
- (d) pay the fee specified in the by-laws,

and thereafter, be issued a Section 12 practicing licence.

*14(2) Notwithstanding that section 13 pharmacists will not directly impact upon patient care without the involvement of another health care professional, the advice and consultation provided by a section 13 pharmacist must be credible and correct and their ability to practice safely in that role should be described and confirmed upon conversion.*

### Converting to a Section 13 practicing licence

**14(2)** Where, during the duration of a pharmacist licence, a member intends to change his or her practice in a manner which would make a Section 13 practicing licence more appropriate, the member must:

- (a) surrender his or her pharmacist licence, issued under section 12, to the registrar;
- (b) advise the registrar as to the nature of the practice intended to be conducted and a description of the ability for the member to perform in the intended practice setting;

- (c) complete the application form prescribed in the by-laws; and
- (d) pay the fee specified in the by-laws

and thereafter, be issued a section 13 pharmacist licence.

**14(3) Temporary conversion to Section 12 practicing licence**

*This section will allow section 13 pharmacists to work temporarily as a section 12 practicing pharmacist with additional conditions imposed by the registrar to ensure patient safety. Conditions might include working with a pharmacy technician, not compounding medication, having on call access to a section 12 pharmacist, etc.*

**Temporary conversion to Section 12 practicing licence**

**14(3)** Where, during the duration of a pharmacist licence, a member intends to practice temporarily ~~in a setting which where it~~ would make a Section 12 practicing licence more appropriate, the member 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 practice intended to be conducted;
- (d) advise the registrar of the location at which the member intends to practice;
- (e) provide evidence satisfactory to the registrar that the member's temporary practice will not place patient safety at risk;
- (f) comply with any conditions on the temporary practice imposed by the registrar; and
- (g) practice ~~temporarily in the temporary setting~~ for a period of not more than 400 hours unless approved by Council.

**Temporary Practice hours may not apply**

**14(4)** Hours of practice under a Temporary Section 12 practicing licence may not apply towards the hours of practice required under s.12(2).

**Short absence from practice**

**15 (1)** ~~Notwithstanding s.12(2)(a) and 13(2), if an applicant is returning to practice after an absence of less than 13 months, 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, 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.

**Long absence from practice**

**15 (2)** If an applicant is returning to practice after an absence of ~~more~~

**Discussion Document: ~~July 30~~April 16, 2007**

~~than 24 months~~~~13 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.

**Renewal of pharmacist licence**

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

- (a) meeting all the same requirements of s.15 of the Act and s.11, 12 and 13 of these regulations for an initial application for a pharmacist licence, and
- (b) providing evidence to the registrar that, in the preceding 12-month period, he or she has:
  - (i) participated in a continuing competence program, or an equivalent program, approved by the council; and
  - (ii) maintained a learning portfolio documenting his or her professional development, in a form and consistent with the requirements approved by the council.

**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**

***21(1) Council must make pharmacist profiles available***

*This section would require, by January 2009, pharmacist profiles be available to the public. The approval of this section is described under Part 5 of the Act and the authority to approve this section rests with Council. However this section is included in the Regulations Discussion Document for review and input by the members. The January 2009 target date should provide enough time, depending when the regulations are passed, to develop and post the profiles. The public access to a professional's profile is government policy and will occur eventually for all health care professions. Presently, the College of Physicians and Surgeons are required to do this and these sections were lifted from the regulations to the Medical Act. The sections were adapted for pharmacy. One change of note is sections 25 and 26 that provide for the Registrar to judge whether the public access information needs to be changed, rather than the Council to decide. If the affected person does not like the ruling of the Registrar in this regard, it can be appealed to Council. The regulations to the Medical Act have the opposite process.*

**Council must make pharmacist profiles available**

**18(1)** Beginning January 1, 2009, 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.

As an exception, if the council reasonably believes that a licenced 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)** Despite 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) by 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 sex;
- (c) the current address at which the member primarily conducts his or her practice;
- (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 10 years by the body named in the profile as regulating the profession that

**Discussion Document: ~~July 30~~April 16, 2007**

the member is or has been licenced to practice, whether in Manitoba or elsewhere, and if the member has initiated an appeal respecting the disciplinary action, this information must be included in the profile;

(i) any current restrictions, terms or conditions imposed 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 issued 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, this information must be included in the profile;

(m) a description of any offence under

(i) the *Criminal Code* (Canada),

(ii) the *Controlled Drugs and Substances Act* (Canada), or

(iii) 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, this information must be included in the profile.

**Information re member's sex not to be included on request**

**20(2)** The council must not include a member's sex 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 him or her before January 1, 2004;

(b) any final disciplinary action taken against him or her on or after January 1, 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.

**Limit on including information re disciplinary action under appeal**

**20(4)** If 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.

As an exception, 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

(c) ~~(b)~~ languages spoken (including American Sign Language), .

**22 Explanatory Information**

*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.*

**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 about the member 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.

**24(1) Change in information in a required category**

*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.*

**Change in information in a required category**

**24(1)** If, 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 he or she reasonably believes that the information is accurate.

**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.

**Profile provided to member before publication on request**

**25(1)** If a member requests an opportunity to review his or her profile before it is made available to the public, the registrar must promptly provide the member with a copy of the profile. At the request of the member, the registrar may satisfy this requirement by providing an electronic version of the profile.

**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.

**Registrar may make profile available despite dispute**

**25(3)** Despite 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) if 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.

**If member fails to provide information**

**26** If 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, 2010, 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) 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 URL of any websites used by or affiliated with the pharmacy.

**Additional business information reported**

**29(1.1)** In addition to the information required on the licence application, the pharmacy owner must report, to his or her knowledge, all businesses in which the pharmacy has entered into an agreement or contract to refer patients to the pharmacy and all agreement or contract where the pharmacy will refer patients to another business.

***29(2) Application for category of licence***

*The document proposes three types of pharmacy licences: community, hospital or clinical practice. Each type of practice is described in the regulations. The community and hospital are clear, the clinical practice is a pharmacy that does not sell or distribute drugs. If an owner applies for more than one type of licence or component, it would not double or triple the fees.*

**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.

***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.*

**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; ~~or~~

~~(d)~~ tele-pharmacy component.~~or~~

~~(d)~~~~(e)~~ intermittent satellite pharmacy.

#### **Application for community pharmacy components**

**29(4)** Where an applicant applies for a community pharmacy licence, the applicant must indicate whether it is applying for one or more of the following additional components to the requested licence:

(a) lock & leave component; or

(b) distance care 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.

#### **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 pharmacist or pharmacy from

providing care where there is an urgent situation and it is important to meet the needs of patients.

### **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 work-flow plan for the proposed pharmacy satisfactory to the registrar;
- (d) a sketch of the physical layout of the proposed pharmacy; and
- (e) 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 he or she 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 who, themselves or by a representative, will attend the pharmacy in person, or who will receive their drugs by delivery within the local community.

### **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 be suitable for a community pharmacy;
- (b) the facility will be staffed and managed by members capable of operating a community pharmacy; and
- (c) the hours of operation will meet the needs of the community served by the pharmacy.

**Lock and leave component**

**32(1)** An applicant for a community pharmacy licence must specify that he or she 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 retail operation; and
- (c) the applicant intends to close off the dispensary and 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 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.

### **33 Distance Care component**

*This area of Pharmacy practice has its own needs for Standards of Practice. It is suggested a separate component of the licence is needed as the practice requires additional standards to provide care from a distance. This component would be required for pharmacies serving patients that do not live in the immediate area and will not attend the pharmacy. This would include the IPS component that occurs now. All patients must be able to contact the pharmacy directly and without communication charges and must be open at least 25 hours per week and pharmacist available for response to questions at least 40 hours per week. The MPhA has received numerous applications for IPS Pharmacies identifying the hours of operation as only 12 to 15 hours per week.*

*An agreement must in place between the College of Pharmacists and the jurisdictions serviced by the pharmacy describing the terms and conditions under which the pharmacy can legally provide drug and services, sharing of information between the jurisdictions and the process by which complaints are investigated. This is similar to the process being done in Alberta. However, Alberta has gone further to prohibit Alberta pharmacies from selling medication to patients residing outside of Canada. The Minister of Health has advised the College (MPhA) of the importance to keep IPS as a business in Manitoba. The Minister can determine who is included as a practitioner through section 73(2) of the Act. In discussions prior to the December passing of Bill 41, Government officials announced the intention to include American physicians as "practitioners" in Manitoba.*

*If Manitoba pharmacies continue to sell drugs for use by Americans, section 33 will overcome some of the difficulties experienced in gathering information and evidence from other jurisdictions and lack of authority for the College to compel witnesses.*

*Under this section Distance Care Pharmacies could continue international activities, now known as IPS, but the conduct now would be defensible and in a safe, legal and ethical manner. This section will also include non-IPS inter- and intra-provincial mail order activities.*

### **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.

### **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.

**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

**Restrictions on distance care**

**33(3)** A pharmacy with a distance care component may only provide services to patients who do not attend the pharmacy in person where:

- (a) the patient resides in Manitoba; or
- (b) the patient resides in another jurisdiction, and
  - (i) the jurisdiction in which the patient resides, or the body governing the practice of pharmacy in that jurisdiction, has entered into an agreement with the college regarding the terms and conditions under which a Manitoba pharmacy may provide services to residents of that jurisdiction; and
  - (ii) the pharmacy agrees to and follows the terms and conditions of the agreement.

**Agreements regarding non-Manitoba patients**

**33(4)** An agreement under s.33(3)(b) must contain terms satisfactory to council relating to:

- (a) the manner in which services may be provided in compliance with the law of the other jurisdiction;
- (b) whether the pharmacy must be licenced or otherwise registered in the other jurisdiction;
- (c) sharing of information between the jurisdictions; and
- (d) complaints originating in the other jurisdiction.

#### **Pharmacy may initiate agreement**

**33(5)** Where no agreement under s.33(3)(b) exists with a particular jurisdiction, an owner may:

- ~~(e)~~(a) initiate discussions with the appropriate authorities in the other jurisdiction;
- ~~(f)~~(b) prepare a draft agreement; and
- ~~(g)~~(c) require the council to review and consider the draft agreement.

*The section on Distance Care will cause difficulty for the International Prescription Service (IPS) Pharmacies, and without an agreement in the jurisdictions outside Manitoba, the IPS business would cease to operate. There is concern that section 33(b)i would not be possible to implement immediately upon the regulations being passed. Council agrees an implementation date should be considered and further information is needed regarding the receptiveness of the State Boards, for example, to participate in such agreement, before this section is considered for draft regulations.*

#### **Long-term care component**

**34(1)** An applicant for a community pharmacy licence or hospital pharmacy licence must specify that he or she is applying for a long-term care component if: the pharmacy will operate to serve patients residing in long-term care facilities and/or personal care homes designated under *The Health Services Insurance Act*.

#### **Requirements for long-term care component**

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

- (a) the facility will be suitable for servicing a long-term care facility;
- (b) facility will be staffed and managed by members capable of serving long-term care facilities; and
- (c) the hours of operation will meet the needs of the community and facilities served by the pharmacy.

**35(1) Hospital Pharmacy Licence**

*Although MPhA presently licences hospital, the College would issue a specific Hospital Pharmacy Licence and additional requirements are listed in 35(2). Hospital Pharmacies selling drugs to person other than inpatients or outpatients would require a Community Licence.*

**Hospital pharmacy licence**

**35(1)** An applicant must specify that he or she 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*.

*35(1.1) This section would allow hospitals to serve other hospitals as “wards” and community pharmacies to service the local hospital as is often done in rural settings.*

**Secondary Hospital Services Component**

**35(1.1)** An applicant for a community pharmacy or hospital pharmacy licence must specify that he or she 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 be suitable for a hospital care pharmacy;
- (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.

**36(1) Central fill component**

*Hospital and Community pharmacies will have the ability to package medication and fill prescriptions for another pharmacy. Because patient care will be provided by the pharmacy that comes in direct contact with the patient, the central fill pharmacy will not contact patients and will only provide the packaging services. Pharmacists only working in a central fill operation would not qualify for a section 12 licence*

**Central-fill component**

**36(1)** An applicant for a community pharmacy or hospital pharmacy licence must specify that he or she 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 be suitable 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 and personal health information;
- (d) the pharmacy will not interact directly with the patient for whom the prescriptions services are provided;
- (e) records are being kept in compliance with sections 58 and 61 of these regulations; and
- (f) the facility 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.

### Central Fill Practice Hours

**36(4)** Any member can practice in a manner described under 36(1), but the hours accumulated in this practice would not qualify under section 12(2)a.

#### **37(1) Tele-pharmacy component**

*This component allows for innovation to serve remote and under serviced areas. The pharmacy can have satellite locations where technology would allow for the preparation and dispensing of medication at the satellite location, remote supervision by licenced pharmacist and patient counseling by the pharmacist through interactive technology without having the patient and the pharmacist physically in the same location. This component is available for Hospital or Community Pharmacy.*

### Tele-pharmacy component

**37(1)** An applicant for a community pharmacy or hospital pharmacy licence must specify that he or she is applying for an tele-pharmacy component if:

- (a) the pharmacy will include at least one ~~remote satellite~~ facility in a remote community used for dispensing or selling drugs, or for preparing drugs for dispensing; and
- (b) the ~~satellite~~ facility will not regularly be staffed by a member.

### 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) at the ~~remotesatellite~~ 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;

**Discussion Document: ~~July 30~~April 16, 2007**

~~(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 remote satellite 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.

**37(2) and 37(3) Requirements for tele-pharmacy component and Satellite Pharmacy**

The M.Ph.A. 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 provide 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 permanent 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.

**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) the satellite facility will be located in a 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;

**Discussion Document: ~~July 30~~April 16, 2007**

- (f) the satellite pharmacy computer will be linked to the primary pharmacy computer, and therefore, have access to the DPIN database;
- (g) a member licensed under section 12 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 prescriptions dispensed from the satellite pharmacy would indicate as such.

**38(1) Clinical Practice Pharmacy Licence**

*This licence allows for practice sites that would not be dispensing or selling drugs. This would allow innovation in the practice site while still protecting the public through the requirement of record keeping and permitting the College inspectors to access the site and audit the practice. Section 38(1) c would allow the licensing of “Model Pharmacy” at the Faculty of Pharmacy and similar training sites in Manitoba. Also, the members practicing in the clinical practice pharmacy could be section 12 pharmacists, with or without conditions, depending upon the type of practice described in the pharmacy license application.*

**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~~ist~~ 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.

**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 be suitable for a clinical practice pharmacy;

**Discussion Document: ~~July 30~~April 16, 2007**

- (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.

**39 Pharmacy Manager Qualifications**

*This is a new section that describes the qualifications a member must possess to become a manager. This section has some flexibility that a pharmacist could receive training, in lieu of the practice hours. It will also require the manager to actually be onsite to "personally and adequately supervise the operation of the pharmacy". There have been patient care incidents giving rise to complaints where managers were new graduates or were experienced pharmacists but were rarely on site.*

**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

**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.

**Corporate owner change**

**40(1)** If 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.

*“Surrender the Licence” in this section means the pharmacy will continue to be licensed, it is the actual paper license that needs to be surrendered to the office in order that a new and updated version of the document can be issued.*

#### **Partnership change**

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

- (a) there is a change in any partner;
- (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)** If 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)** If 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)** If 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 at least 14 days in advance of the change.

### 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.

### Converting licence

**43(1)** Where, during the duration of a pharmacy licence, an owner intends to change his or her 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 his or her 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.

*The conversion of pharmacy license for the addition of categories or components should not be onerous.*

### 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.

#### **45 Business names**

*Until recently, pharmacies operated under one business name. Some IPS Pharmacy owners wanted the ability to operate under a second business name and that has been allowed. The reason given for the second name was to enhance market profile on the World Wide Web. However, two names have caused some confusion by the public, banks, wholesales and other licensing authorities. This section goes back to the concept there is only one business name. However, Council can approve an additional name upon application.*

#### **Business names**

**45** A pharmacy may conduct business:

- (a) under a single business name;
- (b) under additional business names, if approved by and under conditions imposed by council; and
- (c) 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 conspicuous location at each facility included under the pharmacy licence.

#### **Closure of pharmacy**

**47(1)** If 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 of Practice*

*Standards of practice are presently one or two sentence standards that are in the regulations. This will adopt the same concept, but in a schedule format. Rather than placing the standards right in the document and creating some sequential numbering problems, they will be attached as a schedule. The Standards of Practice will remain a one or two sentence statement. Council will provide an interpretative document to assist in the compliance with standards, as it does now.*

### 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 they are responsible;
- (d) students and interns, in conducting the tasks delegated to them; and
- (e) persons operating under the authority of Part 10 of these regulations.

## PART 7 – DUTIES AND DELEGATION

### *Duties and Delegation*

*This section takes the definition of the “practice of pharmacy” and “included practices” as described in section 2 of the act that only a pharmacist can do, and allows the pharmacist to delegate some of these duties to others. It is also important to note when supervision is “direct supervision” and when it is just “supervision”.*

### *50 Duties of Pharmacist*

*This section recognizes that the regulations can describe what can be delegated and to who, but these five tasks cannot be delegated to anyone. In other words, only a pharmacist can do these five tasks. Section 3(2) of the Act does recognize that other health care professionals might do some of these tasks in the practice of their profession.*

### Duties of pharmacist

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

Discussion Document: ~~July 30~~April 16, 2007

- (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; ~~or~~  
~~(e)~~(e) receive and record a verbal prescription from a practitioner or extended practice pharmacist; or

Although the prescription refill approval process for inpatients of hospitals is different from the process in community or for outpatients, there must be a process whereby pharmacist approves the prescribed medication that is being provided (refilled) for inpatient use.

- (~~e~~) educate a patient about a drug and their drug therapy.

**51 Duties of an Intern**

*This section allows all duties of a pharmacist, except those described in section 50, to be delegated to an intern under supervision. However, this is not direct supervision and the intern will have greater latitude than a student. The difference being the interns can do the tasks described in section 50.*

**Duties of interns**

**51** Subject to section 50, an intern may be delegated and engage the practice of pharmacy or any other task supporting the practice of pharmacy, under the supervision of a member with a Section 12 practicing licence.]

This section is to mean that interns can be delegated all the tasks included in the practice of pharmacy and all related tasks as well. Related tasks would be like the ones described under sections 52(4) and 53(2).

### **52 Technicians**

Technicians will not be registered or regulated under Bill 41. When first approached, government advised MPhA that we can define technicians and what they can do, but MPhA would not be able to (register, licence and discipline) technicians.

This section provides a definition of technician and what areas of the practice of pharmacy can be delegated to them. Remember that “dispense” means to provide a drug pursuant to a prescription (i.e. give to a patient and/or send it on delivery). It is possible for a student or technician to dispense when the prescription is approved by the pharmacist for filling under section 50(d) and counseling has occurred. Realizing dispensing is the actual giving of the drug to the patient, it would be difficult for the regulations to only permit a pharmacist to “dispense”. This section would also allow for tele-pharmacy remote site satellite settings where the technician might be the only person in the same location as the patient.

Technicians may also be able to identify drug related problems, through the data entry process for example and then bring this information to the attention of the pharmacist.

Section 52(4) lists other things a technician can do, that really are not included in the definition of the practice of pharmacy. The final check on the preparing medication pursuant to a prescription, for example, is not covered in the practice of pharmacy. So this activity is under section 52(4) whereas “dispensing” is under 52(3) because that is under the practice of pharmacy.

It will be the pharmacy manager and the pharmacist (see sections 55 & 56) who determine who meets the qualifications

### **Delegation to pharmacy technicians**

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

#### **52(2) Qualification of a pharmacy technician**

There is much work being done nationally to set competencies, accredit technician training programs, and develop an examination. There is no plan for “grandfathering” technicians, but section 52(2)c would allow for the technicians now working to qualify through an assessment against the approved competencies. There would be a “sunset clause” for the implementation of this section. A sunset clause means that this section would not be in place until a particular time period after the regulation has passed to allow persons that are now functioning as a technician to meet the qualification described under this section and then be allowed to receive delegation and perform the duties described under this section. The time allowed for this “sunset” implementation cannot be estimated until the content of the section is

#### **52(2) Qualification of a pharmacy technician**

Section 52(2) would include a fluency requirement that would be included in a, b and c.

### **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.

#### 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; and
- (c) operating a tele-pharmacy remote site; and  
~~(e)~~(d) identifying and assessing when drug-related problems require referral to the member.

*52(4) A technician cannot be delegated the duty of advising or counselling patients about drugs nor can they be delegated the explanation of medical devices.*

#### Duties of pharmacy technicians

**52(4)** In addition to the duties described in 54(2), the following duties. The following 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;
- (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;

Allowing the technician to perform the final check of the prepared drugs pursuant to a prescription would be an option for the practice site and not an obligation.

*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.*

(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; and~~

~~(g)(e) provide 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;~~

~~(g)(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) enter the pharmacy when it is closed and, with the exception of (e), (f) and (g), perform the duties listed under this section; and

~~(g)(h) collecting information from a patient for a patient profile.~~

Section(g) does not allow a technician to perform any of the duties listed in 52(3) while the pharmacy is closed and there is not pharmacist located therein.

### ***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.

### **53 Students**

*Students are in the first three years of their pharmacy education. This section describes what can be delegated and what other activities they can do. There is a slight difference that these activities can only be done under direct supervision of a section 12 licenced pharmacist.*

*Section 53(3) anticipates there may be different levels of activities a student may perform depending upon the year of enrollment and individual capabilities.*

### 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 with a Section 12 licence:

- (a) compounding;
- (b) dispensing, subject to approval under s.50(d) and any standards related to 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. The following tasks~~ supporting the practice of pharmacy may be ~~performed delegated by 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;~~
- (a) educating a patient about their drug or drug therapy;
- (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.~~

### 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.

#### **54) Other persons**

*Anything listed in this section or under the definition of practice of pharmacy cannot be delegated to "other persons". Anything listed in 54(2) can be done by anybody under supervision. The high school student, for example, could work in the dispensary to do data entry, collecting addresses, etc.*

### Duties of other persons

**54(1)** A person other than a member, intern, pharmacy technician, or student may 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 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 prepackaging~~ a drug for dispensing;
- (b) selecting an appropriate container;
- (c) attaching the prescription label to the container;
- ~~(d)~~ (d) recording and retrieving data regarding a patient or prescription;
- (e) collecting demographic information from a patient; and
- (f) managing drug inventory.

#### **54(3) Dispensing by health professionals**

*A pharmacist can delegate dispensing (giving a drug to a patient pursuant to a prescription) to another health care professional, if the pharmacist has approved the prescription for filling or refilling. The patient counseling would need to be done as required in the standards of practice. A scenario where this might apply is a pharmacist sending medication prepared pursuant to a prescription to a medical clinic for a nurse or physician to provide the medication to the patient (dispense) and the pharmacist has done the counseling or has sent counseling instructions for the health care professional to provide.*

### 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.

### 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.

### 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 supervisions do not delegate tasks to any person, unless that person is reasonably qualified and competent to engage in the specified 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

*This section may provide compliance challenges for the inpatient records to be kept in a hospital setting and exemptions have been noted. Further exemptions may be needed and members practicing in hospitals are encouraged to provide feedback and reference the pertinent sections.*

### Records required

**57** The records set out in this part are required to be made and kept:

- (a) in a health care practice setting; and
- (b) in a supportive care practice setting.

**58 (I) Authorization record**

*The regulations separate the record keeping for authorizations to fill the prescription from the records being kept for preparing the medication pursuant to the prescription. Because the authorization can come from existing refills or practitioners and members, this was done to make the prescription authorization and filling process and the records clearer.*

**58 Records to be kept**

*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 counselling.*

*If that person was the same pharmacist for all the steps (approval, preparation, checked and counselled) 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.*

*(Throughout this document, there are provisions for keeping records electronically.)*

**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), or 68(1.1) 86 (4) or 90 of these regulations; or
- (b) the date and the authorization by the practitioner or extended practice pharmacist for dispensing the medication pursuant to a prescription, 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.

**58(2) Preparation Record**

*In a pharmacy that receives and documents the authorization and does the filling of the prescription, the records would likely be kept on the same document and in the same location. If one pharmacy does the authorization component and another does the preparation, the records would be in different pharmacies.*

*Regarding the final check under b), the person could be a technician, student, intern or pharmacist, but if it were a technician or student, the record would need the signature or initials of the pharmacist who is supervising.*

*If it is the same member that is approving the prescription under section 50(d) and then is also doing the final check, the member would be required to sign both activities separately.*

**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:

**Discussion Document: ~~July 30~~April 16, 2007**

- (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;~~

*58(2.1) In combination with the standards of practice, only a pharmacist or an intern could counsel the patient about drugs received pursuant to a prescription. If a student given the authority under section 53(1) to do the counseling, the record requires the signature or initials of the supervising member as described in section 58(2.1a)ii.*

**Counselling Record**

**58(2.1)** ~~In addition to section 64(1)a, and a~~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:

~~(a)(i)~~ (i) the signature or initials of the member or intern providing the counselling; and

~~(b)(ii)~~ (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.

**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 and making a decision regarding their care

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

*Discussion Document: ~~July 30~~April 16, 2007*

**58(3)** Depending on the process of authorization, preparation and counselling, all these records could be all on the prescription, or kept in separate locations. The intention is to allow for some flexibility of the record keeping, but requiring the records to be kept.

### 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;

### 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 an electronic signature.

### Hospital records

**58(5)** The record for a drug prescribed to an in-patient in a hospital under *The Health Services Insurance Act*, must show:

- (a) name and location of the patient;
- (b) the person that authorized the prescription as described under section 58(1) and by substituting section 86 (1.1) for 86 (1);
- (c) who prepared the medication for dispensing and performed the final check
- (d) the date the drug was dispensed; 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 tele-pharmacy remote site or 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) strength (where applicable) and quantity of the drug;
- (g) the name or initials of the member approving the prescription for filling or refilling
- (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; and
- (k) the price charged, unless the drug is issued to a patient of a long term care facility designated under *The Health Services Insurance Act*.
- (l) the number of refills, part-fills or doses remaining, and part-fills 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

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

### Hospital medication labels

**59(4)** No drug may be dispensed pursuant to a prescription for an inpatient of a hospital, 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) where the patient is a Manitoba resident and a PHIN is assigned, the PHIN of the patient;

*This section would require the pharmacy to receive the PHIN for patients that receive a dispensed drug from the pharmacy. Council is aware that this may cause some challenges in practice, but decided to leave this section as is in order to solicit comments from the members.*

- (d) a reference to the prescription number for each prescription filled for the patient;
- (e) any written medical history or information collected regarding the patient;
- (f) any declaration waiving of the use of a child resistant container, and the name of the person waiving its use; and
- (g) 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 is responsible for retaining the prescription record, prescription label record, and patient profile required under this part;
- (b) the pharmacy preparing the drug for dispensing must retain the 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

**Discussion Document: ~~July 30~~April 16, 2007**

was prepared for dispensing;

- (e) the patient profile must, in addition to the requirements of s.60(1), include written authority from the patient to share the patient's personal and personal health information with the pharmacy in which the medication is to be prepared for dispensing; and
- (f) the involved pharmacies must meet any other requirements of the standards of practice, or applicable practice directions.

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 statues on limitations, these records need to be kept for seven years and the recommended change is consistent with that requirement.

**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 seven years. 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.

**Return to inventory**

**62(23)** A drug must not be accepted for return to inventory if it has been previously dispensed.

**Exceptions on returns**

**62(34)** Notwithstanding subsection (3), 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 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(45)** Where a drug is returned to inventory, the acquisition 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 prescription number of each drug returned.

*Section 62(5) would require the pharmacy to records when all medication is returned to inventory that was previously dispensed as described under 62(3) and 62(4). Previously dispensed could mean medication that went out on delivery or in the mail and returned, as two examples. It could also include medications dispensed for patients of personal care homes. Council is aware that this may cause some challenges in practice, but decided to leave this section as is in order to solicit comments from the members.*

#### **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**

~~There is a need to keep a record of all "disposal" (i.e. distribution) of drugs by the pharmacy. This would include where drugs are disposed to another pharmacy or physicians office, for example. Included would be the disposal for destruction and disposal for the return to the manufacturer or the person from where it was purchased.~~

~~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.~~

### **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.~~

#### **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.~~

#### **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.~~

#### **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~~

**Discussion Document: ~~July 30~~April 16, 2007**

destroyed;

(c) the ~~reason for destruction drug identification number of the drug destroyed;~~

(d) the strength (where applicable) and quantity of the drug destroyed; ~~and;~~

~~(e)~~(e)the date and manner of the destruction; ~~and 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.~~

~~(f)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.~~

**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;~~

**Method of keeping disposal records**

~~63(54)~~ The records required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.

***64(1) Communication records in a health care setting***

*This is a new section that would enhance the documentation and record keeping of the profession. In the past, records have not always been kept in a manner that would confirm the practitioner was contacted for authorization and/or the patient refused counseling. Also, these records will become important for Distance Care and tele-pharmacy components.*

*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.)*

**64 “Place holder”**

**Communication records in health care setting**

**Discussion Document: ~~July 30~~April 16, 2007**

~~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 tele conferencing services.~~

**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.~~

**Manitoba Prescribing Practices Program 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.61.

**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

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.

- (d) 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)** If 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 person'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 to 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*.

#### **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*.

**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.

**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)(i)~~ prescriptions which were refused to be filled, under s.68(4);
- ~~(k)(j)~~ prescribing record;
- ~~(l)(k)~~ drug administration record;
- ~~(m)(l)~~ test interpretation record; and
- ~~(n)(m)~~ test ordering and results record.

**Access to retained records**

**67(2)** A member or owner must make all records it is required to retain 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 prescription drug, one drug may not be substituted for another, or one brand of drug for another, without the consent of the practitioner, or in accordance with Part 9 of the Act.

**Substitution by members in hospital**

**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.

*Section 8668(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.*

**Recording substitutions**

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

**68(3) Changing prescriptions**

*The present section does not allow for any changes, but does allow for a practice direction to cover matters like the change in form (capsules vs. tablets), formulation (long acting vs. regular), etc.*

**Changing prescriptions**

**68(3)** Except as permitted by any applicable practice directions, 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.

**68(4) Questionable Prescriptions**

*This section follow-up on section 2(3) of the Act and describes the criteria of a valid prescription. The MPhA has had many legal discussions and arguments over the last several years as to whether pharmacists are obligated to scrutinize the prescription, or just blindly fill it as written. This section describes how prescriptions under this section should not be filled.*

**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.

*Section 68(4) would have application in the following examples:*

- *a dentist prescribing medication for hypertension*
- *a medical practitioner prescribing methadone without authorization to do so*
- *the drug or dosage prescribed may not be consistent with the treatment goal indicated*

**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.

**69(1.1) Approved Substances**

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

**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.

**69(2) DPIN required**

*Since the advent of DPIN in Manitoba, the concern has been raised that data entry into the database is optional and the patient can refuse. From a patient care perspective, this should not be optional. This section gives Council the ability to create a practical practice directive regarding this issue and allow for patient that do not have a PHIN or when the DPIN system is not “up”. If this section causes problems leaving patients to potentially go without their prescribed drug, Manitoba Health could issue a pseudo-PHIN and create a database for the number of prescriptions not being entered into a specific DPIN profile. This would only cover pharmacy practice and could not be imposed in other areas.*

**DPIN required**

**69(2)** No drug may be sold or dispensed to a resident of Manitoba who has been issued a PHIN, unless the prescription is recorded in DPIN as required under the appropriate practice direction.

**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 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.

### **Sale of expired drugs prohibited**

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

- (a) the use of which is limited to a prescribed period of time, if that time has passed;
- (b) that has an expiry date, if that date has expired
- (c) that has an expiry date, if it is unlikely the drug would be fully consumed before the 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 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.

### **Maximum quantity**

**72(2)** A drug referred to in subsection (1)(b) may 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 may 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 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.~~

**73 Inducements**

*This is a new section that would prohibit members or pharmacy owners from offering or providing any type of loyalty or affinity program in any activity that falls under the definition of the practice of pharmacy, with the exception of the retail sale of a drug that is not pursuant to a prescription. In other words, selling a schedule 2 or 3 without a prescription or any unscheduled product and providing a loyalty benefit would be permitted. Services like free delivery or parking could still be provided as they would not be considered inducements. Council is aware that this may cause some challenges to current practice, but decided to leave this section in to solicit comments from the members.*

*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.*

**Inducements**

**73** With the exception of the retail sale of a drug, a member or owner may not offer or provide a patient or their agent any of the following in the course of performing any activity described under section 2(1) of the Act :{

- (a) a gift;
- (b) a rebate;
- (c) a bonus;
- (d) points, loyalty points or rewards which can be redeemed for a gift or other benefit; or
- (e) any other inducement of a similar nature.

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 can 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 important to do,so.

*74(5) As other health care professions receive the authority to prescribe drugs, they may be a need for the professionals they license to also received the right to dispense. This section would allow the Committee to engage those other health care professions in order to come to an 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 may 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 sees fit.

### **Appeal**

**75(4)** A decision of the Dispensing Practitioners' Committee can be appealed to council, but there 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 cannot 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 practitioners' 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 may only use his or her designation for a purpose which is reasonably within his or her scope of practice.

### Veterinarians

**78** Subject to s.98, a person licenced 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 sees 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 can be appealed to council, but there no further appeal under these regulations.

## PART 11-EXTENDED PRACTICE PHARMACISTS & SPECIALTY PRACTICE

### Extended practice pharmacist

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

*80(1) In order to qualify as extended practice pharmacist, the pharmacist must be a section 12 pharmacist and have a recognized "specialty" under section 82. Only Extended Practice pharmacists can do the included practices described under section 2(2) of the act.*

#### 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 shall 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) submit an application to the board in the form specified in the by-laws;
- (b) be a member with a Section 12 practicing licence;
- (c) practice in a collaborative [practice setting](#);
- (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)** If 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 advisable.

#### Application not approved

**81(4)** If the board does not approve an application or approves an 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 shall continue until the earlier of:

- (a) the person's registration as a pharmacist or pharmacist licence is cancelled;
- (b) the member no longer holds a Section 12 practicing licence;
- (c) the member ceases to practice in the area or areas of specialty for a period of more than 24 months; or

- (d) the member ceases to practice in a collaborative ~~practice setting~~ 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 in one or more of the following areas, if the applicant meets the requirements of the specialty set out in this part:

- (a) Clinical assistant; or
- (b) any other specialty as created by Council.

### Clinical assistant specialist

**83** A member is qualified as a clinical assistant specialist upon providing evidence satisfactory to the registrar that the applicant is registered as a clinical assistant under *The Medical Act*.

#### **84 Specialty Practice Qualifications**

*Specialty practice is not awarded because a pharmacist has an interest in a specialty area or has developed a greater understanding of a particular area of practice. This program is to be viewed as similar to the Royal College of Physicians and Surgeons that have clear criteria for a physician's specialty designation. A general practice pharmacist may incorporate areas of specialty into their practice and may have enhanced knowledge and provide enhanced patient care as a result. However, the practice and knowledge may not necessarily qualify under the terms of clinical pharmacist.*

*There are "Specialty Boards" and competencies that are established and are being established. The Council will begin actively searching for certification programs, substantive examinations and competency assessments that would provide critical qualification of pharmacist under the section.*

### 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

**Discussion Document: ~~July 30~~April 16, 2007**

- (d) the applicant continues ~~in a collaborative to practice in a setting collaboratively with other health professionals working~~ in the requested area of specialty;

**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.

**Appeal of Renewal**

**84(3)** Should the renewal of Specialty Practice be 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 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.

**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 can be filled by the appropriate appointing body.

**Quorum**

**85(4)** A quorum of the committee is two committee members, and must include representative from at least two of the appointing bodies, including one appointed by council.

**Duties of committee**

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

- (a) review this regulation as it relates to included practices;
- (b) review standards of practice, practice directions, and the code of ethics as they relate to included practices;

Discussion Document: ~~July 30~~April 16, 2007

- (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) to formulate recommendations regarding the appropriateness of included practices being exercised outside of a collaborative practice setting; and
- (g) present the recommendations to council.

### 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

### **86(1) Prescribing by members**

*This section permits all members with a section 12 licence to prescribe a non-prescription drug or a product with a DIN or NPN. Reasons why a patient wants a prescription of these products might in order for it to be covered as a benefit under a drug plan. A similar authority is given to Registered Nurses (Extended Practice). This activity recognizes the role pharmacist has been performing in community practice for many, many years. Section 73 (1k)iv of the Act describes the need to address the potential for conflict of interest where the pharmacist that prescribes the drug, also sells the drug. This is covered under section 87 of these regulations, but may require a change to the Code of Ethics.*

### **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; and
- (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.

### **86 (1.1) Prescribing by members in hospitals**

*Presently, hospital pharmacists are permitted to make changes in the drug orders that are consistent with the hospital formulary and permitted by the Pharmacy and Therapeutics Committee. This section would ensure that ability continues.*

### Prescribing by members in hospital

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

~~(c) issue a new prescription for a drug deemed equivalent by the facility formulary to the one specified in the original prescription; or~~

~~(d) issue a new prescription for a different dosage or dosage form.~~

*Section 86(1.1) might be best located under section 68 of these regulations. If left here, 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. **This section is relocated to 68(1.1)***

*86(2) Just a reminder that extended practice pharmacists have a section 12 (health care practice setting) licence, have qualified either through the regulations to the Medical Act (as a clinical assistant), or through their own specialization, and practice in a collaborative practice setting.*

### 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.

### Prescribing by clinical assistant specialist

**86(3)** In addition to the requirements of this part, a member who qualifies as a clinical assistant specialist may prescribe a drug only in accordance with the requirements of *The Medical Act* and regulations applicable to clinical assistants.

### *86(4) Prescribing in Emergency*

*In cases of emergency such as a pandemic event where there is a need to get prescription medication to the general population, Council is able to approve members to prescribed certain drugs for certain conditions.*

### Prescribing in emergency

**86(4)** Notwithstanding subsection (2), where the minister gives 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 a drug where:

(a) the member has made a reasonable inquires to assess whether the

**Discussion Document: ~~July 30~~April 16, 2007**

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.

~~(g)~~(h) the 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 under that Act.

**89(1) Prescribing Record**

*The prescribing record will largely reflect the requirement for the prescription record as described under 58(3) of these regulations and can be on the same document if the medication is being filled at the same pharmacy. Consistent with RN(EP)s and Clinical Assistants, the record must also indicate the treatment goal, diagnosis or clinical indication.*

**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) date of birth of the patient
- (c) where the patient is a Manitoba resident and a PHIN is assigned, the

**Discussion Document: ~~July 30~~April 16, 2007**

PHIN of the patient;

*Requiring the patient to provide their PHIN in order for the pharmacist to prescribe may cause challenges in practice where some patients refuse to provide the information. However, this section was included in the Discussion Document in order to allow members the opportunity to provide feedback on this issue.*

- (d) the name of the drug prescribed;
- (e) the strength (where applicable) and quantity of the prescribed drug;
- (f) the directions for use;
- (g) the number of refills available to the patient;
- (h) the name of the member issuing the prescription;
- (i) the date of the prescription; and
- (j) 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.

**90(1) ~~Continued~~Care refills**

*As presently allowed under the Joint Agreement the MPhA has with the College of Physicians and Surgeons under a interpretation of professional judgment, pharmacists will now have the authority under the regulations to provide a refill of chronic care medication. As stated in the Joint Agreement this authority is not to replace medical care, but is in support of it. As such, this is really only intended as a one refill event.*

**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) 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;

- (e) the prescription was previously filled at the same pharmacy; and
- (f) the member complies with any applicable practice directions.

**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.

**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.

**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

*91(1) in this section, orally would include sublingually and buccally and topical would include ophthalmic, otic and intranasal.*

**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.

**91(2) Certification in drug administration**

*If a member wants to administer drugs beyond the three routes identified in 91(1) without becoming an extended practice pharmacist, Council can establish a training program to do so. As described in section 91(4), this certification would permit subcutaneous, intramuscular injections and IV through an established line.*

*As described in section 91(5), a clinical assistant specialist can administer drugs in accordance with the authority to do so as granted under the regulations to the Medical Act.*

*A section 12 member cannot delegate the administration of a drug to anyone else, except an intern.*

**Certification in drug administration**

**91(2)** Council may establish a training program to certify members in other methods of drug administration that includes enhanced safety measures and emergency resuscitation, and specify the frequency 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**

**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 or peripheral venous access device.

**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;

**Discussion Document: ~~July 30~~April 16, 2007**

- (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; ~~and~~  
(g)(h) any adverse events, and
- (h)(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**

**93 Interpretation of tests by members**

*Any test that is considered a patient administered automated test, like pregnancy test, blood glucose for example, can be interpreted by a section 12 licenced member and the member can provide advice to the patient. Presently, it may be considered outside the scope of practice and outside any malpractice insurance.*

**Interpretation of tests by members**

**93** Any member with a Section 12 practicing licence may interpret and advise the patient of the results and implications of any patient administered automated tests.

~~Section 94(1) would require the recording of routine tests like blood pressure, pregnancy and blood glucose, to be recorded. It is important for members to be aware of this when providing feedback on this section.~~

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.

**Test interpretation record**

**94(1)** A member who interprets and makes a recommendation to advises 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.

#### **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

*The section of the act that allows the regulations to permit pharmacist to order and receive tests, is silent on the matter of interpretation. It would likely not be permitted for pharmacist to interpret these tests. Sections 95(1), (2) and (3) described how tests can be ordered and reports received and section 95(4) describes how pharmacists can consult with a health care professional to interpret the result and be delegated the authority to speak to the patient.*

*A list of tests that can be ordered by members under this section would need to be developed. The registered nurses extended practice have similar authority and their regulation and list the specific tests in a schedule. Should this section receive favourable support through the consultation process, a list of tests may need to be created as well.*

#### **Ordering tests by members**

**95(1)** Any member with a Section 12 practicing licence may, upon approval from the patient's practitioner, order and then receive copies of a screening or diagnostic test.

#### **Ordering tests by members in hospital**

**95(2)** Any member with a Section 12 practicing licence practicing 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 this section, 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 can advise the patient when delegated the authority 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 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 made communicated by the member available to ~~other 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

### **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.*

### Professional liability insurance

**97(1)** Every member unless registered under section 14 of the Act, must be covered by professional liability insurance to a minimum limit of \$2,000,000.

### **Pharmacy Insurance**

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

## **PART 17 – PUBLICATION**

### **College newsletter**

**98(1)** 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, through a website, or any combination of these methods.

### **Discipline committee decisions**

**99(1)** After the service of a decision of the discipline committee on the investigated person, council shall cause the newsletter to contain an article:

- (a) summarizing the matters and circumstances considered by the discipline committee;
- (b) summarizing the findings and orders of the discipline committee; and
- (c) where there has been an order against the investigated person under section 55 or 56 of the Act, publishing the name of the investigated person.

### **Complaints committee decision**

**99(2)** Except in the case of a voluntary surrender, where the licence or registration of an investigated person is cancelled or suspended by the complaints committee under s. 40 of the Act, council may give immediate notice to the profession and shall 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) publishing 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, council may give immediate notice to the profession and shall cause the newsletter to contain an article:

- (a) summarizing 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.

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 – Drug acquisition and handling**

Members are responsible for the purchase, receipt, storage, and disposal of drugs in a safe, legal and ethical manner.

**Standard 2 – Patient counselling**

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

**Standard 3 – Incidents and Discrepancies**

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

**Standard 4 – Pharmacy facilities**

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

**Standard 5 – 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 information.

**Standard 6 – Dispensing and sale**

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

**Standard 7 – Pharmacy hours**

Members and Owners must ensure pharmacist services must be made available to patients on reasonable hours of operation.

**Standard 8 – Prescribing**

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

**Standard 9 – Administration of drugs**

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

**Standard 10 – Test interpretation**

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

**Standard 11 – Test orders**

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

**Standard 12 – Policies for staff**

Pharmacy managers must develop, implement and maintain current written policies and procedures for the training of pharmacy staff with clear direction on the scope and limitations of their functions for the safe, legal and ethical operation of the pharmacy.

**Standard 13 – Scope of Practice or Operation**

Members can only practice within the provision of the act.

**Standard 14 – Pharmacist to staff ratio**

Pharmacy managers 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 d the practice of pharmacy which is conducted in a safe, legal and ethical manner.

**Standard 15 - Drug Information**

Members must provide accurate, unbiased, pertinent drug information.

**Standard 16 - Documentation**

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

**Standard 17 - Extemporaneous Compounding**

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