

EXECUTIVE SUMMARY OF PROPOSED CHANGES

The practice of pharmacy has gone beyond the responsibility of distributive function. The value of pharmacy practice is extended to include “pharmaceutical care”. Pharmaceutical care has been defined as patient-centred, outcome oriented pharmacy practice that requires the pharmacist to work in concert with the patient and along with the patient’s other healthcare providers to promote health, to prevent disease and to assess, monitor, initiate, and modify medication use to assure that drug, and non-drug, therapy regimens are safe and effective. The goal of pharmaceutical care is to optimize the patient’s health related quality of life, and achieve positive clinical outcomes, within realistic economic expenditures.

Certainly, the importance of patient safety involved with the accurate distribution of prescribed medication is a primary importance. Notwithstanding, the pure technical function of distribution could be delegated to the trained, certified technicians and employee technical advances available on the market. A pilot project has been underway for several months at the St. Boniface Hospital to examine the accuracy of pharmacy technicians in the packaging of medication under the PYXIS distribution system. All reports from the pilot project are supportive of safe, accurate distribution.

By recognizing and condoning the pharmaceutical care role of the pharmacist, it enhances patient care in both institutional practice and community practice. Many studies have shown the cost of prescription drug misuse. In the March/April 2001 issue of the *Journal of the American Pharmaceutical Association*, drug misuse cost the American health care system \$177.4 billion and resulted in 218,000 deaths per year. The Canadian Pharmacists Association reported an estimated 12,500 deaths, 2 million lost work days and \$150 million lost in earnings because people do not take their medication as prescribed. In addition, 10% of all hospital admissions are due to non-compliance, and the figure rises to 25% for the elderly.

The proposed act changes address the following areas:

- definition of practice
- where pharmacy can be practiced
- pharmacist’s authority to provide prescription medication without first receiving authorization from a practitioner
- patient directed “no substitution”
- addition of one person to the Complaints Committee and a change in the complaint investigation process
- waving of the timelines for Complaints and Discipline Committees when mutually agreed

The proposed regulation changes address the following areas:

- include a structured practical training program under the definition of internship
- adjust some of the student registration criteria to better reflect current practice
- change the regulations to comply with the Mutual Recognition Agreement, as signed by the M..Ph.A, in compliance with the Agreement on Internal Trade.
- establish a “conditional register” to better facilitate foreign graduates into pharmacy practice
- establish recognition of pharmacist “specialty licensing”
- establish criteria for “technician” and duties they are able to perform in a hospital setting
- include the pharmacy manager as jointly responsible with the owner for compliance with the rules of pharmacy practice and require the pharmacy manager to be a “patient care setting pharmacist”
- permit the accreditation of a pharmacy for specialty services
- change the Standards of Practice to reflect the national standards
- move “Lock & Leave” from the regulations to the Standards of Practice
- recognize electronic recording systems
- create permissive regulations for “Centralized Prescription filling”
- create permissive regulations for the Minister to establish a schedule of medications and the conditions there under, that would allow a pharmacist to provide medication without prior authorization from a practitioner

Some of these legislative and regulatory changes are innovative and others have already been implemented in other jurisdictions. Pharmaceutical care is a process of drug therapy management that requires a change in the orientation of traditional professional attitudes and a re-engineering of the traditional pharmacy environment. The changes described in this document will facilitate the greater emphasis by pharmacists on patient orientated care and enhanced drug utilization and distribution.

Please be advised the following items have been passed by the membership of The Manitoba Pharmaceutical Association and are forwarded for proposed changes to the pharmaceutical act of Manitoba and regulations thereto:

Act Changes

Definitions:

The “Practice of Pharmacy” means

- a) the interpretation, evaluation and implementation of medication orders;*
- b) the dispensing of medication pursuant to a prescription;*
- c) subdividing or breaking up of a manufacturer’s original package of a drug for the purpose of re-packaging the drug in large or smaller quantities for re-distribution or sale by retail;*
- d) participation in drug and device selection, drug administration, drug regimen reviews and drug or drug related research;*
- e) provision of patient counselling and the provision of those acts or services necessary to provide pharmaceutical care in all areas of patient care , including primary care and collaborative pharmacy practice; and*
- f) the responsibility for compounding and labelling of drugs and devises, proper and safe storage of drugs and devices, and maintenance of proper records for them.*

Change section 48(1) to the Act

Change the act to read “A pharmacist may engage in the practice of pharmacy only in a *practice site, or affiliated with a practice site, as described in the regulations.*” And add a section in the regulations to read that the sites described in the act are:

- 1) a licensed pharmacy
- 2) a licensed pharmacy with *satellite dispensing units
- 3) a business premises that would meet the requirements as described in the Standards of Practice (or another guideline/statement as approved by Council).

(* Satellite dispensing unites would be defined in the regulations as a remote locations presently not services by a pharmacy. A certified technician would be able to perform their duties and have the tasks checked by a pharmacist through the use of web-cam type technology. This would permit a licensed pharmacist in a pharmacy to set-up “dispensing units” in remote areas. The dispensing unit would be real-time linked to the pharmacy and allow the pharmacist to verify medication orders, check dispensing, patient counsel, etc)

Change section 73 of the act; Code of Ethics

Change to permit the Code of Ethics to be adopted at a general meeting and not just the annual general meeting.

Change to the Act:

2(2) Nothing in this act:

- a) prevents a pharmacist from providing a drug if to do so is permitted under the regulations.

Under the Prescribed Drugs Regulations add:

Schedule 4 drugs: Pharmacist Providing Drugs Prescription Medication

3(5) Pharmacists, certified by the Board of Examiners, may provide the drugs listed in schedule 4 and for the purpose described therein, as approved by the Minister.

Change section 76 of the Act to allow patient directed no sub:

Section 76(2a) Subsection (1) does not apply to prescriptions where the pharmacist has received direction from the prescriber or the patient that the manufacturer's product actually prescribed is to be dispensed by using the words "no sub" or "no substitution".

Section 76(2b) The direction described in subsection (2a) must be documented on the original prescription or in another suitable record maintained for at least two years in a readily retrievable manner.

Section 76(3) If an interchangeable product is prescribed for a person on a continuing basis and the record described in section 76(2b) is kept, any subsequent verbal authorizations for the continuation of that prescription shall be dispensed according to the "no substitution" instruction, unless the patient or prescriber rescinds the "no substitution" instruction.

Section 76(4) If a prescription that includes a "no substitution" instruction thereby directing the dispensing of a product listed in the formulary, the dispenser shall not charge more for the product than the sum of

- a) the cost for the product that is listed in the formulary; and
- b) the maximum additional amount prescribed in the regulations,

and shall issue a receipt clearly indicating the price charged as if the product was priced under section 76(1) and the price actually charged as described under 76(4).

Change section 17 of the Act, Complaints Committee

Section 17(c) of the Act changed to "two members of the Association who are not members of Council."

Add a section to the Complaints Committee section that would permit a complaint investigation to commence before it is presented to the Complaints Committee. However, all written complaints, previously investigated or not, must be reviewed by the Complaints Committee.

Add a section in 21(1) of the Act

e) come to an agreement with the member regarding terms or conditions imposed upon their license to practice.

Change Section 28(2) of the Act

Change the wording to read “The hearing before the discipline committee shall commence on a date within 120 days after the date on which the matter is referred, or, another date that is mutually agreed upon by the investigated person and the Registrar.”

Change section 39(4) of the Act

Change the wording to this section that clearly state that if the investigated person want the transcript, they have to pay for it. (The wording from the proposed act of AOTM is: “At the request of the person appealing the Discipline Committee’s decision, the registrar shall give the person, at the person’s expense, a certified copy of the record of proceeding and any documents that the committee considered in making its decision.”

Change section 43(2) of the Act

Change the wording to read “The hearing shall commence on a date within 120 days after the date of service of the notice of appeal on the registrar under subsection 42(3), or, another date that is mutually agreed upon by the investigated person and the Registrar.

Regulation Changes

Change the definition to: – “internship” means a period of structured practical training in a pharmacy taken by an applicant for registration under the supervision of a pharmacist preceptor approved by the council;

Add a new section after 4(1) that reads, “For a student failing to comply with this section, they would not be recognized as a student and would be subject to an additional late filing fee as prescribed in the by-laws.”

Change section 4(2) to read:

Section 4(2) In addition to the requirements set out in subsection 15(1) of the Act, an applicant shall provide:

- a) proof that the applicant is of good moral character and reputation; and
- b) one copy of a recent passport style photograph of the applicant.

Change section 3(2) to read: In addition to the requirements set out in subsection 10(1) of the Act, an applicant shall:

(a) provide proof of successfully completing a licensing examination or assessment based on the Professional Competencies for Canadian Pharmacists at Entry to Practice as approved by Council,

(b) provide confirmation of good moral character

(c) serve a period of internship as determined by the Council of the Association.

(d) provide a declaration of scope of practice.

(e) provide a recent photograph

(f) provide evidence of meeting the requirements of a continuing competence program or, until such time that this program is implemented, those standards set out in a continuing competence program of their current jurisdiction as approved by Council, and,

(g) demonstrate competence in jurisprudence.

in order to be registered with the Association.

Change section 3(3) to read: All pharmacists that are licensed/registered on or prior to July 1, 2001 by a provincial regulatory authority that has signed a mutual recognition agreement with the Association are exempt from requirements 3(2a) and 3(2c).

Change section 3(4) to read: All pharmacists who have do not comply with section 3(2a) may be listed on a conditional register.

Make the following changes under “Licensing”, section 5 of the regulations.

5(1) An applicant applying for a license to practice pharmacy must be:

- a) on the register of pharmacists, or,
- b) on the conditional register,

and shall submit an application to the registrar on a form approved by council.

5(2) An applicant shall specify whether the application is for

- a) a patient care license; or
- b) a non-patient care license.

5(3) A pharmacist applying for a patient care license must provide proof of 400 hours of practice in, or supervised a patient care setting, or proof of graduation, as described in section 10 of the act, within the previous two years.

5(4) A pharmacist applying for a non-patient care license must provide proof of 400 hours of practice in a non-patient care setting, patient care setting or proof of graduation, as described in section 10 of the act, within the previous two years.

5(5) In addition to the requirements set out in subsection 10(1) of the act and this section, and, where an applicant has been registered by a signatory jurisdiction as described in the Mutual Recognition Agreement but is not presently licensed as a pharmacist, the applicant must:

- b) serve period of internship as determined by the Board of Examiners;

5(6) An applicant for a license to practice pharmacy shall,

- a) disclose whether he or she is under suspension or investigation by an association of persons governing the practice of pharmacy in Canada or elsewhere,
- b) participate in a continuing competency program or an equivalent program as currently approved by council,
- c) maintain their own learning professional development profile, as determined by council, documenting their professional development, and
- d) meet other requirements specific to his/her scope of practice.

5(7) If the applicant is returning to practice and was without a license for 13 months or less, he or she shall, in addition to the requirements identified in this section, comply with the returning to practice requirements as determined by the Board of Examiners.

5(8) If the applicant is returning to practice after an absence of greater than 13 months, he or she shall:

- a) if the application is for a patient care license,
 - i) serve a period of internship as determined by the Board of Examiners and receive a satisfactory report in a patient care setting,
 - ii) provide a professional development profile that meets the requirements as determined by the Board of Examiners,
 - iii) successfully complete any other requirements prescribed by the Board of Examiners, and

- iv) meet any other conditions prescribed by council under subsection 62(2) of the Act.
- b) if the application is for a non-patient care license,
 - i) serve an internship and receive a satisfactory report in a non-patient care setting approved by the registrar for two weeks for every year absent from practice
 - ii) provide a professional development profile that meets the requirements as determined by the Board of Examiners,
 - iii) successfully complete any other requirements prescribed by the Board of Examiners, and
 - iv) meet any other conditions prescribed by council under subsection 62(2) of the Act.

Add a section to the regulations entitled “Pharmacist License Renewal” to read:

If the pharmacist is presently licensed and is applying for a renewal of the annual license to practice he shall submit an application to the registrar on a form approved by the council and must comply with sections 5(1), 5(2), 5(3) and 5(4) as well as the requirements described under the continuing competency program and professional development profile as approved by Council.

Add a section for specialty licensing:

Council may establish criteria for certification of specialty area pharmacist practice. Any pharmacist receiving certification may advertise and promote their services. (would require wording changes in the Code of Ethics.)

Change 17(3) under the regulations to read:

17(3) The following procedures may be delegated to a person other than a licensed pharmacist but must be carried out under the direction and supervision of a licensed pharmacist in a licensed pharmacy:

- a) preparing a prescription label
- b) attaching a prescription label to a prescription container
- c) pre-packaging pharmaceuticals
- d) compounding pharmaceuticals to the extent allowed by 17(1)e
- e) entering prescription data into a database and patient profiles
- f) replenish medication stored at drug storage sites except those described under A(b)f.

Add a section to read: The tasks described under 17 (3) b, c and d must be checked by a pharmacist or technician checker before being released for patient use.

Add a section to read:

An application for registration as a certified technician shall be approved by the Registrar, if the applicant;

- a) is not less than 18 years of age,
- b) successfully complete an examination as determined by council,
- c) provides evidence of work experience as determined by council,
- d) provides a letter of qualification from a licensed pharmacist,
- e) pays the fee as prescribed in the by-laws, and
- f) meets any other requirements prescribed in the regulations.

The following tasks may be performed by a certified technician for hospital inpatients and as individually approved by the pharmacy manager for a specific certified technician:

- b) duties as a technician checker
- c) contacting the prescriber's office to relay prescription information for renewal authorization inquiry (not including narcotic, controlled or targeted substances)
- d) receiving unaltered renewal authorization or cancellation information in response to the inquiry described in (b)
- e) clarify the technical aspects of the prescription with the prescriber's office
- f) *preparing intravenous admixtures, parenteral nutrition solutions and chemotherapeutics solutions in accordance with procedures and calculations verified by a pharmacist
- g) *replenishing the medications stored in night cupboards, emergency boxes and cardiac arrest kits.

The approval identified in above section must be documented and signed by both the certified technician and the pharmacy manager.

A pharmacy manager may designate a certified technician as a technician checker when the following criteria are met:

- a) six months continuous employment under the supervision of a pharmacy manager
- b) successful completion of a didactic evaluation, accuracy verification and practical training program as approved by council

The designation identified in the above section must be documented and signed by both the certified technician and the pharmacy manager and a copy forwarded to the registrar.

A technician checker must undergo a continual quality improvement program as determined by council.

A technician checker may perform any or all of the following duties for hospital inpatients, as determined by the pharmacy manager:

- a) the final check of procedures described in 17 (3)b,17(3)c and 17(3)d.
- b) the final check of tasks e) and f) described in section *.

- c) the final check on refill medication, once the order has undergone a drug order review and the patient has been counselled by the pharmacist
- d) provide prescription copies to the patient named therein or a trustee acting on behalf of the patient

The pharmacist manager is responsible for ensuring that a person who performs tasks as a certified technician or a technician checker is registered with the association prior to performing the approved tasks.

Create a new section of the regulations that reads: The pharmacy practise sites described in the act are:

- 1) licensed pharmacy
- 2) a business premises that would meet the requirements as described in the Standards of Practice (or another guideline/statement as approved by Council).

Change to section 6(1) of the regulations

The section to read: In addition to the requirements set out in Part 6 of the act, an applicant for a pharmacy license *and the pharmacy manager* shall provided an undertaking...

Change section 6(7) of regulations Narcotic Signing Authority

Change to permit any licensed pharmacist to have signing and ordering authority under the Controlled Drugs and Substances act and regulations by virtue of being a licensed pharmacist.

Add a section 6(8) to the regulations that requires a pharmacy manager to be a patient care setting pharmacist.

Add to section 6 of the regulations

To read: "In addition to the requirements set in part 6 of the Act, an applicant for a pharmacy license can be given specialty accreditation under the terms and conditions established by Council."

Change the Standards (7 to 15) in the Regulations to read:

The pharmacist, using unique knowledge and skills to meet a patient's drug related needs, practises patient-focused care in partnership with patients and other health care providers, to achieve positive health outcomes and/or to maintain or improve quality of life for the patient.

The pharmacist practises within legal requirements and ethical principles, demonstrates professional integrity, and acts to uphold professional standards of practise.

The pharmacist identifies, retrieves, evaluates, interprets and provides appropriate drug and pharmacy practise information to achieve safe and effective patient care.

While respecting the patients right to confidentiality, the pharmacist communicates and educates to provide optimal patient care and promote health.

The pharmacist manages drug distribution by performing, supervising or reviewing the functions of selection, preparation, distribution and storage of drugs to ensure safety, accuracy and quality of supplied products.

The pharmacist applies knowledge, principles and skills of management as they pertain to the site of pharmacy practise, with the goal of optimizing patient care and inter-professional relations.

Remove section 16 of the regulations

This section covers rules for “Lock and Leave” and probably better placed in the Standards of Practice.

- OR -

Change 16(4) of the regulations to read:

The pharmacy area must be open at least 40 hours per week or 50% of the weekly hours of the balance of the store or as determined by Council from time to time.

Change Section 17 (4) to read

“A licensed pharmacist shall supervise persons referred to in subsection (3) in a ratio of pharmacist to technician that supports adherence to the Standards (of Practise) and delivery of pharmaceutical care.”

Change section 18(1) of the Regulations

Add to the end of the statement “...on the hard copy of the prescription, or in another recording system approved by Council:

Change section 18(1g),(1h) and 18(2) of the Regulations

Add the statement “...in his or her own handwriting, or other electronic identifiable record,

Add Centralized Prescription Processing to the Regulations

Add the definition to the regulations:

“Centralized Prescription Processing” means the processing by a Pharmacy of a request from another Pharmacy to fill or refill a Prescription Drug Order or to perform processing functions such as dispensing, Drug Utilization Review, claims adjudication, refill authorizations, and therapeutic interventions.

Add a section to the regulations:

Centralized Prescription Processing can occur in practice sites established in accordance with the regulations.

Labelling

(1) All drugs dispensed to a patient that have been filled via a centralized prescription processing system shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmaceutical care activities.

Centralized Prescription Processing

(1) A Pharmacy may perform or outsource centralized prescription processing services provided the parties:

- (a) are licensed pharmacies, and both have the same owner; or
- b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and
- (c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order.

(2) The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available for inspection and review upon request and that includes, but is not limited to, the following:

- a) A description of how the parties will comply with federal and provincial laws and regulations;

- (b) The maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counselling processes;
- (c) The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
- (d) The maintenance of a mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order;
- (e) The provision of adequate security to protect the confidentiality and integrity of patient information;
- (f) The maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

Under the Prescribed drugs regulations add:

Schedule 4 drugs: Pharmacist Providing Drugs Prescription Medication
3(5) Pharmacists, certified by the Board of Examiners, may provide the drugs listed in schedule 4 and for the purpose described therein, as approved by the Minister.

Pharmacists are allowed to continue chronic medication for their patients as described in the policy approved by Council.