

Explanation Document: *DRAFT Pharmaceutical Regulations*

Council of the Manitoba Pharmaceutical Association committed to provide the members a regulation explanation document. This document will highlight the regulation changes that occurred from the second *Regulations Discussion Document* and included in the recently distributed *DRAFT Pharmaceutical Regulations Policy Document (December 3rd, 2007)* as well as and include a description of the voting procedures, the government process and practice implementation.

This Explanation Document covers the following areas:

- 1) Identification, Explanation and Clarification of changes resulting in the *DRAFT Pharmaceutical Regulations Policy Document*.**
- 2) Voting Process**
- 3) After the Vote by Members**
- 4) Government Approval Process**
- 5) Education and Implementation**

1) Identification, Explanation and Clarification

The MPhA sent out the *DRAFT Pharmaceutical Regulations Policy Document (December 3rd, 2007)* on December 10th, 2007 for review and consideration by the voting members. Further changes were made from the second *Regulations Discussion Document* in response to some of the questions and concerns raised in the meetings convened and the response documents forwarded to the MPhA. The following information identifies sections where the changes made were “substantial” from what was included in the second *Regulations Discussion Document*.

Section 8 Registration of Students

The registrar will administer the registration of students under the parameters determined by Council. Previously, the registrar was determining the parameters and this has been changed to reflect the registration process for interns.

Section 12 and 13 designation removed

Presently, pharmacist 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.

There are pharmacists practicing directly with patients and/or practitioners who will have an impact upon the care patients receive. Also important are practices that indirectly impact on patients and directly impact upon the practice of pharmacy and pharmacists. During the

discussion generated in response to the two *Regulations Discussion Documents*, questions arose for the need and value of having two categories to practice pharmacy. Initially, it was thought the Act would not permit licencing pharmacists who did not engage in the practice of pharmacy as defined in section 2(1) and 2(2) of the Act. Upon further review and consideration, an ability exists in section 73(1)cc of the Act to define "words and phrases that are used in this Act but are not defined in the Act". Under section 13(1) of the draft regulations, further clarification of the practice of pharmacy would include supervisory and regulatory roles that oversee the practice of pharmacy and "specialized" drug information practices.

In addition, it was the feeling of the members, and supported by Council, that practicing pharmacists would be obligated not to place themselves in a practice for which they are not competent. This is reflected in the new section 14. Also, section 55(4) places responsibility on the pharmacy manager to have pharmacists working in the pharmacy who are competent in the practice of pharmacy being performed.

Section 20(1)h & 20(1)l Profile Content

As a reminder, the part regarding "Pharmacist Profile" only needs the approval of Council in order to be forwarded to the government for approval. However, it was included in the *Regulations Discussion Documents* in order to consult with members and stakeholders and solicit feedback. These particular sections were changed to reflect the "final disciplinary action since January 1, 2004" rather than the "last ten years" as stated in the *Regulations Discussion Documents*.

Section 29(3) Application for components

A Distance Care component was included in the list of possible components in this section as it could also apply for a hospital pharmacy license.

Section 33 Distant Care Component of a Pharmacy Licence

Changes to the section 33 of the *Regulations Discussion Documents* were made to address questions regarding when distance care component would apply. In reviewing this issue, it became apparent that distance care should not apply when a pharmacy in Manitoba serves patients in Manitoba regardless of whether or not there is substantial distance between the patient and the pharmacy. As a result, distance care components would only be required where the business of the pharmacy is intended to serve patients who do not reside in Manitoba or do not attend the pharmacy in Manitoba.

Consider the following examples:

If a pharmacy intends to do mail order service to patients located in another province or provinces, a distance care component is required if the patient has never attended the pharmacy. The MPhA would need to have an agreement with the respective provincial regulatory authority regarding inspection and complaint investigation (as described in section 68(5) later in this document).

If a patient lives in another province and travels to Manitoba to receive medical care, a distance care component of the pharmacy license is not required.

If a patient attends the pharmacy in Manitoba and brings a prescription issued by a practitioner licenced in another province, a distance care component is not required. The MPhA would need to have an agreement with the respective provincial regulatory authority regarding inspection and complaint investigation (as described in section 68(5) later in this document).

Section 39 Pharmacy Manager Qualifications

Council recommends keeping this section requiring a training program or experience for a pharmacy manager as it is in the best interest of the public. Council suggests a decrease in the number of practice hours, as an indicator of ability, from 4000 to 2000 hours in the second *Regulations Discussion Document*. Under the new Act and regulations, pharmacy managers will have enhanced responsibility to ensure compliance with the statutes at the pharmacy they manage. As a reminder, this section has some flexibility that a pharmacist could receive training, in lieu of the practice hours.

Section 52 Pharmacy Technicians

This section provides a definition of technician and what areas of the practice of pharmacy can be delegated to technicians. Remember that “dispense” means to provide a drug to the patient pursuant to a prescription (i.e. give to a patient and/or send it on delivery). It is possible, therefore, for a student or technician to dispense a drug when the prescription is approved by the pharmacist for filling under section 50(d) and the patient counseling has occurred. Realizing that 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 the tele-pharmacy remote sites where the technician, and not the pharmacist, might be the person in the same demographic 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 prepared medication pursuant to a prescription, for example, is not covered in the practice of pharmacy. So the final check is under section 52(4) whereas “dispensing” is under 52(3) because that is under the practice of pharmacy.

Some members expressed concern that technicians are not qualified to perform the delegations and duties that are listed. Others suggested that Community Practice Pharmacy be excluded from this section for the time being and have this section only apply to hospitals. Council reviewed these concerns and is convinced that technicians can be qualified to safely perform the activities described in the *Regulations Discussion Documents* regardless of the practice site. As a reminder, there is no obligation for the pharmacist to delegate to a technician or to permit the “other duties” being performed under their supervision.

Section 52(2.1) is new and was added to the Draft *Regulations Policy Document* to address the need for the continuing qualification of a pharmacy technician.

Section 55(1.1) Safe Use of Automation

This section is new and was included to address the responsibility of the pharmacy managers to ensure that any automated or computerized systems used in the prescription filling processes are working properly and safely. Pharmacists working with an automated system would not necessarily be held accountable should, unbeknownst to him or her, some of the automation installed or system used in the pharmacy was error prone, not being maintained or of poor quality.

Section 55(5) Delegation not Required

This is a new section that provides the necessary authority for a pharmacist to refuse to delegate if there is uncertainty about the qualifications or competence of the individual.

Section 58 Record Keeping

This section requires the following records to be kept:

- Who ordered and/or authorized the prescription (section 58(1))?
- Which pharmacist approved the prescription to be filled (section 58(2))?
- Who counselled the patient or their agent (section 58(2.1)) or their caregiver (section 58(2.2)) about the medication, or, if counseling was refused, which pharmacist was advised of the refusal (section (58(2.1)b))?
- What are the details of the prescription and who did the final check on the medication prepared pursuant to the prescription (section 58(3))?

The above requirements are not substantially different from the records that are being kept now. All the information required can be kept on the prescription and, as appropriate, the refill log. For patient counselling or the refusal of counselling, a separate record could be maintained to keep this information which is being done in many pharmacies now. Under section 58(3)j when someone other than the pharmacist does the preparation and final check, the signatures/initials are required to identify who prepared the medication for dispensing and who did the final check.

The intention of this section is to allow for some flexibility in the manner of record keeping, but requiring the records to be kept.

Section 58(5) Hospital Records

Where a prescription has been issued for an inpatient of a hospital, this section describes the information that needs to be maintained. If the hospital is not dispensing a patient specific, labeled medication and the drug will be taken from ward stock (including the automated “PYXIS”), there is no need for an authorization record, approval record, counseling record or prescription record. If however the hospital pharmacy does prepare and dispense a patient specific medication, the authorization record (section 58(1)), the approval record (section 58(2)) and prescription record (section 58(5)) must be created and maintained. The record might be contained in the hospital patient chart and/or in combination with the records kept by the pharmacy.

Section 59(3) and 59(4) Hospital and personal care home medication labels

Personal care homes were added to these sections and labeling of the medication for these sections would be covered by standards of practice or a practice direction.

Section 60(1)c PHIN required

Council can approve a practice direction that provides exemptions, should that be necessary to do so. However it is generally agreed from a patient care and safety perspective, all patients that have a PHIN should have their medication entered into the DPIN.

Section 62(2) Return to Inventory

Medication prepared pursuant to a prescription and dispensed (i.e. given to the patient or their agent) cannot be returned to inventory with the exceptions described in section 62(3).

Medication prepared pursuant to a prescription in community practice pharmacy, and never picked-up or through an unsuccessful local delivery, could be returned to inventory without further documentation about the drug being returned (the prescription record and DPIN would need to be adjusted).

Hospital pharmacies delivering medication as ward stock (including automated machines like “PXYIS”) or dispensed for inpatients and not used for the patient would not be covered under section 62(2) and 62(3). These medications could be returned to inventory without the recording requirements described in section 62(4).

Medication sent through a mail order or distant courier system would be considered dispensed and could not be returned to inventory unless, in the opinion of the pharmacist, it qualifies under section 62(3). If it were returned to inventory under the exceptions permitted under section 62(3), the records of section 62(4) would be needed.

Section 67(1) Retention of records

The reason for suggesting the current time frame for keeping records from two years to seven years is based upon requirements existing in other federal and provincial legislation.

The Personal Health Information Act (PHIA), for example, includes the authority to make a regulation governing retention of personal health information, but no such regulation has been made. The reason for this is that most health care providers (trustees) do keep such information for at least 7 years for adults and for 7 years past the age of 18 for minors. The 7 years is a period that syncs with other periods such as retention of income relevant information under tax statutes and the 6 year period within which someone can bring an action for breach of contract. A person who is a minor does not have a legal right to sue someone until the minor reaches the age of majority. This creates the potential of record keeping for minors of 7 years past the time the person turns 18 years old.

Pharmacists have been advised of this interpretation under PHIA and compliance could be accomplished through keeping the hard copy record for 2 years and an electronic version of the record for an additional 5 years from the last date of filling a prescription or providing care. The electronic storage could also apply for care provided to minors.

Section 68(5) & 68(6) Prescriptions from Practitioners licensed in other provinces

These sections, that were previously included under the distance care section 33 in the *Regulations Discussion Documents* regarding the need for agreements with jurisdictions where part of the patient care occurs outside of Manitoba, have been changed slightly and moved to section 68(5) and 68(6). The reason for the move is these sections are better located under the sections of "Dispensing of Drugs" and "Prescriptions". The MPhA requires these inter-jurisdictional agreements in order to provide the protection of the patient by covering the gaps in inspection and complaint investigation authority. Should the regulations be approved and this section maintained, the MPhA will initiate contact with other provinces to set these agreements in place. No such action will be initiated with jurisdictions outside of Canada as the International Prescription Service (IPS) component of the Pharmacy licence will not exist after June 30, 2008 (subject to discussion now occurring with representatives of the IPS industry and government).

Section 70 Child Resistant Containers not required

Within this section under the second *Regulations Discussion Documents*, practitioners could declare that child resistant containers were not needed. Upon review, this section was deemed unnecessary and removed. Should the practitioner request non-child resistant containers, the decision will ultimately rest with the pharmacist and that information would be included in the decision under section 70(2) b.

Section 73 Inducements

This section has received a lot of attention in the meetings and written responses. Council has suggested changing this section to allow for inducements to be offered in all areas of the "practice or pharmacy", including the included practices under section 2(2) of the Act. Inducements, therefore, can be offered and provided for the:

- retail sale of all drugs,
- sale of drugs pursuant to a prescription,
- prescribing of drugs,
- administration of drugs,
- the interpretation of patient-administered automated tests, and,
- the ordering and receiving of reports of screening and diagnostic tests.

Inducements cannot be offered or provided:

- for the portion of the cost of the dispensed drug (pursuant to a prescription) or service that is paid by a third party, or,
- during a promotion event that would provide an increase in the usual amount of inducement provided.

Section 79.1 Prescribing by Members

This is a new section that would require pharmacists, who plan to prescribe and dispense their own prescriptions, to apply for prior approval in order to sell what they have prescribed. This is consistent with the requirement for a practitioner under this section. Pharmacists prescribing non-prescription drugs and devices (section 86(1)) and prescribing continued care prescriptions (section 90(1)) would be exempt.

Schedule A: Standards of Practice

The MPhA’s Standards of Practice Committee made recommendations for changes to Schedule A based upon their review of the existing standards, the standards under the second *Regulations Discussion Documents*, the NAPRA Standards and the Canadian Patient Safety Institute Standards.

Council supported the recommendations and drafted the new Schedule A, Standards of Practice. The standards were reworded, reordered and four new standards were added. The new standards appear in the proposed schedule A as:

- Standard 1 – Collaborative practice
- Standard 13 – Additional practice direction
- Standard 20 – Technology
- Standard 21 – High risk practices

2) Voting Process

In September 2007, Council approved a by-law that permits a mail-in vote for matters other than an election. Prior to this, mail-in votes were only permitted for the election of council members.

At the December 3rd, 2007 Council meeting, Council decided to conduct a mail-in vote for the members to approve the regulations under the new *Pharmaceutical Act*, referred to as Bill 41. Also at the same meeting, Council instructed the Registrar to prepare a ballot that would approve the majority of the draft regulations in one vote and also include separate votes for certain specified sections. Enclosed is a ballot for members to vote regarding the draft *Pharmaceutical Regulations Policy Document*. The vote on this matter will impact upon the care of patients and practice of pharmacy for many years to come. It is important that all members take the time to consider the information and vote accordingly. **Ballots must be returned to the Registrar, at the office of the Manitoba Pharmaceutical Association located at 187 St. Mary’s Road, by 4:00 pm on March 7th, 2008** in order to be included in the tally of votes. The following is the information on the ballot **(THIS IS NOT THE BALLOT, please only use the enclosed ballot):**

With the following excerpts listed below for which I will vote separately, I approve the Pharmaceutical Regulations Policy Document dated December 3, 2007.

Yes _____ No _____ Abstain _____

I approve section 68(5) “Prescriptions from practitioners not licensed in Manitoba” of the Pharmaceutical Regulations Policy Document dated December 3, 2007.

Yes _____ No _____ Abstain _____

I approve section 68(6) “Agreements regarding out of province prescriptions” of the Pharmaceutical Regulations Policy Document dated December 3, 2007.

Yes _____ No _____ Abstain _____

I approve section 68(7) "Pharmacy may initiate agreement" of the Pharmaceutical Regulations Policy Document dated December 3, 2007.

Yes _____ No _____ Abstain _____

I approve section 73 "Inducements" of the Pharmaceutical Regulations Policy Document dated December 3, 2007.

Yes _____ No _____ Abstain _____

For any of the votes to pass successfully, a simple majority of the members voting is required. The abstentions will be included to achieve quorum (5% of the members), but not included in calculating whether the majority voted yes or no. If the entire ballot is returned without any voting markings, it will be considered spoiled. If the ballot is returned with some areas marked, the vote will be considered for only the areas marked, that being either yes, no or abstain.

3) After the Vote by Members

With the five votes that appear on the ballot, the result could vary from all votes passing to all votes failing, or various combinations thereof. The result of the vote will be reported to the members as soon as possible upon the completion of the tally.

Clearly, the critical vote is the first one for the majority of the document. Should that fail to pass, the Council will need to review the *Regulations Policy Document* entirely and discover why the members were not supportive. If one or more of the four specified sections pass without the main document passing, there would be no point in forwarding the approved specified sections to government.

If the members pass the majority of the document by voting in favor on the first vote, but not supportive of one or more of the specified sections, the approved sections would still be forwarded to the government. As these are regulations policy statements, the regulations would be created knowing that the failed specified sections should not be part of the final regulations approved by government.

4) Government Approval Process for Regulations and Bill 41

Keeping in mind the explanation described above, the approved regulations policy, with or without the specified sections, will be forwarded to the Minister of Health. The usual process includes forwarding the document to the Legislative Unit. The Legislative Unit views the document as policy approved by the members and may make some wording changes that would not change the intent of any section. The Legislative Unit would work closely with the Registrar, MPhA legal counsel and also the Legislation Drafting Unit of the Manitoba Health. Once the review and wording changes have been completed, the document will be prepared in both official languages.

The new *Pharmaceutical Act* will not be proclaimed until the regulations are approved by the Lieutenant Governor in Council (which is the essentially the Cabinet of the Manitoba government). Part of the proclamation might include a date the act and regulations will come into effect in order to allow the MPhA, or the “College of Pharmacists of Manitoba”, to hold educational seminars for pharmacists and pharmacy owners on how to implement the new requirements of practice.

5) Education and Implementation

Once the members have approved the regulations, Council will continue the work on developing by-laws and practice directions. Also, a review of the Code of Ethics will be considered.

As described above, it is the plan of Council to have educational forums for pharmacists and pharmacy owners to understand the changes that will occur in the practice site and how to implement the changes. There will be numerous opportunities for pharmacists to learn what patients, other health care professionals and the College expects to occur under the enhanced practice of pharmacy.

February 6, 2008