

**Bill 41 Regulations – Issue and Options Analysis**  
**Issues #5: Pharmacist Prescribing**  
**- and -**  
**Issues #8: Extended Practice Pharmacists**  
**& Specialty Care Practice**



**Date: September 10, 2009 (revised)**

## Introduction and Background

PricewaterhouseCoopers LLP (“PwC”) has been engaged to work with the Manitoba Pharmaceutical Association (“MPhA”) and the Manitoba Society of Pharmacists (“MSP”) to assist with building consensus around thirteen issues, which were identified by the Steering Committee (see Appendix A), and which relate to the Bill 41 Regulations, thereby facilitating progress towards approval of the Regulations.

On March 5, PwC facilitated a Stakeholder Mapping Workshop that was attended by members of the Steering Committee and a representative of Manitoba Health and Healthy Living (“MHHL”). This workshop resulted in validation of the key stakeholders and a documented understanding of which stakeholder organizations/groups were perceived to be most interested in being engaged in consultations regarding each of the thirteen issues.

On April 7, 2009, PwC facilitated a full-day retreat (“Retreat”) involving several representatives of MPhA and MSP, and a representative of MHHL. During the retreat, PwC facilitated a series of discussions regarding twelve of the thirteen identified issues; the “Distance Care” issue was not addressed during the retreat because it was deemed too complex for productive discussion within the time available. During the Retreat, MSP and MPhA agreed upon specific action plans for seven of the twelve issues that were discussed; MSP and MPhA also agreed that further facilitated consultation was merited in relation to the remaining five issues.

At the Retreat, MPhA and MSP agreed to the following Action Plan regarding the regulations pertaining to Pharmacists Prescribing:

- MSP and MPhA to collaborate and consider expanding the scope of prescribing in Community pharmacy practice.
- MSP to provide MPhA with a recommendation regarding all pharmacists being able to prescribe drugs for minor ailments, which reflects practices being considered and/or implemented in other Provinces.

At the Retreat, MPhA and MSP agreed to the following Action Plan regarding the regulations pertaining to Extended-practice Pharmacists and Specialty Care:

- MPhA to provide a clearer definition of Extended Practice Pharmacists (along with some examples) and revise the composition of the Advisory Committee, giving consideration to the structure of similar-purpose committees in other health professions and other jurisdictions.

On August 26, 2009, PwC facilitated a Focus Group with representatives from key stakeholder groups to this issue. The objectives of the Focus Group were as follows:

- To ensure that the Option Paper accurately reflects significant perspectives held by key stakeholders;
- Where necessary, to improve common understanding of the intent of the Regulations and/or stakeholder concerns;
- To build consensus around the most popular/preferred options for resolving stakeholder concerns, which will be presented to MPhA members in a Town Hall Meeting on September 16; and
- To help facilitate subsequent approval of a (revised) Bill 41 Regulations document by the MPhA membership.

See Appendix B for material that was located in the body of this Option Paper when this Paper was provided to the Focus Group participants prior to the event. This material was moved from the body to the Appendix after the Focus Group event when the report was updated to reflect the insight and directional recommendations from the Focus Group.

## Overview of Issue

This Option Paper discusses two issues:

### A. Pharmacist Prescribing

The concept of *Pharmacists Prescribing* includes all of the following activities: initiating prescriptions for pharmaceuticals and medical devices, prescribing under emergency situations, adapting (i.e. modifying)

prescriptions and renewing prescriptions (i.e. providing continued care). The December 2007 Draft Regulations, if approved, would provide all Manitoba Pharmacists with the following prescribing privileges:

- Prescribe Schedule 2 and Schedule 3 drugs (see Section 86(1) of the draft Regulations for details);
- Prescribe Schedule 1 drugs in an emergency, subject to conditions and constraints set by Council (See Section 86(4) in the draft Regulations);
- Provide continued care (i.e. renew a prescription) when the practitioner (i.e. prescriber) is not available (see details in Section 90(1) through 90(3)); and
- Provide for Hospital pharmacists, under section 68(1.1) to issue a new prescription for therapeutically equivalent medication or the medication in a different form consistent with the hospital formulary.

The December 2007 Draft Regulations did not explicitly provision the privilege to adapt a prescription to all pharmacists; however, the wording of the draft Regulations (in section 68(3)) would accommodate provision of this privilege through a practice direction. Furthermore, the draft Regulations did not provide all pharmacists with the privilege to initiate prescriptions for Schedule 1 drugs, other than in an emergency, as determined by Council.

MPhA has made the following observations regarding the provision of the privilege to initiate prescriptions for Schedule 1 drugs:

- The authority to initiate prescriptions for Schedule 1 drugs for all pharmacists was a controversial issue in the fall of 2007; therefore, inclusion of this privilege in the draft Regulations was not considered at that time.
- Over the last two years some previously existing barriers have been broken down and in some provinces, as discussed at the Retreat, there may now be greater opportunity for all pharmacists to initiate Schedule 1 drugs for minor ailments.

## **B. Extended Practice Pharmacists & Specialty Care Practice**

In Manitoba, there is general agreement that the practice of pharmacy is evolving and that there is opportunity to expand the (historical) role of Pharmacists. As a result, there is a move to identify and recognize Pharmacists that have an expanded scope of practice because they work in a specialty care practice.

The purpose for creating and defining the role and title of *Extended Practice Pharmacists* in the Regulations is to define the criteria that a pharmacist must satisfy in order to be granted certain extended privileges, in particular relating to prescribing and ordering tests. The purpose for creating and defining areas of *Specialty Practice* in the Regulations is to define the areas of specialization that could qualify for Extended Practice. Thus, a pharmacist that has a recognized area of specialty care, could seek recognition as an Extended Practice Pharmacist such that he/she is bestowed certain extended privileges, which could include more extensive privileges for prescribing. It is important to note that there are a number of criteria that must be satisfied to be recognized as an Extended Care Pharmacist, including, but not limited to, having a recognized area of specialty care and working in a collaborative practice environment.

For clarity's sake, it is important to understand the following points regarding Pharmacists Prescribing and Extended Practice Pharmacists:

- The Extended Practice Pharmacist regulations were intended to provide extended privileges only to those pharmacists who have a defined and readily identifiable area of specialty practice and advanced knowledge;
- It is expected that the minority of pharmacists would meet the qualifications to be recognized as an Extended Practice Pharmacist;
- The Extended Practice Pharmacist were not intended as a means to provide *all* general practice pharmacists with extended prescribing privileges;
- Any stakeholders concerns regarding the prescribing privileges provided to *all* pharmacists are concerns that pertain to regulations under the category of *Pharmacists Prescribing*; concerns regarding the prescribing privileges of *all* pharmacists do not pertain to Extended Practice.

The only area of Specialty Care Practice that is predefined in the December 2007 Draft Regulations is a *Clinical Assistant*, as it is defined in The Medical Act; other areas of specialty practice may be defined by Council. This approach provides Council with the flexibility to define new areas of specialty care practice as they evolve and/or are identified without having to obtain approval for changes to a fixed list within the Regulations.

## Options Paper

The remainder of this document provides information and background related to both of the above issue, which may help you in preparing for the focus group. Specifically, the following information has been provided for each issue:

- **Issue Analysis and Suggested Course of Action:** A summary analysis of the issue and suggested course(s) of action that reflect the concerns, perspectives, and directional recommendations that evolved in the Focus Group on this issue and from prior consultations, and research.
- **Summary of Positions:** A summary of the positions of MPhA, MSP, and the Government of Manitoba has been provided. This summary identifies each stakeholder's high-level concerns and/or current opinion regarding the issue.
- **Jurisdictional Comparison:** A high-level summary of how other jurisdictions in Canada address the issue has been provided; and
- **Background:** The background document provides additional detail regarding the issue, including pertinent sections of the proposed Draft Regulations, detailed information on stakeholder concerns and/or positions; and a more detailed summary of how key jurisdictions within Canada address the issue.

## PwC's Suggested Course of Action

### Issue Analysis and Suggested Course(s) of Action

The following table breaks the issue down into a number of constituent concerns, articulates key perspectives associated with each of the concerns, and advocates one or more course of action to address the concerns. Please note the following points regarding the manner in which information has been organized and presented within the table:

- The **Situation** column contains information that PwC understands to be factual and is necessary to understand the corresponding *concerns*.
- The listed **Concerns** were identified through the work conducted prior to the Focus Group and/or during the Focus Group itself. Listing of a concern does not imply that the concern has been validated, nor does it imply that the concern is widely held; listing of a concern simply acknowledges that the concern has been expressed by one or more stakeholders. The *concerns* were grouped according to commonality of the respective *situation, perspectives, and suggested course of action*.
- The **Perspectives** are arguments, claims, and assertions, which may be based on facts, anecdotal information, and/or opinions. Inclusion of a *perspective* does not imply that the underlying assertion has been validated. Concerns relate to the situation and concerns are either supported or refuted by the *perspectives*.
- The **Suggested Course of Action** reflects PwC's analysis of the respective situation, concerns, and perspectives. In most cases, the suggested course of action aligns very closely with the directional recommendations from the Focus Group; in some cases the suggested course of action also reflects additional research and analysis that PwC conducted after the Focus Group.

Situation	Concerns	Perspectives	Suggested Course of Action
<p>The December 2007 Draft Regulations would enable pharmacists that are recognized as Extended Practice Pharmacists in a particular area of Specialty Care to prescribe Schedule 1 drugs related to their area of specialization; however, the draft Regulations would not permit pharmacists who have not been recognized as Extended Practice Pharmacists to initiate prescriptions for any Schedule 1 drugs.</p> <p>It is expected that few pharmacists would qualify as Extended Practice</p>	<ul style="list-style-type: none"> <li>• Should all pharmacists have the discretionary privilege to initiate (new) prescriptions for a limited formulary of Schedule 1 drugs to treat minor, self-diagnosed, or self-limiting conditions?</li> </ul>	<ul style="list-style-type: none"> <li>• Granting the privilege to prescribe a limited formulary of Schedule 1 drugs to all pharmacists is consistent with the broadly held vision for expansion of the role of the pharmacist.</li> <li>• Some pharmacists are strongly interested in acquiring the privilege to initiate prescriptions for a limited formulary of Schedule 1 drugs.</li> <li>• If all Manitoba pharmacists were granted the privilege to prescribe a limited number of Schedule 1 drugs, some</li> </ul>	<ul style="list-style-type: none"> <li>• MPhA Council to consider revising the Regulations to permit all pharmacists to initiate prescriptions for a limited formulary of Schedule 1 drugs, subject to the conditions and constraints defined in a Practice Direction.</li> <li>• N.B. This recommendation is predicated on the parallel recommendations specific to Practice Directions that are documented in the Issues and Analysis (i.e. Option Paper) regarding</li> </ul>

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Situation	Concerns	Perspectives	Suggested Course of Action
<p>Pharmacists. The Extended Practice category was envisioned to be limited to those pharmacists who have substantial expertise in a particular area of patient care, including significant incremental training and specialized practice experience. Furthermore, the concept of collaborative practice that was envisioned for Extended Practice Pharmacists, although flexible through its broad definition, is not expected to encompass most or all practices.</p>		<p>pharmacists might exercise a discretionary right not to use this privilege.</p> <ul style="list-style-type: none"> <li>• Depending on the drugs and conditions that are included in the scope of this privilege, it may be appropriate to place certain requirements on training, practices, and/or processes in order to access and exercise this privilege.</li> <li>• The formulary and any conditions and constraints would be defined in a Practice Direction, not in the Regulations.</li> <li>• If the Regulations are not revised to allow all Pharmacists to prescribe Schedule 1 drugs, subject to conditions and limitations defined in a Practice Direction, it may prove difficult to introduce this facility after the Regulations are (initially) approved; thus, the provision should be made in the Regulations, even if the initial scope of the underlying Practice Direction is very narrow.</li> <li>• Whether or not a Pharmacist will prescribe could become a basis for competitive differentiation; e.g. some patients might prefer to deal with Pharmacists that are more willing or inclined to prescribe.</li> <li>• Would it be necessary for the Pharmacist to notify a physician</li> </ul>	<p>Practice Directions.</p>

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Situation	Concerns	Perspectives	Suggested Course of Action
		<p>in every instance when the Pharmacist prescribes?</p> <ul style="list-style-type: none"> <li>• Are there potential conflicts of interest arising from granting all Pharmacists the privilege to prescribe Schedule 1 drugs; if so, do the same conflicts of interest arise from prescribing Schedule 2 and 3 drugs.</li> </ul>	

Situation	Concerns	Perspectives	Suggested Course of Action
<p>The wording (of Section 68(3)) in the December 2007 Draft Regulations prohibits Pharmacists from adapting prescriptions, except as allowed by a Practice Direction.</p> <p>At the April 7 Retreat involving MPhA Council, the MSP Board, and MHHL, MPhA Council indicated that it had “no specific plans to issue any Practice Directions in proximity to the ratification of the Regulations, except for a Practice Direction regarding PHINs, as discussed during this Retreat; i.e. no specific application for the Practice Direction provision, other than for PHINs, is currently contemplated by MPhA.”<sup>1</sup></p>	<ul style="list-style-type: none"> <li>• There is significant interest amongst members in gaining the privilege to adapt prescriptions (for drugs of all Schedules).</li> </ul>	<ul style="list-style-type: none"> <li>• The fact that the Regulations are worded such that adapting prescriptions is prohibited, except as permitted by a Practice Direction, is perceived negatively; i.e. members perceive that the intent of 68(3) is to prohibit adapting by members, rather than to enable it.</li> <li>• The fact that MPhA Council indicated that no specific Practice Directions, other than a Practice Direction relating to PHINs, were being contemplated by Council as of April 7. One possible logical inference from this assertion is that Council was not, at that time, contemplating development of a Practice Direction relating to Adapting of Prescriptions by all Members.</li> <li>• Members would prefer that the Regulations use affirmative language in reference to the privilege of adapting prescriptions; e.g. the Regulations could be worded to the effect that “Members may adapt prescriptions, subject to the limitations and constraints defined in a Practice Direction.”</li> <li>• Care should be taken to use language in the Regulations that does not limit the future</li> </ul>	<ul style="list-style-type: none"> <li>• MPhA Council consider revising Section 68(3) to use more affirmative language that conveys a positive intent to grant members the privilege to adapt prescriptions for drugs from all Schedules.</li> <li>• MPhA Council consider drafting a Practice Direction for adaptation of prescriptions by pharmacists (not limited to Extended Practice Pharmacists) for consideration with the Regulations.</li> <li>• MPhA to consider aligning its policy regarding adaptation of prescriptions by Pharmacists with Alberta’s policy.</li> </ul>

<sup>1</sup> Excerpted from the approved minutes from the April 7, 2009 Retreat.

Situation	Concerns	Perspectives	Suggested Course of Action
		<p>scope of modification; e.g. if the initial definition of adapting excludes substituting, it should not preclude future amendment to include substituting.</p> <ul style="list-style-type: none"> <li>Consider Alberta’s Regulations regarding adaptation as a model for Manitoba.</li> </ul>	
<p>The December 2007 Regulations contain many references to Practice Directions, yet MPhA Council has indicated that it was not contemplating releasing any Practice Directions coincidentally with the Regulations.</p> <p>Practice Directions carry the same legal authority as the Regulations themselves.</p> <p>References to Practice Directions are not limited to the Regulations pertaining to Prescribing and/or Extended Practice and Specialty Care. In fact, one of the defined issues is specific to Practice Directions. A discussion of Practice Directions is included here because there was significant discussion regarding Practice Directions during the Focus Group on this subject.</p>	<ul style="list-style-type: none"> <li>Why are there so many references to Practice Directions in the Regulations, yet Council has indicated that it does not plan to issue any Practice Directions coincidentally with the Regulations?</li> <li>Why is it necessary to use Practice Directions? Why not simply incorporate the content that is destined for a Practice Direction into the Regulations themselves.</li> <li>What process(es) will Council follow to develop and consult with stakeholders on Practice Directions?</li> </ul>	<ul style="list-style-type: none"> <li>Practice Directions are approved by Council and do not require approval by the Membership, whereas changes to the Regulations require ratification by the Membership; therefore, it may be easier to make future changes to Practice Directions than to the Regulations themselves. This feature of Practice Directions can be perceived to be both an advantage and a disadvantage.</li> <li>Some members are concerned that the use of Practice Directions affords Council the ability to impose rules that would not be supported by the membership at large; however, Practice Directions afford Council the ability to move forward with a change that is desired by the membership much faster than if the change had to be approved by the membership at large.</li> <li>In cases where it is likely that changes to the “rules” will be contemplated in the future (e.g. as the practice of pharmacy</li> </ul>	<ul style="list-style-type: none"> <li>MPhA Council to develop and publish the process that it will follow when it develops Practice Directions and the process it will follow to consult with stakeholders regarding the Practice Direction through development.</li> <li>MPhA Council to develop and publish draft versions of select Practice Directions (e.g. adapting prescriptions) coincidentally with the development of revised Draft Regulations.</li> </ul>

Situation	Concerns	Perspectives	Suggested Course of Action
		<p>continues to evolve), it may prove beneficial to have codified these rules in Practice Directions rather than in the Regulations themselves.</p> <ul style="list-style-type: none"> <li>Given that no examples of Practice Directions have been shared with the membership, there is a fear of the unknown.</li> <li>Will Practice Directions use broad, inclusive language or be so specific that they dictate procedures?</li> </ul>	
<p>Extended Practice Pharmacists must practice in a collaborative setting, which is defined in the Regulations to mean means a practice setting in which a member works closely and cooperatively with other health care professions;</p>	<ul style="list-style-type: none"> <li>Does “work closely” mean physical co-location? Does it mean that there is frequent interaction?</li> <li>Who will have the authority to interpret and judge whether a particular setting satisfies this definition.</li> </ul>	<ul style="list-style-type: none"> <li>Members prefer a broad interpretation of this definition.</li> </ul>	<ul style="list-style-type: none"> <li>MPhA Council to consider opportunities to clarify the the definition of collaborative care, e.g. must the Pharmacist be co-located with the other health professionals to be considered to be practicing in a collaborative care environment?</li> </ul>
<p>The December 2007 Draft Regulations utilize the concept of areas of Specialty Care to define scopes of practice for Extended Practiced Pharmacists.</p>	<ul style="list-style-type: none"> <li>Specific, broadly recognized definitions for the terms specialty care and/or areas of specialization are evolving/emerging nationally and internationally; it could become problematic in the future to have used these terms and similar terms the way they are used in the Draft Regulations.</li> <li>Why is necessary to</li> </ul>	<ul style="list-style-type: none"> <li>Remove the concept of “areas of specialty care” from the Regulations and, instead, specify the scope of practice for Extended Practice Pharmacists will be defined and limited through the application and approval process. This will avoid future conflicts with more broadly recognized definitions for areas of specialty care.<sup>2</sup></li> <li>Use of two concepts, i.e.</li> </ul>	<ul style="list-style-type: none"> <li>MPhA to recompose the Extended Practice and Specialty Care section of the Regulations by removing references to Specialty Care and imposing limits on the scope of practice for each Extended Practice Pharmacist on a case-by-case basis. This would be effected by moving the</li> </ul>

<sup>2</sup> If, for example, a nationally recognized definition for a Renal Specialist Pharmacist were to evolve, it might be problematic to have defined a Renal Pharmacy Specialty in Manitoba that might not be consistent with the more broadly recognized definition.

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	<p>specifically list “Clinical Assistant” as an area of Specialty Care, given that it is recognized through other legislation/regulations?</p>	<p>Extended Practice and Specialty Care, where one concept, Extended Practice, would suffice, introduces unnecessary complexity into the Regulations, which has resulted in misunderstanding and confusion.</p> <ul style="list-style-type: none"> <li>• Making specific reference to Clinical Assistant as an area of Specialty Care, leaving all other areas open to definition by Council, raises suspicions as to why one area is listed specifically in the Regulations and all others are left for definition in Practice Directions. Members would be more comfortable with the concept of “by approval of Council” if no areas of Specialty Care were specifically defined (in the Regulations Document) instead of defining only one Area. There was consensus amongst the Focus Group participants that there were no advantages to listing Clinical Assistant as an area of specialty care in the Regulations. Furthermore, the fact that a Clinical Assistant is defined in other legislative or regulatory documents might imply that all areas of specialization need to be defined by other legislation or regulations.</li> </ul>	<p>scope restrictions out of the Regulations Document into Practice Directions and/or specific limitations that would be attached to individual Extended Practice licenses.</p>

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Situation	Concerns	Perspectives	Suggested Course of Action
<p>The Draft Regulations specify that the Extended-practice Pharmacist Advisory Committee will consist of the following:</p> <ul style="list-style-type: none"> <li>• Two (2) pharmacists appointed by council, including one as chair.</li> <li>• One (1) member appointed by the College of Physicians and Surgeons of Manitoba; and</li> <li>• One (1) representative appointed by the College of Registered Nurses.</li> </ul>	<ul style="list-style-type: none"> <li>• Does the committee, as defined in the Draft Regulations, have too few members?</li> <li>• Should the committee be composed primarily of pharmacists or public representatives?</li> <li>• Should MSP have an ex-officio seat on this committee?</li> </ul>	<ul style="list-style-type: none"> <li>• There is no known precedent for a health profession's advocacy organization to have an ex-officio seat on such a committee.</li> <li>• The Registered Nursing Extended-practice committee might serve as a good working model for such a committee.</li> <li>• The Committee should have at least one member who is an Extended-practice Pharmacist.</li> </ul>	<ul style="list-style-type: none"> <li>• Increase the size of the committee, possibly modeling the composition of the committee after the RNEP committee, and impose a requirement that there is always at least one Extended-practice Pharmacist on the committee.</li> </ul>

## Issue # 5: Pharmacist Prescribing

### Summary of Positions

MPhA Council	MSP (Board)	MHHL
<ul style="list-style-type: none"> <li>▪ MPhA Council recognizes that pharmacist prescribing is the future of the profession.</li> <li>▪ The Draft Regulations enable MPhA Council to recognize Family Practice as a Specialty Care area of practice under the provisions for extended practice</li> </ul>	<ul style="list-style-type: none"> <li>▪ MSP (Board) agrees that pharmacist prescribing is the future of the profession and it would benefit the current shortage of family physicians in Manitoba.</li> <li>▪ MSP (Board) is interested in community pharmacists gaining prescribing privileges for a limited formulary of Schedule 1 drugs (in addition to Schedule 2 and Schedule 3 drugs).</li> </ul>	<ul style="list-style-type: none"> <li>▪ MHHL encourages the stakeholders to consider what is achievable, and models have been implemented in other jurisdictions.</li> <li>▪ MHHL would prefer a conservative approach to pharmacists prescribing, as it is a relatively new concept.</li> </ul>

#### Proposed Action Plan:

The MPhA Council and the MSP Board agreed upon the following Action Plan at the April 7, 2009 Retreat:

MPhA to provide a clearer definition of Extended Practice Pharmacists (along with some examples) and revise the composition of the Advisory Committee, giving consideration to the structure of similar-purpose committees in other health professions and other jurisdictions.

## Jurisdictional Comparison

	Ontario	Saskatchewan	Alberta	British Columbia
<b>Do Pharmacists have Prescribing Abilities?</b>	<ul style="list-style-type: none"> <li>▪ Enabling legislation was introduced in May 2009.</li> <li>▪ Legislation must be passed before additional actions can be taken.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Enabling legislation introduced in 2003;</li> <li>▪ Prescribing authority for pharmacists is partially in practice.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Yes.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Yes.</li> </ul>
<b>Details and Limitations (if applicable)</b>	<ul style="list-style-type: none"> <li>▪ Not yet defined.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Privilege to prescribe oral contraception is currently in place.</li> <li>▪ Collaborative prescribing agreements, therapeutic substitution, and altering drug dosage and/or dosage regimen (not yet in practice).</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pharmacists are authorized to:                             <ul style="list-style-type: none"> <li>- Adapt a prescription;</li> <li>- Prescribe in an emergency;</li> <li>- Manage ongoing drug therapy; and</li> <li>- Administer injections.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Pharmacists are authorized to:                             <ul style="list-style-type: none"> <li>- Change a prescription's dose, formulation and frequency;</li> <li>- Renew an expiring script for up to a year; and,</li> <li>- Substitute a drug for another.</li> </ul> </li> </ul>
<b>Future Changes</b>	<ul style="list-style-type: none"> <li>▪ Regulations have not been created.</li> <li>▪ It is expected that regulations will not be circulated for consultation until 2010.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Regulations are expected to be implemented in the fall or winter.</li> </ul>		

## Background - Pharmacist Prescribing

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Draft Pharmaceutical Regulations: Policy Document, December 3, 2007	
<b>Substitution by members in hospital</b>	<p>68(1.1) Any member working in a hospital pharmacy may, upon receipt of a prescription to be dispensed to an in-patient of a facility designated under The Health Services Insurance Act:</p> <ul style="list-style-type: none"> <li>(a) issue a new prescription for a drug deemed equivalent by the facility formulary to the one specified in the original prescription; or</li> <li>(b) issue a new prescription for a different dosage or dosage form.</li> </ul>
<b>Changing Prescriptions (by members)</b>	<p>68(3) Except as permitted by an 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:</p> <ul style="list-style-type: none"> <li>(c) a revised written prescription must be issued by the practitioner or extended practice pharmacists; or</li> <li>(d) a verbal prescription recorded.</li> </ul>
<b>Prescribing by members</b>	<p>86(1) Subject to this part, any member may prescribe the following:</p> <ul style="list-style-type: none"> <li>(a) a drug listed on schedule 2 of the manual;</li> <li>(b) a drug listed on schedule 3 of the manual;</li> <li>(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</li> <li>(d) a medical device approved by Health Canada.</li> </ul>
<b>Prescribing by extended practice pharmacists</b>	<p>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.</p>
<b>Prescribing by clinical assistant specialist</b>	<p>86(3) In addition to the requirements of this part, a member who qualifies as a clinical assistant specialist must prescribe a drug only in accordance with the requirements of The Medical Act and regulations applicable to clinical assistants.</p>
<b>Prescribing in emergency</b>	<p>86(4) Notwithstanding subsection (2), where the minister gives council written notice that a public health</p>

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	<p>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.</p>
<b>Criteria for prescribing</b>	<p>87 A member may only prescribe where:</p> <ul style="list-style-type: none"> <li>(a) the member has made a reasonable inquiry to assess whether the drug will be safe and effective in the circumstances of the patient, including:               <ul style="list-style-type: none"> <li>(i) the patient's symptoms;</li> <li>(ii) the patient's medical history or information;</li> <li>(iii) the patient's allergies;</li> <li>(iv) other medications the patient may be taking; and</li> <li>(v) any other inquires reasonably necessary in the circumstances.</li> </ul> </li> <li>(b) the member has assessed the patient in person, in compliance with the standards of practice or practice directions;</li> <li>(c) the drug is prescribed in a circumstance which is within the member's usual scope of practice or specialty;</li> <li>(d) the member has complied with any policies or rules related to prescribing at the pharmacy at which the member practices;</li> <li>(e) the member has complied with any applicable practice directions;</li> <li>(f) the member has determined that the prescription is reasonably necessary or desirable to treat the patient; and</li> <li>(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 his or her agent, reasonable and available therapeutic options and costs.</li> <li>(h) the device is needed to meet the care needs of the patient.</li> </ul>
<b>Controlled substances</b>	<p>88 This Part is subject to the restrictions set out in the Controlled Drugs and Substances Act (Canada) and the regulations thereunder.</p>

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<b>Continued care prescriptions</b>	<p>90(1) Subject to this section, a member may authorize an additional refill of a prescription, beyond those authorized by the original practitioner issuing the prescription, where:</p> <ul style="list-style-type: none"> <li>(a) the patient has a continuing need or chronic condition;</li> <li>(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;</li> <li>(c) the history of the patient with the subject drug has not changed;</li> <li>(d) the patient advises that they have not recently experienced any adverse drug reactions to the subject drug;</li> <li>(e) the prescription was previously filled at the same pharmacy; and</li> <li>(f) the member complies with any applicable practice directions.</li> </ul>
<b>Requirements for continued care prescriptions</b>	<p>90(2) Where a member authorizes a refill under subsection (1), the member must</p> <ul style="list-style-type: none"> <li>(a) promptly notify the original practitioner who issued the prescription, subject to their death or retirement described in section 90(1)b;</li> <li>(b) enter the refill into DPIN; and</li> <li>(c) keep the records required by part 8 of this regulation.</li> </ul>
<b>Restrictions on continued care prescriptions</b>	<p>90(3) A member must not authorize a refill under subsection (1):</p> <ul style="list-style-type: none"> <li>(a) where the refill quantity is in excess of the original prescribed refill amount;</li> <li>(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;</li> <li>(c) where the drug is a benzodiazepine, unless:             <ul style="list-style-type: none"> <li>(i) the drug is used to manage a convulsive disorder; or</li> <li>(ii) there is a serious risk of seizure due to</li> </ul> </li> </ul>

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	<p>sudden withdrawal;</p> <p>(d) where the patient appears to be using continuing care refills to avoid obtaining ongoing medical care.</p>
Positions	
<b>MPhA (Council) Position / Comments</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MPhA Council recognizes that pharmacist prescribing is the future of the profession.</li> <li>▪ MPhA Council believes that Family Practice could be considered an area of Specialty Care Practice, thereby enabling the special prescribing provisions for Extended-practice Pharmacists to apply to Family Practice Pharmacists.</li> </ul>
<b>MSP (Board) Position / Comments</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MSP (Board) agrees that pharmacist prescribing is the future of the profession and it would benefit the current shortage of family physicians in Manitoba.</li> <li>▪ MSP (Board) is interested in community pharmacists gaining prescribing privileges for a limited formulary of Schedule 1 drugs (in addition to Schedule 2 and Schedule 3 drugs).</li> </ul> <p><b>Document: MSP Position Statement (December 9, 2008)</b></p> <p>The Manitoba Society of Pharmacists supports the concept of prescriptive authority as detailed in the Regulations Discussion Document re: Schedule II and Schedule III as a first step (see Attachment 1).</p> <p>The MPhA is encouraged to work with Stakeholders including the Manitoba Society of Pharmacists to incorporate in the new regulations the ability for pharmacists to prescribe pursuant to a limited formulary with a reasonable reimbursement model to treat minor, self-diagnosed or self-limiting conditions. This new ability if managed correctly and subject to reasonable protocols can achieve improved health outcomes, make better use of the finite number of health professionals, and achieve overall savings to the health care system.</p>
<b>MHHL</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MHHL encourages the stakeholders to consider what is achievable, and models have been implemented in other jurisdictions.</li> <li>▪ MHHL would prefer a conservative approach to</li> </ul>

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	<p>pharmacists prescribing, as it is a relatively new concept.</p>
<b>Surveys</b>	<p><b>Document: MSP Questionnaire 12 – Prescribing by Members</b></p> <ul style="list-style-type: none"> <li>▪ 81 percent of respondents (59) agree with the intent of Section 86(1) Prescribing by members which permits all members with a section 12 license to prescribe a non-prescription drug or a product with a DIN or NPN.</li> <li>▪ At least 85 percent of respondents are in agreement with the subsections as set forth in section 86(1).</li> <li>▪ 86 percent of respondents support the prescribing by extended practice pharmacists as set forth in section 86(2).</li> <li>▪ 88 percent of respondents support the prescribing by clinical assistant specialists as set forth in section 86(3).</li> <li>▪ 93 percent of respondents support the prescribing in emergency situations as set forth in section 86(4).</li> <li>▪ At least 77 percent of respondents support the criteria for prescribing as set forth in section 87.</li> <li>▪ 96 percent of respondents agree with continued care prescriptions as set forth in section 90(1); 82 percent agree with the requirements set for in 90(2); and at least 89 percent agree with the restrictions placed as set forth in 90(3).</li> </ul> <p><b>April 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 68: 84% (167) in favour</li> <li>• Section 86: 91% (177) in favour</li> <li>• Section 87: 97% (193) in favour</li> <li>• Section 88: 99% (182) in favour</li> <li>• Section 90: 98% (193) in favour</li> </ul> <p><b>July 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 68(1.1): 96% (91) in favour</li> <li>• Section 86(1): 96% (94) in favour</li> <li>• Section 87: 97% (92) in favour</li> <li>• Section 90: 93% (overall average)</li> </ul>

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MPhA Subcommittees	N/A
Pharmacist Prescribing in Other Jurisdictions	
Ontario	<p>Ontario introduced Bill 179 May 11, 2009 which expands the scopes of pharmacists. The new scope of practice statement includes OCP's recommendation to the Health Professions Regulatory Advisory Council (HPRAC) to acknowledge the pharmacist's role in promotion of health, prevention and treatment of disease, and in monitoring and management of medication therapy. The Bill grants pharmacists several new authorized acts, including prescribing, administering a substance by inhalation or injection, performing a procedure on tissue below the dermis. All of these new authorized acts are subject to terms, conditions and limitations set out in regulations which will have to be developed and approved by government before the new scope of practice comes into effect.</p> <p>The College is reviewing Bill 179 and will be providing comments over the summer months. Regulations will be created and circulated for consultation in 2010.</p> <p>In June 2008, the Ontario College of Pharmacists responded to the Health Professional Regulatory Advisory Council ("HPRAC")'s Applicant Questionnaire respecting the scope of practice review for Pharmacy. The submission supported an amended scope of practice statement that more accurately reflected pharmacists work:</p> <p><b>"The practice of pharmacy is the promotion of health, prevention and treatment of disease, dysfunction and disorders through medication and non-medication therapy; the monitoring and management of medication therapy; the custody, compounding and the dispensing of drugs; the provision of health care aids and devices and information related to their use".</b></p> <p>Under this scope, pharmacists, in addition to their current practice, could:</p> <ul style="list-style-type: none"> <li>▪ Dispense a prescription without further authorization from a prescriber under certain circumstances, including:           <ul style="list-style-type: none"> <li>- Adapting an existing prescription to facilitate patient compliance, such as changing the dosage form, changing the dosage regime, changing the dosage form to one reimbursable by the patient's third party drug benefit plan, and when the prescribed dose or dosage form</li> </ul> </li> </ul>

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	<p>is not commercially available.</p> <ul style="list-style-type: none"> <li>- Authorizing further extension of a prescription where there are no exiting refills for continuity of care</li> <li>- Providing schedule II and III drugs as a prescription when required for reimbursement under drug plans</li> <li>- Adjusting dosage of medication in response to monitoring</li> </ul> <ul style="list-style-type: none"> <li>▪ Administer drugs, including through injection and inhalation for patient education</li> </ul> <p><i>It is important to note that no known changes to legislation have occurred.</i></p>
<b>Saskatchewan</b>	<p>Effective September 2003 legislation allowed qualified pharmacists to prescribe emergency contraceptives. A Standards and Guidelines document for Pharmacists Prescribing emergency contraceptives has been developed and is used in practice.</p> <p>The SCP issued a Position Statement September 2008 supporting interdependent pharmacist prescribing in collaborative practice environments. SCP has determined that pharmacists be allowed to prescribe under two different levels of authority:</p> <p>Level 1: Recognizes the basic level of knowledge, skills and training that all pharmacists have:</p> <ul style="list-style-type: none"> <li>▪ Includes the following range of activities:           <ul style="list-style-type: none"> <li>- Continuing Therapy;</li> <li>- Drugs in emergency circumstances;</li> <li>- Incomplete or inaccurate prescriptions;</li> <li>- Refills of medications during physician absence;</li> <li>- Medications for self care;</li> <li>- Exempted Codeine Products;</li> <li>- Non-prescription drugs; and</li> <li>- Seamless care.</li> </ul> </li> </ul> <p>Level II: recognizes that pharmacists are capable of undertaking advanced training:</p> <ul style="list-style-type: none"> <li>▪ Includes the following range of activities:           <ul style="list-style-type: none"> <li>- Part A – provision of oral contraception and lifestyle and health promotion; and</li> <li>- Part B – Collaborative prescribing agreements,</li> </ul> </li> </ul>

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	<p style="text-align: center;">therapeutic substitution, and altering drug dosage and/or dosage regimen.</p> <p>Prescribing abilities (beyond emergency contraceptives) not yet in practice. New Policies and by-laws are for approval with an aim of mid fall/early winter implementation.</p>
<b>Alberta</b>	<p>On April 1, 2007 legislation came into effect that allows Alberta pharmacists to expand the scope of services they offer. Pharmacists are authorized to:</p> <ol style="list-style-type: none"> <li>1. Adapt a prescription;</li> <li>2. Prescribe in an emergency;</li> <li>3. Manage ongoing drug therapy; and</li> <li>4. Administer injections.</li> </ol> <p>Only pharmacists on the clinical register are eligible to prescribe.</p> <p>Registration on the Clinical Register is determined according to the <i>Health Professions Act – Pharmacists Profession Regulation</i>. Specifically:</p> <p>3(1) An applicant for registration as a regulated member on the clinical register must</p> <ol style="list-style-type: none"> <li>(a) have received a baccalaureate degree in pharmacy from a pharmacy program approved by the Council;</li> <li>(b) have successfully completed a structured practical training program; and</li> <li>(c) have successfully passed the registration and the ethics and jurisprudence examinations approved by the Council.</li> </ol> <p>(2) An applicant:</p> <ol style="list-style-type: none"> <li>(a) must have completed the requirements set out in subsection (1)(b) and (c) within the one-year period ending immediately before the applicant submits a complete application; or</li> <li>(b) must demonstrate to the satisfaction of the Registrar that the applicant is currently competent to practise pharmacy.</li> </ol> <p>Pharmacist prescribing describes a wide range of activities. It includes:</p> <ul style="list-style-type: none"> <li>▪ prescribing drugs to treat minor, self-diagnosed or self-limiting disease conditions;<sup>3</sup></li> </ul>

<sup>3</sup> The privilege to prescribe new drug therapy is restricted to pharmacists that meet defined requirements that are incremental to the requirements applicable to registration as a clinical pharmacist; additionally, pharmacists that are qualified to initiate prescriptions (i.e. new drug therapy) must consult with another

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	<ul style="list-style-type: none"> <li>▪ adjusting dosages and dosage forms;</li> <li>▪ monitoring and refilling prescriptions to ensure appropriate and effective care;</li> <li>▪ providing emergency supplies of previously prescribed medication;</li> <li>▪ providing comprehensive drug therapy management where the pharmacist, working with other health professionals, takes full responsibility for establishing and maintaining a patient’s chronic drug therapy; and</li> <li>▪ substituting another drug that is expected to have a similar therapeutic effect.</li> </ul> <p>Pharmacists will assess and triage each patient as required. If the pharmacist has the competencies and appropriate information to initiate drug therapy for minor, self-limiting or self-diagnosed conditions, he or she may initiate treatment. Alternatively, the pharmacist may refer the patient to another part of the health system.</p> <p>The ACP recognizes that the healthcare environment has undergone significant changes and pharmacists increasingly participate in the following:</p> <p><u>Health Promotion:</u> Wellness screening programs for osteoporosis, diabetes, cholesterol, immunizations, nutrition and diet counseling, home visits, tobacco reduction, family planning and reproductive health, breast pump counseling.</p> <p><u>Disease Management:</u> Education programs for patients that help them manage their health (hypertension, cholesterol, asthma, depression, anticoagulation, women's health, arthritis, pain management, osteoporosis), blood sugar and blood pressure monitoring, readings and interpretations, interim refills.</p> <p><u>Ensuring Effective Drug Therapy Outcomes:</u> Medication reviews, home visits, specialty compounding, drug information consultations, interim refills, addictions/substance abuse counseling (methadone, opiate dependency).</p> <p><u>Primary Health Care:</u> Treatment of minor injury and ailments (mouth ulcers, burns/scalds, colds, influenza, constipation, diarrhea, etc.), fitting of braces, crutches, wheelchairs, walkers, pressure stockings, triage</p>

health professional that has prescribing privileges on a case-specific basis; accordingly, the pharmacist prescribing model for the initiation of prescriptions (i.e new drug therapy) that has been implemented in Alberta is similar to the model that results from the combination of the Pharmacist Prescribing and Extended-practice Care provisions of the December 2007 Regulations. Both approaches restrict pharmacist prescribing of new drug therapy to collaborative/extended care practice models/environments.

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telephone inquiries and counseling natural health and herbal therapy.

The Act identifies the restricted activities for the following “classes” of pharmacists:

- A **Clinical Pharmacist** is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists’ Standards of Practice, the restricted activities as detailed in Section 16 of the Act.
- A **Provisional Pharmacist** is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists’ Standards of Practice, the restricted activities referred to in section 16 under the supervision (either direct or indirect, as considered appropriate to ensure the safe and effective performance) of a clinical pharmacist or courtesy pharmacist.
- A **Courtesy Pharmacist** is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists’ Standards of Practice, the restricted activities referred to in section 16(1) if the restricted activity is directly related to the purpose for which the regulated member is registered on the courtesy register.
- A **Student Pharmacist** is authorized to perform, within the practice of pharmacy, in accordance with the Pharmacists’ Standards of Practice and within the rules of the structured practical training program, the restricted activities referred to in section 16 under the supervision of a clinical pharmacist or a courtesy pharmacist.

**Clinical Pharmacists Roles under the Act.**

**16(1)** A clinical pharmacist is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists’ Standards of Practice, the following restricted activities:

- (a) to dispense, compound, provide for selling or sell a Schedule 1 drug or Schedule 2 drug;
- (b) to administer a vaccine or parenteral nutrition;
- (c) to compound blood products;
- (d) to insert or remove instruments, devices or fingers beyond the anal verge, and beyond the labia majora;
- (e) to prescribe a Schedule 1 drug for the purpose of adapting an existing prescription;

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	<p>(f) to prescribe blood products for the purpose of adapting an existing prescription;</p> <p>(g) to prescribe a Schedule 1 drug if it is not reasonably possible for the patient to see a health professional to obtain the prescription, and there is an immediate need for drug therapy;</p> <p>(h) to prescribe blood products if it is not reasonably possible for the patient to see a health professional to obtain the prescription, and there is an immediate need for blood products.</p> <p><b>(2)</b> In subsection (1), “adapting an existing prescription” means:</p> <p>(a) altering the dosage, formulation or regimen for a Schedule 1 drug that has been prescribed for a patient;</p> <p>(b) substituting another drug for a prescribed Schedule 1 drug if the substituted drug is expected to deliver a therapeutic effect that is similar to the therapeutic effect of the prescribed drug;</p> <p>(c) substituting a generic drug for the prescribed drug;</p> <p>(d) renewing a prescription to dispense a Schedule 1 drug or blood product to ensure continuity of care.</p>
<b>British Columbia</b>	<p><b>Medication Management (Adapting a Prescription)</b></p> <ul style="list-style-type: none"> <li>▪ Medication Management is an umbrella term that encompasses all professional activities that a pharmacist undertakes, as the medication experts, to optimize safe and effective drug therapy outcomes for patients.</li> <li>▪ Pharmacists’ involvement in medication management activities continue to expand as the needs of patients and the demands of the healthcare system continue to increase.</li> <li>▪ This lead to Bill 25 – <u>The Health Professions (Regulatory Reform) Amendment Act, 2008</u>, which, specific to the pharmacy profession, formalizes a pharmacist’s authority to ‘renew existing prescriptions’.</li> <li>▪ As of January 2009 (enabled by the Health Professions (Regulatory Reform) Amendment Act 2008), pharmacists are permitted to:             <ul style="list-style-type: none"> <li>– change a prescription’s dose, formulation and frequency;</li> <li>– renew an expiring script for up to a year;</li> <li>– substitute a drug for another from the same</li> </ul> </li> </ul>

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	<p>therapeutic class.</p> <p>The College of Pharmacists of BC's Professional Practice Policy #58 entitled "Protocol for Medication Management – Adapting a Prescription," provides the framework to guide pharmacists in the safe and effective adaptation, including renewals, of existing prescriptions.</p>

**Issue # 8: Extended Practice Pharmacists & Specialty Care Practice**

**Summary of Positions**

MPhA Council	MSP (Board)	MHHL
<ul style="list-style-type: none"> <li>▪ MPhA Council is prepared to revisit the composition of the Advisory Committee, taking into consideration the composition models adopted by other professions for similar committees.</li> <li>▪ The Draft Regulations enable MPhA Council to recognize Family Practice as a Specialty Care area of practice under the provisions for extended practice.</li> </ul>	<ul style="list-style-type: none"> <li>▪ MSP (Board) would like the Regulation to define Extended-practice Pharmacists and Specialty Care Practice more clearly (i.e. define the Specialty Care Practices that are additional to Clinical Assistant).</li> <li>▪ MSP (Board) believes the Advisory Committee should have more than four committee members.</li> <li>▪ MSP (Board) believes that the Advisory Committee should be composed predominantly of pharmacists.</li> <li>▪ MSP (Board) wishes to have an ex-officio seat on the committee.</li> </ul>	<ul style="list-style-type: none"> <li>▪ MHHL believes it is not the regulator’s responsibility to determine compensation for Advisory Committee members.</li> <li>▪ MHHL believes the Advisory Committee should include public/lay representation.</li> </ul>

## Jurisdictional Comparison

	Ontario	Saskatchewan	Alberta	British Columbia
<b>Does an Extended Scope of Practice Exist?<sup>4</sup></b>	<ul style="list-style-type: none"> <li>Enabling legislation introduced in May 2009.</li> </ul>	<ul style="list-style-type: none"> <li>No.</li> </ul>	<ul style="list-style-type: none"> <li>Yes.</li> </ul>	<ul style="list-style-type: none"> <li>No.</li> </ul>
<b>Details and Limitations (if applicable)</b>	<ul style="list-style-type: none"> <li>The new scope of practice acknowledges the role in promotion of health, prevention and treatment of disease, and in monitoring and management of medication therapy.</li> <li>Pharmacists would be prescribing, administering a substance by inhalation or injection, performing a procedure on tissue.</li> </ul>		<ul style="list-style-type: none"> <li>Alberta doesn't use the term Extended Practice Pharmacist; however, Alberta does define criteria that pharmacists must satisfy in order to be permitted to prescribe Schedule 1 drugs. While the approach taken in Alberta model is not exactly equivalent to Manitoba's approach, the concept and objectives are similar.</li> </ul>	<ul style="list-style-type: none"> <li>The practice of pharmacy is based on a Framework of Professional Practice which defines role of the pharmacist beyond dispensing drugs.</li> <li>Pharmacists are authorized to change a prescription's dose, formulation and frequency; renew an expiring script for up to a year; and substitute a drug for another.</li> </ul>
<b>Future Changes</b>	<ul style="list-style-type: none"> <li>Regulations to be made and approved by the Government of Ontario - likely in 2010.</li> </ul>	<ul style="list-style-type: none"> <li>Regulations for further prescribing abilities to be implemented late fall / early winter.</li> </ul>		

<sup>4</sup> It is important to note that the answer to this question depends upon the interpretation of "Extended Practice". The answers indicated in the table are based on interpretation of "Extended Practice" as a reference to a special class or category of pharmacists that have privileges beyond those privileges granted to all pharmacists. Conversely, if "Extended Practice" is interpreted to include the granting expanded privileges to all pharmacists, then the answers to the question would become "Yes" for both Saskatchewan and British Columbia because both of these jurisdictions have recently expanded the role of all pharmacists by granting certain prescribing privileges.

## Background – Extended Practice Pharmacists & Specialty Care Practice

Issue #8: Extended Practice Pharmacists & Specialty Care Practice	
Draft Pharmaceutical Regulations: Policy Document, December 3, 2007	
<b>Extended practice pharmacist</b>	80(1) A member must not engage in any included practice unless he or she is registered as an extended practice pharmacist, or as otherwise permitted by these regulations.
<b>Use of title</b>	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.
<b>Pharmacist license</b>	80 (3) The pharmacist license of an extended practice pharmacist must note this designation and any specialty or specialties of the member;
<b>Requirements of registration</b>	81(1) An applicant for registration as an extended practice pharmacist must: <ul style="list-style-type: none"> <li>(a) submit an application to the board in the form specified in the by-laws;</li> <li>(b) be a member;</li> <li>(c) practice in a collaborative practice;</li> <li>(d) be qualified as a specialist in one or more areas under this part; and</li> <li>(e) pay the fee provided for in the by-laws.</li> </ul>
<b>Registration</b>	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.
<b>Conditions</b>	81(3) An approval under subsection (2) may be made subject to any conditions that the board considers appropriate.
<b>Application not approved</b>	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 s21 of the Act shall apply, with necessary modifications.
<b>Duration of registration</b>	81(5) The registration of a extended practice pharmacist shall continue until the earlier of: <ul style="list-style-type: none"> <li>(a) the person's registration as a pharmacist or</li> </ul>

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	<p>pharmacist licence is cancelled;</p> <p>(b) the member ceases to practice in the area or areas of specialty for a period of more than 24 months; or</p> <p>(c) the member ceases to practice in a collaborative practice for a period of more than 24 months.</p>
<b>Specialty Practice</b>	<p>82 A member may request that his or her pharmacist license 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:</p> <p>(a) Clinical assistant; or</p> <p>(b) any other specialty as created by Council.</p>
<b>Clinical assistant specialist</b>	<p>83 A member is qualified as a clinical assistant specialist upon providing evidence satisfactory to the registrar that he applicant is registered as a clinical assistant under The Medical Act.</p>
<b>Specialty Practice Qualifications</b>	<p>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:</p> <p>(a) the applicant has practiced at least 3 years, within the previous five years, in a health care setting;</p> <p>(b) the applicant has:</p> <ul style="list-style-type: none"> <li>(i) obtained certification as a specialist in the requested area through an organization or agency acceptable to council;</li> <li>(ii) passed an examination related to the requested specialty approved by council; or</li> <li>(iii) has work experience related to the requested specialty and passed a competency assessment acceptable to council.</li> </ul> <p>(c) the applicant continues to practice consistent with the requested area of specialty; and</p> <p>(d) the applicant continues in a collaborative practice in the requested area of specialty.</p>
<b>Renewal of Specialty Practice Qualifications</b>	<p>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</p>

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	<p>providing evidence to the registrar that:</p> <ul style="list-style-type: none"> <li>(a) confirms the continued qualification under section 84; and</li> <li>(b) documents professional development in the area of specialty.</li> </ul>
<b>Appeal of Renewal</b>	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.
<b>Extended practice pharmacist practice advisory committee</b>	<p>85(1) Council must establish an extended practice pharmacist advisory committee, consisting of:</p> <ul style="list-style-type: none"> <li>(a) two pharmacists who are members, appointed by council, one of which shall be chair;</li> <li>(b) one representative appointed by the College of Physicians and Surgeons of Manitoba; and</li> <li>(a) (c) one representative appointed by the College of Registered Nurses of Manitoba.</li> </ul>
<b>Committee may consult</b>	85(1.1) The Committee may consult with other health care professions and individuals as it may deem appropriate.
<b>Term on committee</b>	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.
<b>Vacancies</b>	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.
<b>Quorum</b>	85(4) A quorum of the committee is two committee members, and must include a representative from at least two of the appointing bodies, including one appointed by council.
<b>Duties of committee</b>	<p>85(5) The committee must, on at least an annual basis:</p> <ul style="list-style-type: none"> <li>(a) review this regulation as it relates to included practices;</li> <li>(b) review standards of practice, practice directions, and the code of ethics as they relate to included practices;</li> <li>(c) review the outcomes of inspections and audits which relate to included practices;</li> <li>(d) formulate recommendations regarding the</li> </ul>

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	<p>qualification of specialists;</p> <p>(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;</p> <p>(f) formulate recommendations regarding the appropriateness of included practices being exercised outside of a collaborative practice; and</p> <p>(g) present the recommendations to council.</p>
<b>Council may decide</b>	85(5.1) Council may decide to accept, reject or alter the recommendations made by the committee.
<b>Sharing of inspection information</b>	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.
<b>Positions</b>	
<b>MPhA Council Position / Comments</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MPhA Council is prepared to revisit the composition of the Advisory Committee, taking into consideration the composition models adopted by other professions for similar committees.</li> <li>▪ The Draft Regulations enable MPhA Council to recognize Family Practice as a Specialty Care area of practice under the provisions for Extended Practice.</li> </ul>
<b>MSP (Board) Position / Comments</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MSP (Board) would like the Regulation to define Extended-practice Pharmacists and Specialty Care Practice more clearly (i.e. define the Specialty Care Practices that are additional to Clinical Assistant).</li> <li>▪ MSP (Board) believes the Advisory Committee should have more than four committee members.</li> <li>▪ MSP (Board) believes that the Advisory Committee should be composed predominantly of pharmacists.</li> <li>▪ MSP (Board) wishes to have an ex-officio seat on the committee.</li> </ul> <p><b>Document: MSP Position Statement December 9, 2008</b></p> <p>The Manitoba Society of Pharmacists supports the introduction of extended practice pharmacists. In addition to the opportunities available to extended</p>

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	<p>practice pharmacists, this new category of pharmacists provides a vehicle to increase public consciousness of the larger role all licensed pharmacists can assume in the health care system.</p> <p>The MPhA is encouraged to revisit the composition, structure and function of the Extended Practice Advisory Committee. The Manitoba Society of Pharmacists as the recognized representative for the professional and economic interests of Manitoba Pharmacists requests representation on the Practice Advisory Committee.</p> <p>It has been established both in Canada and in other countries that the introduction of extended practice initiatives are not successful without necessary compensation models.</p> <p>The Committee would benefit from increased and broader representation such as including representation from the Faculty of Pharmacy. In addition the representatives appointed by the College of Nurses of Manitoba, and the College of Physicians and Surgeons of Manitoba should be required to hold a license with their respective regulatory bodies.</p> <p>Certification programs, substantive examinations and competency assessments as they relate to extended practice licensing and specialty practice need to be consistent with the "Mutual Recognition Agreement for the Profession of Pharmacy in Canada".</p>
<b>MHHL</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ MHHL believes it is not the regulator's responsibility to determine compensation for Advisory Committee members.</li> <li>▪ MHHL believes the Advisory Committee should include public/lay representation.</li> </ul>

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<b>Surveys</b>	<p><b>Document : Questionnaire 8 – Extended Practice Pharmacists and Specialty Practice</b></p> <p>Stakeholder Survey (69 Responses): 83 percent of respondents agree with the intent of the sections of the regulations which address “Extended Practice Pharmacists” and “Specialty Practice” 80(1) and the included practices 2(2).</p> <p>Other questions received a majority of support.</p> <p><b>April 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 85: 98% (187) in favour</li> </ul> <p><b>July 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 85(1): 98% (91) in favour</li> </ul>
<b>MPhA Subcommittees</b>	N/A
Extended Practice Pharmacists & Specialty Care Practice in Other Jurisdictions	
<b>Ontario</b>	N/A
<b>Saskatchewan</b>	Position Statement on Enhanced Authority to Prescribe in Saskatchewan speaks to the extended practice of pharmacists. No documents found which mentions that a new category of pharmacists would be created for these proposed prescribing capabilities.
<b>Alberta</b>	<p><b>(3)</b> Subject to subsection (4), a clinical pharmacist is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists’ Standards of Practice, the restricted activities of prescribing a Schedule 1 drug and prescribing blood products if the clinical pharmacist:</p> <ul style="list-style-type: none"> <li>▪ has provided evidence satisfactory to the Registrar of having successfully completed the Council requirements to prescribe Schedule 1 drugs and blood products; and</li> </ul> <p>(a) has received notification from the Registrar that the authorization is indicated on the clinical register.</p> <p><b>(4)</b> A clinical pharmacist authorized under subsection (3) may prescribe a Schedule 1 drug or blood products only if the clinical pharmacist</p> <p>(a) has determined that a Schedule 1 drug or blood products are appropriate for the patient through an assessment of the patient,</p> <p>(b) has received a recommendation that the patient</p>

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	<p>receive drug therapy from a health professional who is authorized to prescribe a Schedule 1 drug or blood products, or</p> <p>(c) has determined in consultation with or has determined in conjunction with a health professional that a Schedule 1 drug or blood products are appropriate for the patient.</p> <p><b>(5)</b> A clinical pharmacist is authorized to perform, within the practice of pharmacy and in accordance with the Pharmacists' Standards of Practice, the restricted activity of administering anything by an invasive procedure on body tissue below the dermis or the mucous membrane for the purpose of administering subcutaneous or intramuscular injections if the clinical pharmacist</p> <p>(a) has provided evidence satisfactory to the Registrar of having successfully completed the Council requirements for the administration of injections; and</p> <p>(b) has received notification from the Registrar that the authorization is indicated on the clinical register.</p>
<b>British Columbia</b>	<p>The practice of pharmacy in British Columbia is based on a <b>Framework of Professional Practice (“FPP”)</b>. This framework describes what B.C. pharmacists do in their daily work and how they know they are doing it well.</p> <p>According to BC, the work of pharmacists goes beyond ‘dispensing drugs’. The role of pharmacists is to:</p> <ol style="list-style-type: none"> <li>1. Provide Pharmaceutical Care;</li> <li>2. Produce and Distribute Drug Preparations and Products;</li> <li>3. Contribute to the Effective Operation of the Pharmacy;</li> <li>4. Maintain Professional Development &amp; Contribute to the Professional Development of Others; and</li> <li>5. Contribute to the Effectiveness of the Health Care System.</li> </ol>

## Appendix A - Brief Overview of the 13 Issues

- 1. Pharmacy Manager Qualifications:** requirement to satisfy a number of practice hours as a pharmacist or a training program in order to be eligible to become a pharmacy manager;
- 2. Professional Liability Insurance:** requirement for both pharmacists and pharmacies to carry professional liability insurance.
- 3. Pharmacy Technicians:** the ability of the Regulations to establish qualifications, experience and other assessments that must be held by a pharmacy technician and the role and duties they can perform.
- 4. Pharmacist Profiles:** the development of a profile for certain health care professionals (i.e., in this case, for each Pharmacist) – a record which includes personal, professional, and other information for the purpose of being made available to the public.
- 5. Pharmacist Prescribing:** the ability of pharmacists to prescribe medication and /or treatment. .
- 6. Tele-pharmacy:** the provision of pharmacy services to residents in remote communities that do not have reasonable access to pharmacy services. (See section 37 of draft)
- 7. Central Fill Component:** the ability of Hospital and Community Pharmacies to package medication and fill prescriptions for another pharmacy.
- 8. Extended Practice Pharmacists & Specialty Care Practice:** the establishment of extended practice pharmacists, and the role of the Extended Practice Advisory Committee.
- 9. Inducements:** the offering or providing of gifts, rebates, bonuses, or inducements while engaging in the practice of pharmacy.
- 10. Practice Directions / Standards of Practice:** the ability of the Council to make practice directions in over 20 discrete areas.
- 11. Distance Care Component:** the standards required to provide services to patients who do not attend the pharmacy in person. This can involve International Pharmacy Services (“IPS”), inter-province services, and intra-province services.
- 12. Personal Health Identification Number (“PHIN”):** a prescription may not be dispensed unless a patient profile made and retained; in cases where the patient is a Manitoba resident that has been assigned a PHIN, the PHIN of the patient shall be recorded in the profile in accordance with the appropriate practice directions.
- 13. Record Keeping:** the need for Pharmacists to maintain records and documentation related to work conducted.

## Appendix B – Focus Group Preparation Materials

This Issue and Options Analysis has been developed to provide context and structure to the Focus Group concerning Pharmacist Prescribing and Extended Practice Pharmacists & Specialty Care Practice.

### A. Pharmacist Prescribing

The primary concern that stakeholders have raised regarding pharmacists prescribing is that the privilege to initiate prescriptions for Schedule 1 drugs was restricted to Extended Practice Pharmacists (Clinical Assistant are a form of Extended Practice Pharmacists) in the December 2007 Draft Regulations. Conversely, 86% of the respondents to a questionnaire issued by the Manitoba Society of Pharmacists supported permitting all pharmacists to initiate prescriptions for a limited formulary of Schedule 1 drugs to treat minor, self-diagnosed, or self-limiting conditions. Accordingly, the primary concern that stakeholders have expressed regarding pharmacist prescribing is:

- i. Should all pharmacists be provided the privilege to initiate prescriptions for a limited formulary of Schedule 1 drugs to treat minor, self-diagnosed, or self-limiting conditions?

**N.B. the purpose of the above list is to acknowledge concerns that have been expressed some stakeholders and to provide structure for the Focus Group discussions; inclusion of a concern in this list does not imply that the concern has been validated. Furthermore, inclusion of a concern does not imply that the concern is common to the majority of Manitoba Pharmacists.**

### B. Extended Practice Pharmacists & Specialty Care Practice

Stakeholders have expressed the following concerns regarding the regulations pertaining to Extended-practice Pharmacists and Specialty Care:

- ii. Which is the better/preferred approach to defining the areas of Specialty Care: (i) define the areas of Specialty Care in the Regulations, or (ii) allow the areas of Specialty Care to be defined by Council outside of the Regulations?
- iii. Does the proposed composition of the Extended Practice Advisory Committee consistent with good practices? What is the most appropriate composition for this Committee?

**N.B. the purpose of the above list is to acknowledge concerns that have been expressed some stakeholders and to provide structure for the Focus Group discussions; inclusion of a concern in this list does not imply that the concern has been validated. Furthermore, inclusion of a concern does not imply that the concern is common to the majority of Manitoba Pharmacists.**

### Purpose

The purpose of this Focus Group is to discuss the concerns that have been raised by stakeholders, which are listed above, and to identify the preferred option to resolve the concerns.

### Discussion Questions

In order to foster a knowledgeable and fruitful discussion of this issue during the focus group, the following questions are being provided for your thoughtful consideration when you prepare to participate in the Focus Group.

1. Other than the role of Clinical Assistant, what other roles do you believe should be recognized as areas of Specialty Care under the extended-practice Regulations? What are the advantages and disadvantages of specifically listing the areas of Specialty Care in the Regulations versus allowing Council to define these areas as they are identified and/or evolve?

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2. What limitations should there be on Pharmacists Prescribing, particularly in relation to Schedule 1 drugs? In particular, under what circumstances and with which restrictions, should all Manitoba pharmacists have the privilege to initiate prescriptions (i.e., new drug therapy/minor elements) for Schedule 1 drugs? What could be included in the “minor elements” list?
3. How should the Extended Practice Pharmacy Advisory Committee be structured (i.e. what is the best composition model for the committee) to be most effective and valuable?

**Potential Options: Issue 5: Pharmacist Prescribing**

#	Concern	Option 1	Option 2
I	Should all pharmacists be provided the privilege to initiate prescriptions for a limited formulary of Schedule 1 drugs to treat minor, self-diagnosed, or self-limiting conditions?	Maintain existing wording of the Draft Regulations, which permits all pharmacists to prescribe Schedule 2 and Schedule 3 drugs, but restricts prescribing of Schedule 1 drugs to only recognized Extended-practice Pharmacists and Clinical Assistant Specialists.	Change the wording of the Draft Regulations to allow all pharmacists to initiate, prescriptions for a limited formulary of Schedule 1 drugs.

**Potential Options: Issue # 8: Extended Practice Pharmacists & Specialty Care Practice**

#	Concern	Option 1	Option 2
ii.	Which is the better/preferred approach to defining the areas of Specialty Care: (i) define the areas of Specialty Care in the Regulations, or (ii) allow the areas of Specialty Care to be defined by Council outside of the Regulations?	Maintain existing working of the Draft Regulations, which identifies that: <i>A member may request that his or her pharmacist license 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:</i>  (c) <i>clinical assistant; or</i>  (d) <i>any other specialty as created by Council.</i>	Define additional specialties within the Regulations. For example: <ul style="list-style-type: none"> <li>▪ Oncology</li> <li>▪ Cardiology</li> <li>▪ Diabetes</li> <li>▪ Others?</li> </ul>
iii.	Does the proposed composition of the Extended Practice Advisory Committee consistent with good practices? What is the most appropriate composition for this Committee?	Maintain the existing composition or weighting of the Extended-practice Pharmacist Advisory Committee, which includes: <ul style="list-style-type: none"> <li>▪ Two (2) pharmacists appointed by council, including one as chair.</li> </ul>	Expand the membership of the Advisory Committee to include other representatives. For example: <ul style="list-style-type: none"> <li>▪ Public/lay members;</li> <li>▪ Additional pharmacists;</li> <li>▪ Government representation;</li> </ul>

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#	Concern	Option 1	Option 2
		<ul style="list-style-type: none"> <li>▪ One (1) member appointed by the College of Physicians and Surgeons of Manitoba; and</li> <li>▪ One (1) representative appointed by the College of Registered Nurses.</li> </ul>	and/or <ul style="list-style-type: none"> <li>▪ Representation by MSP.</li> </ul>