

# Bill 41 Regulations – Issue and Options Analysis

## Issue #6: Tele-pharmacy



**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 Tele-pharmacy regulations:

- MSP will draft and propose to MPhA definitions for “remote” and “reasonable access” that would address their concerns.
- MPhA will consider incorporating the definitions proposed by MSP into the Regulations.

On August 28, 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

In Manitoba, there are a number of communities that do not have reasonable/adequate access to pharmacy services. Tele-pharmacy has been proposed as a means of enabling better/adequate access to pharmacy services in the communities that are presently under-serviced.

The December 2007 Draft Regulations use the term *Tele-pharmacy* specifically to refer to the delivery of pharmacy services to a Manitoba community that does not have reasonable access to pharmacy services using a two-way video link between a Qualified Pharmacy Technician, who is located in the community where the medication is being dispensed, and a real-time supervising Pharmacist, who is located in the primary pharmacy in another community.<sup>1</sup>

The Government of Manitoba has determined that there are communities in Manitoba that do not have reasonable access to pharmacy services; furthermore, the Government is looking to MPhA to facilitate improvements to

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<sup>1</sup> Qualified Pharmacy Technician is capitalized to make specific reference to a technician that has met the qualification standards for recognition as a Qualified Pharmacy Technician as defined in the Regulations. See the Issue and Option Analysis Paper on Pharmacy Technicians for a discussion of the qualification standards.

pharmacy service levels in these communities. The Government views Tele-pharmacy as a potential means of improving access to pharmacy services in communities that do not presently have reasonable access to such services. Accordingly, there is general agreement that an alternative to the traditional pharmacy service delivery model is required to improve access to pharmacy services in the effected communities. Tele-pharmacy is an alternative service delivery model that has been proposed by MPhA in the draft Regulations to facilitate improvements to the service levels in communities that do not presently have reasonable access to pharmacy services. The draft Tele-pharmacy regulations were not intended to facilitate the replacement of existing pharmacies, which are staffed by licensed pharmacists, with tele-pharmacies.

## Options Paper

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

- **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 Council, the MSP (Board), and MHHL 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.

### 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 intent of the Tele-pharmacy component license (Section 37 in the December 2007 Draft Regulations) is to facilitate improvements to service levels for pharmacy services in communities that otherwise do not have reasonable access to pharmacy services.</p> <p>Section 33, entitled <i>Distance Care</i>, in the December 2007 Draft Regulations, was intended to apply to out of province mail</p>	<ul style="list-style-type: none"> <li>• Is <i>Tele-pharmacy</i> the most appropriate term to use to refer to the delivery of pharmacy care to under-served communities?</li> <li>• <i>Tele-pharmacy</i>, as defined in the Regulations, is one particular model for delivering pharmacy services to clients/patients that do not interact in-person with the Pharmacist and/or the Pharmacist is not co-located with the client/patient; i.e.</li> </ul>	<ul style="list-style-type: none"> <li>• There is broad recognition there are communities in Manitoba that do not have reasonable (or adequate) access to pharmacy services.</li> <li>• There was consensus amongst the participants of the August 28<sup>th</sup> Focus Group that <i>Tele-pharmacy</i> is too specific and restrictive of a term for this Section; the participants of the Focus Group on Tele-pharmacy agreed that the Regulations should allow Pharmacists to</li> </ul>	<ul style="list-style-type: none"> <li>• Change the name of Section 33, which was entitled Distance Care in the December 2007 Draft Regulations, to a title that better describes the intent of that Section, e.g. "out of province distribution of dispensed medication".<sup>4</sup></li> <li>• Change the name of Section 37 from “Tele-pharmacy” to “Distance and Remote Care” or equivalent.</li> </ul>

Situation	Concerns	Perspectives	Suggested Course of Action
<p>order/delivery for non-Manitoba patients.<sup>2</sup> The following scenarios would not require the Distance Care Component License that is described in Section 33:</p> <ul style="list-style-type: none"> <li>• in province mail order/delivery for MB Residents; and</li> <li>• out of province mail order/delivery for patients that normally attend the pharmacy, but may reside out of the Province.</li> </ul> <p>Forms of Distance Care (i.e. providing pharmacy services without direct, in-person interaction between the patient and the client) in many states and (now) provinces has followed two distinct models:</p> <ul style="list-style-type: none"> <li>• <i>Pharmacist centric model: A pharmacist at a Central Pharmacy extends pharmacy services into a remote/off site location.</i></li> <li>• <i>Physician centric model: A remote offsite Pharmacist provides services to a dispensing Physician.</i></li> </ul>	<p>they involve the provision of care across a distance. Several other models for providing pharmacy service across a distance have already been implemented in other jurisdictions (see Appendix D for a listing of some of these service models). The Regulations should allow Pharmacists to utilize any new and/or existing processes and technologies to achieve improved care for their clients, respecting the same principles that govern traditional pharmacy (such as standard of care, confidentiality, patient's right to choose, and patient consent). Are these other distance care service delivery models allowed under the proposed Regulations?</p> <ul style="list-style-type: none"> <li>• What are the implications of not adopting a broader definition of distance care in lieu of enabling one specific type of distance care (i.e. supervision of a Technician</li> </ul>	<p>use a variety of service models and technology to provide services over a distance; i.e. to provide pharmacy services without in-person interaction between the pharmacist and the patient/client and/or without co-location of the pharmacist and the patient/client.</p> <ul style="list-style-type: none"> <li>• Some of the potential service delivery models for delivering pharmacy services/care remotely (i.e. over a distance) do not require a Qualified Technician (see Appendix D);<sup>3</sup> Pharmacists should be able to implement any form of remote distance care service delivery model that achieves the defined standard(s) of care. MPhA should regulate the standard of practice for any distance care service model in the same manner that it regulates such for the traditional pharmacy service delivery model (i.e. co-location of the client and pharmacist and/or in-person interaction between the pharmacist and the client).</li> <li>• Unless one reads the details of</li> </ul>	<ul style="list-style-type: none"> <li>• Broaden the scope of Section 37 to encompass any new and/or existing processes and technologies to deliver services remotely and/or over a distance, in accordance with Practice Directions, where necessary. Relocating content that is specific to particular service delivery models from the Regulations document into Practice Directions will afford greater flexibility as new service models and technologies evolve/emerge.</li> <li>• Where necessary, develop Practice Directions to enable specific service delivery models that involve processes and/or technologies that require unique controls (e.g. Tele-pharmacy, as defined in the December 2007 Regulations).</li> <li>• Any regulations that are required to address the distribution of dispensed</li> </ul>

<sup>2</sup> Section 33 originally included IPS; however, in December 2007 it was modified to exclude IPS, reflecting Council's intent, at that time, not to renew the IPS Component licenses.

<sup>3</sup> In this case, the term Qualified Technician is used to refer to a technician that has met the qualification standards defined in the regulations for recognition as a Qualified Technician.

<sup>4</sup> The Contextual environment for Section 33 has evolved since this section was drafted in December 2007; accordingly, Section 33 merits review and possible revisions; the title for this Section should reflect any revisions that result from the review.

Situation	Concerns	Perspectives	Suggested Course of Action
	<p>via a video link) at this time?</p> <ul style="list-style-type: none"> <li>At present, Manitoba Pharmacists have the opportunity to proactively regulate the practice of Tele-pharmacy or remote dispensing. However, Manitoba Pharmacists should not assume that the choice of whether Tele-pharmacy happens in Manitoba is exclusive to pharmacists. The choice that Pharmacists are currently facing is whether Pharmacists would prefer Tele-pharmacy/distance care to be governed by their College or implemented by other regulated health professionals and/or government approvals?</li> </ul>	<p>Section 37 carefully, one assumes that it describes pharmacy services provided via telephone conversation; the title has led to confusion regarding the service model.</p> <ul style="list-style-type: none"> <li>The means (i.e. process and technology) by which Distance Care can be delivered could be defined in Practice Directions under the Distance Care section; i.e. the <i>Tele-pharmacy Component</i> section could be deleted and replace with a Practice Direction that is referenced under Distance Care (Section 33).</li> <li>The Regulations that govern the delivery of Distance Care should not define specific processes and technologies as this could become disabling or limiting with future changes (e.g. advancements in technology). References to specific technologies or processes, if documented, should be documented in Practice Directions rather than in the Regulations.</li> <li>Some stakeholders have not understood that Council intends to decline applications for <i>Tele-pharmacy</i> licenses if there are not reasonable grounds to conclude that the community in question does not have reasonable access to pharmacy services.</li> </ul>	<p>medication outside of Manitoba would be incremental to Section 37 and would be addressed outside of Section 37. For example, a pharmacy that provides Distance Care to a community in Nunavut would be subject to both Section 37 and Section 33.</p> <ul style="list-style-type: none"> <li>Ensure that the regulations governing Distance Care (i.e. Section 37) allow for provision of distance care into communities that do not have a technician who meets the standards required to be recognized as a Qualified Pharmacy Technician, as defined in the Regulations.</li> <li>Carry out further research into the distance care models that are in practice in other jurisdictions (e.g. Alberta, B.C. and North Dakota).</li> </ul>

Situation	Concerns	Perspectives	Suggested Course of Action
		<ul style="list-style-type: none"> <li>• Members would like to better understand how distance care is being delivered in other jurisdictions, including both Canadian and international jurisdictions. Furthermore, members would like to understand how these other jurisdictions have legislated/regulated the provision of distance care and what have been the successes and challenges in the other jurisdictions.</li> <li>• The need for flexibility in distance care models is going to increase, not decrease, because of the migration of population distribution from rural communities to urban communities, which is affecting the viability of rural pharmacies.</li> <li>• Tele-pharmacy is supported by patient, government, third party payers and the public.</li> <li>• There are instances where it may not be possible to have a qualified Pharmacy Technician regularly present in some remote communities; the Regulations should facilitate provision distance care to communities where there is no Qualified Pharmacy Technicians;</li> <li>• Does the <i>Distance Care</i> component allow a pharmacy that is located in Manitoba to fill</li> </ul>	

Situation	Concerns	Perspectives	Suggested Course of Action
		<p>prescriptions for a patient in another Province? If so, why is the <i>Distance Care Component</i> section silent on process and technology, yet the <i>Tele-pharmacy Component</i> references specific enabling technology? There is not a clear differentiation between the <i>Tele-pharmacy</i> and <i>Distance Care Components</i>.</p>	
<p>Section 37(1) refers to a <i>remote facility</i> in a <i>remote community</i>.</p> <p>Section 37(2)(a) uses the phrase, <i>does not have reasonable access to pharmacy services</i>.</p>	<ul style="list-style-type: none"> <li>• What is a “community” in terms of this regulation? For example, if there is a hospital in a suburb of Winnipeg that does not have a pharmacist on duty 24 hours a day, 7 days a week, does it qualify as a community that does not have reasonable access to pharmacy services?</li> <li>• In which of its possible senses is the word <i>remote</i> used in this Section? Is it intended to mean (i) out-of-the-way; secluded, e.g. a remote village; a remote mountaintop; or (ii) operating or controlled from a distance, as by remote control, e.g. a remote telephone answering machine. This is not clear from the Regulations.</li> <li>• What criteria will be applied to assess whether a community has reasonable access to pharmacy services?</li> </ul>	<ul style="list-style-type: none"> <li>• Attempts to define terms such as <i>remote</i>, <i>under-served</i>, or <i>reasonable access</i> may become limiting or disabling; however, some pharmacists are not comfortable leaving the interpretive application of these terms to the discretion of Council.</li> <li>• The language in the Regulations does not effectively convey the intended scope of this Regulation; members are uncertain how tightly or loosely Council will interpret terms such as <i>remote</i> and <i>reasonable access</i>.</li> <li>• The concept of a <i>Manitoba community that does not have reasonable access to pharmacy services</i> should be sufficiently broad that it would include, for example, an urban hospital that does not have a pharmacist on duty at all times.</li> </ul>	<ul style="list-style-type: none"> <li>• Clarify the sense in which the word <i>remote</i> is used.</li> <li>• Provide an explanation of the intent of this Section in plain, simple language.</li> <li>• Engage in dialogue with the membership at large regarding the advantages and disadvantages of trying to define <i>reasonable access</i> more specifically.</li> <li>• Do not restrict the concept of <i>Distance Care</i> to geographically isolated communities; allow the concept of <i>distance care</i> to include provision of care in any sense where the pharmacist does not have in-person interaction with the patient/client and/or is not co-located with the patient.</li> </ul>

Situation	Concerns	Perspectives	Suggested Course of Action
<p>Pharmacists are not certain what impacts the introduction of Tele-pharmacy, or, more broadly, distance care, might have on the practice of pharmacy in the Province of Manitoba.</p>	<ul style="list-style-type: none"> <li>The introduction of the tele-pharmacy regulations could result in a reduction in the number of pharmacists required in Manitoba if MPhA were to approve tele-pharmacy component license applications that would result in replacement of a locally-resident licensed pharmacist with a Tele-pharmacy (service delivery model).</li> </ul>	<ul style="list-style-type: none"> <li>If Tele-pharmacy and other distance care service models are not allowed under the Regulations, how will service levels be improved in currently-under-served communities; if there were a business case to have a locally staffed pharmacy, there probably would be a locally staffed pharmacy.</li> <li>There are communities located in remote regions where few pharmacists wish to reside; furthermore, there are needs for pharmacists to be available in acute care facilities at times of the day/week when too few pharmacists are willing to work.</li> <li>There are two ways to look at this issue: one is that Tele-pharmacy, and, more broadly, distance care creates new business opportunities for pharmacists; the other is that service models such as Tele-pharmacy might supplant more traditional pharmacy models.</li> <li>History provides many examples that indicate that people will find ways to work around rules that try to prevent adoption of technological advancements that provide real improvements and benefits.</li> </ul>	<ul style="list-style-type: none"> <li>Hold a Town Hall Meeting specific to this topic. Provide information about the distance care experiences of other jurisdictions. Allow the Manitoba <i>Champions</i> of distance care to discuss their service delivery models. Allow members to air their concerns over potential job losses.</li> <li>Provide Manitoba Pharmacist with an explanation of the intent of the proposed Regulation.</li> </ul>

Situation	Concerns	Perspectives	Suggested Course of Action
<p>The draft Regulations restrict operation of the remote tele-pharmacy site to <i>qualified</i> pharmacy technicians.</p> <p>The Regulations also set out the criteria that must be satisfied in order to be recognized as a qualified technician.</p> <p>Council recently passed a motion that was intended as an expression of Council's intent to bring the qualification criteria for Pharmacy Technicians in Manitoba into alignment with evolving National Standards, which require Pharmacy Technicians to have passed the National Pharmacy Qualifying Examination.</p>	<ul style="list-style-type: none"> <li>Is it adequate that technicians in the remote facility be qualified, or is it critical that they also be regulated?</li> </ul>	<ul style="list-style-type: none"> <li>Council's expressed intent to align the criteria for qualification as a Pharmacy Technician with the evolving national standard sets a very high standard for qualification as a pharmacy technician.</li> <li>The way that <i>Tele-pharmacy</i> is defined in the draft Regulations, the Technicians work must be supervised by video conference. If unregulated Technicians can carry out such work under the supervision of Pharmacist within a common facility, why couldn't a qualified Technician carry out the same work under the supervision (by video conference) of a Pharmacist in a different facility?</li> <li>The Tele-pharmacy Section facilitates supervision by video conference technology; it is not the Section of the Regulations that enables or governs delegation of Pharmacists' duties to Pharmacy Technicians.</li> <li>Requiring tele-pharmacies to have a regulated technician is not appropriate as technicians working a tele-pharmacy do not actually have delegated functions as the pharmacist is still involved.</li> <li>Given that there is currently no plan to regulate Technicians in</li> </ul>	<ul style="list-style-type: none"> <li>Ensure that all members understand that the Tele-pharmacy service model, as currently defined, involves supervision of the Technician by video conference, which is similar to supervision in person; i.e. Tele-pharmacy, as defined in the draft Regulations, is not the component of the Regulations that facilitates delegation to a Pharmacy Technician.</li> <li>Ensure that members understand that, if they object to delegation to Technicians, that the objection relates to Section 52, Pharmacy Technicians, not to Tele-pharmacy.</li> </ul>

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Situation	Concerns	Perspectives	Suggested Course of Action
		<p>Manitoba, the Regulations would be disabling, rather than enabling, if only Regulated Technicians could provide Tele-pharmacy services.</p> <ul style="list-style-type: none"> <li>• MHHL has intimated that it is expecting MPhA to enable improvements to service levels in communities that presently do not have reasonable access to Pharmacy Services.</li> </ul>	

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### Summary of Positions

MPhA Council	MSP (Board)	MHHL
<ul style="list-style-type: none"> <li>▪ MPhA believes that there are communities in Manitoba that do not presently have reasonable access to hospital and/or community pharmacy services.</li> <li>▪ This Regulation is intended to enable service level improvements in communities that do not presently have reasonable access to pharmacy services; it is not expected to detrimentally impact service levels;</li> <li>▪ It is problematic to define <i>remote and under-serviced</i> or <i>reasonable access</i> in terms of location or size; it will be more effective to evaluate each situation on its own merits;</li> <li>▪ MPhA has agreed to clarify what constitutes Tele-pharmacy.</li> </ul>	<ul style="list-style-type: none"> <li>▪ MSP (Board) acknowledges that there are communities in Manitoba that do not have reasonable access to pharmacy services and MSP (Board) recognizes that tele-pharmacy is an enabling service delivery model that could improve service levels in select communities.</li> <li>▪ MSP (Board) is concerned that this Regulation, as drafted, may detrimentally impact the profession and/or create incentive(s) for an existing, traditional pharmacy service to be supplanted by a tele-pharmacy service. In particular, the MSP (Board) is concerned that the phrase <i>reasonable access</i> is unspecific and, therefore, subject to interpretation, which could facilitate approval of tele-pharmacy licenses as a replacement for local, licensed pharmacists, with a potentially detrimental impact to the service levels within a community and/or the Profession.</li> <li>▪ MSP (Board) believes that only Regulated Technicians should be able to provide tele-pharmacy services.</li> <li>▪ The concept of <i>tele-pharmacy</i> is relatively new; therefore, there are few reference models that help predict the likely impacts and outcomes.</li> </ul>	<ul style="list-style-type: none"> <li>▪ There is an absolute need for tele-pharmacy in Manitoba.</li> <li>▪ The tele-pharmacy service delivery model is intended to enable improvements in pharmacy service levels in communities where there are presently no, or too few, licensed pharmacists in the local community.</li> <li>▪ MHHL has determined that there are communities in Manitoba that do not have reasonable access to pharmacy services; furthermore, the Government is looking to MPhA to facilitate improvements to pharmacy service levels in these communities. The Government views Tele-pharmacy as a potential means of improving access to pharmacy services in communities that do not presently have reasonable access to such services</li> </ul>

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**Proposed Action Plan:**

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

MSP to suggest definitions for “remote” and “reasonable access” that would address their concerns.

MPhA will consider these definitions for use in the regulations.

## Jurisdictional Comparison

	Ontario	Saskatchewan	Alberta	British Columbia
<b>Is Tele-pharmacy Regulated?</b>	<ul style="list-style-type: none"> <li>Enabling legislation introduced in May 2009.</li> <li>Indirectly regulated through Standards of Practice.</li> </ul>	<ul style="list-style-type: none"> <li>Indirectly through Standards of Practice.</li> </ul>	<ul style="list-style-type: none"> <li>No.</li> </ul>	<ul style="list-style-type: none"> <li>Yes</li> <li>Professional Practice Policy (No. 55) on tele-pharmacy.</li> </ul>
<b>Criteria</b>	<ul style="list-style-type: none"> <li>Must be associated with an accredited bricks and mortar pharmacy with a designated Manager.</li> </ul>	<ul style="list-style-type: none"> <li>Onus placed on the pharmacist to ensure care is delivered at the highest level, regardless if technology is being utilized in the delivery.</li> </ul>		<ul style="list-style-type: none"> <li>Registration for both remote site and central site must occur.</li> <li>The pharmacy technician at the remote site is responsible for receiving and processing.</li> <li>The pharmacist at the central site is responsible for final check of the prescription.</li> <li>Other criteria identified in background document.</li> </ul>
<b>Future Changes</b>	<ul style="list-style-type: none"> <li>Regulations yet to be created and approved.</li> <li>There is a need to define remote and under-serviced communities in regulations.</li> </ul>		<ul style="list-style-type: none"> <li>ACP is researching standards for tele-pharmacy to accommodate the requirements of “direct supervision” at a distance.</li> <li>Regulations will be revised to accommodate any changes.</li> </ul>	
<b>Key Challenges</b>	<ul style="list-style-type: none"> <li>Concept of remote pharmacies.</li> </ul>			

## Background

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Draft Pharmaceutical Regulations: Policy Document, December 3, 2007	
<b>Tele-pharmacy component</b>	<p>37(1) An applicant for a community pharmacy or hospital pharmacy license must specify that he or she is applying for a tele-pharmacy component if:</p> <ul style="list-style-type: none"> <li>(a) the pharmacy will include at least one remote facility in a remote community used for dispensing or selling drugs, or for preparing drugs for dispensing; and</li> <li>(b) the facility will not regularly be staffed by a member.</li> </ul>
<b>Requirements for Tele-pharmacy component</b>	<p>37(2) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for a tele-pharmacy component must provide evidence satisfactory to the registrar that:</p> <ul style="list-style-type: none"> <li>(a) the remote facility will be located in a Manitoba community that does not have reasonable access to pharmacy services;</li> <li>(b) the facility and equipment will be suitable for tele-pharmacy;</li> <li>(c) reasonable arrangements have been made to protect personal and personal health information;</li> <li>(d) supervision of technician(s) at the remote facility will be provided by a member, in part by a live two-way video telecommunication link;</li> <li>(e) a member must provide an on site inspection of the remote facility a minimum of every two months;</li> <li>(f) Patients and health care professionals will be able to communicate with a supervising member by way of a live two-way video telecommunication link;</li> <li>(g) the remote facility will not be open when the primary pharmacy is not; and</li> <li>(h) the remote facility and the primary pharmacy each have a policy and procedure manual available outlining:             <ul style="list-style-type: none"> <li>(i) the records which must be kept;</li> <li>(ii) compliance with relevant standards of practice and practice directions regarding the patient counseling; and</li> <li>(iii) the procedure for performing a final</li> </ul> </li> </ul>

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	check on the packaging or pre-packaging of drugs, container selection, and labeling, prior to dispensing.
<b>Requirements for Intermittent Satellite Pharmacy component</b>	<p>37(3) In addition to the requirements of s.64(2) of the Act and s.29 of these regulations, an applicant for an intermittent satellite pharmacy component must provide evidence satisfactory to the registrar that</p> <ul style="list-style-type: none"> <li>(a) the satellite facility will be located in a Manitoba community that does not have reasonable access to pharmacy services;</li> <li>(b) describes the needs of the community and the collaborative practice that will occur;</li> <li>(c) describes the location, suitability for the practice of pharmacy and hours of operations;</li> <li>(d) the satellite facility and equipment will be suitable to meet the needs of the care provided;</li> <li>(e) non-medicinal products or non-medical devices will not be sold;</li> <li>(f) the satellite pharmacy computer will be linked to the primary pharmacy computer that has access to the DPIN database;</li> <li>(g) a member will be onsite during all hours of operation;</li> <li>(h) drugs will not be left onsite when the satellite is not open;</li> <li>(i) the telephone number and address of the primary pharmacy will be identified on all printed materials and prescription labels; and</li> <li>(i) all drugs dispensed from the satellite pharmacy would indicate as such.</li> </ul>
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 will provide a clearer definition of what constitutes tele-pharmacy.</li> <li>▪ Do not want to define remote in terms of distance but relative need.</li> <li>▪ These regulations are meant to help extend service, enabling pharmacists to service communities that are otherwise under-served.</li> <li>▪ This is enabling legislation, not reducing service, through the use of technology to bring a pharmacist</li> </ul>

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	to a location that currently has no local service.
<b>MSP (Board) Position / Comments</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ Remote community has not been clearly defined.</li> <li>▪ Need to understand what impact this will have on the profession; perhaps a pilot program is required. Concerned that communities may be at risk of losing the bricks and mortar pharmacy by introduction of the tele-pharmacy.</li> <li>▪ Part of the MSP (Board)'s challenge is that this is new concept, and there aren't that many Canadian examples of tele-pharmacy.</li> <li>▪ Tele-Health is not for profit, the proposed tele-pharmacy could be for profit.</li> </ul> <p><b>Document: MSP Position Statement September 15, 2008</b></p> <p>The Manitoba Society of Pharmacists believes defining "remote" and "under-served" in the regulations is necessary to ensure the geographical limitations are fully understood, before MPhA members vote on the passage of the regulations. With the considerable change proposed there is corresponding trepidation that the new opportunities do not produce unforeseen harmful outcomes. For example it would be unfortunate if the presence of a remote facility in a community dissuaded an actual pharmacy from being constructed. Alternatively, it would be regrettable if existing pharmacies in remote communities choose to close to allow for a remote facility to be established.</p> <p>The Manitoba Society of Pharmacists is not convinced that the services provided through the tele-pharmacy component will provide clients with pharmacy services equal to the standard provided in community and hospital pharmacies. However, it is understood that for residents in these communities this may be the best available option.</p> <p>The MPhA Pharmacy Technicians Sub-Committee Report recommends that only regulated pharmacy technicians should operate a tele-pharmacy site. MSP supports the sub-committee recommendation.</p> <p>MPhA is encouraged to build on the experiences of other jurisdictions and would be well served to contact the College of Pharmacists of British Columbia to assist in determining current best practices.</p>
<b>MHHL</b>	<p><b>Meeting: Retreat April 7, 2009</b></p> <ul style="list-style-type: none"> <li>▪ Tele-pharmacy, as proposed, will enable improvements to pharmacy service levels in communities where there are presently no licensed</li> </ul>

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	<p>pharmacists in the local community.</p> <ul style="list-style-type: none"> <li>▪ There is an absolute need for tele-pharmacy in Manitoba.</li> <li>▪ MHHL will challenge MPhA if there are under-serviced areas.</li> <li>▪ Should consider how this is different than Tele-health.</li> </ul>
<b>Surveys</b>	<p><b>Document: MSP Questionnaire 6 – Tele-pharmacy</b></p> <ul style="list-style-type: none"> <li>▪ 86 percent of respondents (96) agree with 37(1) which serves as an indication of the intent of the sections of the regulations which address tele-pharmacy.</li> <li>▪ 84 percent of respondents (93) support defining “remote” and “under serviced areas” in the regulations.</li> <li>▪ At least 73 percent agree that the satellite facility should be allowed to dispense, sell drugs, and prepare drugs for dispensing.</li> <li>▪ 82 percent support the concept of a licensed pharmacist supervising staff through the utilization of a live two-way video telecommunication link.</li> <li>▪ 88 percent support the concept of communications between a (supervising) licensed pharmacist and patient being facilitated with a live two-way video telecommunication link.</li> </ul> <p><b>April 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 37: 92% (186) in favour</li> </ul> <p><b>July 2007: MPhA Discussion Document Membership Response</b></p> <ul style="list-style-type: none"> <li>• Section 37(2): 92% (89) in favour</li> </ul>
<b>MPhA Subcommittees</b>	<p><b>Document: MPhA Pharmacy Technicians Sub-Committee Report to the Manitoba Pharmaceutical Association Council September 15, 2008</b></p> <p>Recommended that only <i>regulated</i> pharmacy technicians should operate a tele-pharmacy remote site or satellite pharmacy.</p>
Tele-pharmacy in Other Jurisdictions	
<b>Ontario</b>	<p>Ontario introduced Bill 179 May 11, 2009 which expands the scopes of pharmacists, including provisions for remote dispensing, such that a site could operate without a pharmacist needing to be physically present.</p>

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	<p>Regulations will be created over the next few months, which will define remote and under-serviced.</p> <p>To be a remote dispensing site will need to be associated with an accredited pharmacy – bricks and mortar pharmacy with a designated manager, a person ultimately responsible to take ownership and be held accountable. May be restrictions placed on the drugs disbursed at these locations to be determined.</p> <p>ePrescribing is the electronic generation, authorization (signature) and transmission of prescriptions from doctors/prescribers to pharmacists/dispenser. Two locations in Ontario are piloting this project with full deployment by April 2009. The OCP is engaged to ensure practioners are able to meet their professional requirements. The findings will be shared to help determine whether any changes to professional practice regulations, standards and guidelines are needed.</p>
<b>Saskatchewan</b>	<p>No regulations, by-laws, or enabling legislation.</p> <p>Onus is placed on the pharmacist to ensure Standards of Care are met, and quality of care is delivered at the highest level, regardless if technology is being utilized in the delivery.</p>
<b>Alberta</b>	<p>Regulations and standards of practice do not accommodate for tele-pharmacy. ACP is researching standards for tele-pharmacy to accommodate the requirements of “direct supervision” at a distance. There would have to be regulation changes to accommodate any changes that may result.</p> <p>There is no provision in the Pharmacists Profession Regulation for involvement by technicians in the restricted activity of “dispensing.”</p> <p>There have been a couple pilot projects with tele-pharmacy. ACP recognizes this as an area they need to address, but have not taken any action to-date.</p>

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<b>British Columbia</b>	<p><b>Professional Practice Policy (No. 55) – Tele-pharmacy</b> (abbreviated)</p> <ul style="list-style-type: none"><li>▪ Tele-pharmacy prescription processing can only occur in a site licensed to receive tele-pharmacy service from a site licensed to provide tele-pharmacy service.</li><li>▪ An application for establishing a tele-pharmacy operation shall be made to the Registrar.</li><li>▪ The remote site is under the supervision of the pharmacist at the central site.</li><li>▪ The pharmacy technician at the remote site is responsible for receiving and processing the prescription while the pharmacist at the central site must access the appropriateness and final check of the prescription.</li><li>▪ The pharmacist must counsel the patient on all prescriptions using video and audio link. Written information may be provided to reinforce, but is not sufficient alone. All patient questions regarding drug therapy and over-the-counter products shall be answered by the pharmacist at the central site.</li><li>▪ A sign shall be posted at the dispensary counter of the remote site when services are provided using tele-pharmacy.</li><li>▪ A remote site may not remain open (no prescriptions shall be disbursed) if an interruption in data, video or audio occurs, or if the technician is not on duty at the remote site or if the pharmacist is not on duty at the central site.</li><li>▪ Prescriptions dispensed at the remote site must be distinguishable (unique label and unique identifier in the data base) from those dispensed at the central site.</li><li>▪ There must be policies and procedures in place to ensure the safe and effective distribution of pharmaceutical products and delivery of required pharmaceutical care.</li></ul>

## Appendix C: Qualification, registration, and regulation of Pharmacy Technicians

At present, the role of *Pharmacy Technician* is not a regulated profession in the Province of Manitoba; there are no authoritative criteria that must be met to be recognized as a qualified pharmacy technician, and there is no provincial program for registering pharmacy technicians. To ensure common understanding of the information presented here and in the Focus Group discussions, it is important to clearly differentiate between the following terms (used in relation to the profession of pharmacy technician): “qualified”, “registered”, and “regulated”. Whether or a not pharmacy technician is “qualified” must be determined by specific, documented criteria that are established by a recognized authority. Accordingly, MPhA has set out specific criteria for the “Qualification of Pharmacy Technicians” in the Section 52(2) of the draft Bill 41 Regulations. Registration of “Qualified Technicians” would require an authority to maintain a list of pharmacy technicians that have satisfied the qualification criteria; thereby providing stakeholders a means to confirm whether a given technician is *qualified* (against the authority’s defined criteria).

The draft Bill 41 Regulations did not explicitly require registration of qualified pharmacy technicians; however, on July 27, 2009, MPhA Council passed a motion supporting the idea that Pharmacy Technicians should be accredited subject to being graduates of an accredited pharmacy technician program as well as writing and passing the PEBC OSPE, in order to be a qualified Pharmacy Technician (i.e. both criteria must be satisfied in order to be registered as a qualified pharmacy technician).

Regulation is highly differentiated from registration; *regulation* of a profession imposes many standards and requirements beyond that of registration; for example, legislated regulatory authority over a profession generally includes, but is not limited to, investigative authority, disciplinary authority, and the authority to impose mandatory standards of practice; none of the cited examples are provided by simple *registration*.

To date, the Government of Manitoba has not made either a legislative or policy commitment to any particular regulatory framework for Pharmacy Technicians. The Government has indicated that Pharmacy Technicians could make an application to the Government of Manitoba to form their own regulatory college under the Regulated Health Professions Act, when it comes into force; however, this option does not necessarily preclude other options for regulation of Pharmacy Technicians, including the possibility that Technicians could be regulated by the Manitoba College of Pharmacy (i.e. the future MPhA). Accordingly, the draft Regulations were developed in the absence of a defined regulatory framework for Pharmacy Technicians.

The currently in-force Regulations to the Pharmaceutical Act do not make explicit reference to *Pharmacy Technicians*; however, they permit licensed pharmacists to delegate certain tasks to other persons (i.e. persons who are not licensed pharmacists) working under the direct supervision of a licensed Pharmacist. Some hospitals have implemented pilot programs that facilitate an expanded role for pharmacy technicians; one such pilot program is the *tech-check-tech* program that permits a technician to check certain work performed by another technician; however, even under these pilot programs, the final check and sign-off is still presently performed by a licensed pharmacist. Other Canadian jurisdictions have moved, or are in the process of moving towards expanded roles for pharmacy technicians, see the jurisdictional comparison and Appendix B – Blueprint for Pharmacy. Similarly, there is generally broad support for advancement of the role of pharmacy technician in Manitoba, which will involve pharmacists delegating some activities previously conducted only by licensed pharmacists.

## 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 Tele-pharmacy regulations.

Although most stakeholders agree that there is a need to improve access to pharmacy services in certain communities in Manitoba and that tele-pharmacy could address this need, Manitoba Pharmacists have raised two primary concerns regarding the implementation of Tele-pharmacy:

- i. The introduction of the tele-pharmacy regulations could result in a reduction in the number of pharmacists required in Manitoba if MPhA were to approve tele-pharmacy component license applications that would result in replacement of a locally-resident licensed pharmacist with a Tele-pharmacy (service delivery model); and
- ii. The draft Regulations restricts operation of the remote tele-pharmacy site to qualified pharmacy technicians; the Regulations also set out the criteria that must be satisfied to be recognized as a qualified technician; some stakeholders believe that pharmacy technicians that operate the remote site of a tele-pharmacy should not only be qualified, they should be regulated. For a discussion of the difference between qualification, registration, and regulation of pharmacy technicians, please see Appendix C.

It is important to note that with respect to “Satellite Pharmacy” as noted in section 37(3) of the December 2007 regulations, that there is one satellite pharmacy now open in the province of Manitoba.

**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 and to identify the preferred option to resolve the above noted 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. Are there any hospitals/communities in Manitoba that do not have reasonable access to traditional pharmacy services? Are there any hospitals/communities that have been unable to attract a full-time pharmacist because of the geographic location and/or size of the community or because there is not an attractive business case for a full-time pharmacist and traditional pharmacy in the community?
2. What non-traditional pharmacy service models, which may depend upon use of advanced technology, might address the existing requirements in these “under-served” communities?
3. What approaches, other than tele-pharmacy, might be taken to improve the access to pharmacy services in communities that don’t presently have reasonable access to pharmacy services?
4. Is the proposed tele-pharmacy service delivery model, which relies on video-link technology, a potentially effective means of providing service to the currently “under-served” communities?

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5. What are the risks, in terms of impact and likelihood, of not providing a rigorous definition for *reasonable access*?
6. Is the proposed service delivery model for *tele-pharmacy* likely to create business incentives to replace traditional pharmacies, which are staffed by a local/resident licensed pharmacist, with tele-pharmacies?
7. Is it feasible to define *reasonable access* more rigorously to mitigate perceived concerns? If yes, how could this phrase be better defined (e.g. geographic location, population, distance/access to a licensed pharmacist, pharmacy presence in community, other)?
8. What type of technician should be able to carry out activities of the technician in the provision of *tele-pharmacy* services? (see Appendix A for a discussion of the qualification for, registration of, and regulation of pharmacy technicians).
9. What should the limitations be on the use of tele-pharmacy in Manitoba?
10. What are the key barriers to implementing tele-pharmacy?

### Potential Options

#	Concerns	Option 1	Option 2
i	The introduction of the tele-pharmacy regulations could result in a reduction in the number of pharmacists required in Manitoba if MPhA were to approve tele-pharmacy component license applications that would result in replacement of a locally-resident licensed pharmacist with a Tele-pharmacy (service delivery model)	Maintain the existing wording of the draft regulations without specifically defining <i>reasonable access</i> ; <i>AND include a new Section 37(2)</i> that specifically states that a tele-pharmacy component license will not be granted to an applicant if the community is already served by a pharmacy that is staffed by a licensed Pharmacist .	Include a more specific definition of <i>reasonable access</i> .This definition might be based on: <ul style="list-style-type: none"> <li>▪ Geographic location;</li> <li>▪ Population;</li> <li>▪ Distance to a pharmacy that is staffed by a licensed pharmacist;</li> <li>▪ Presence of a licensed pharmacist in a community;</li> <li>▪ Ratio of licensed pharmacists to the gross, local population; or</li> <li>▪ Other criteria.</li> </ul>
ii	The draft Regulations restricts operation of the remote tele-pharmacy site to qualified pharmacy technicians; the Regulations also set out the criteria that must be satisfied to be recognized as a qualified technician; some stakeholders believe that pharmacy technicians that operate the remote site of a tele-pharmacy should not only be qualified, they should be regulated.	Maintain existing wording of the draft regulations, which allows for qualified technicians to work in tele-pharmacies, under the supervision of a licensed pharmacist (through a two-way video telecommunications link).	Change the draft regulation to require the <i>technicians</i> to be <i>regulated</i> pharmacy technicians, which do not presently exist in Manitoba.  This option would defer implementation of Tele-pharmacy (in Manitoba) until regulation of pharmacy technicians has been implemented (in Manitoba).

**Appendix C: Blueprint for Pharmacy**

## **Appendix D: Blueprint for Pharmacy**

There are several current applications that can be utilized to deliver a pharmacy service to a remote/distant client. These include, but are not limited to:

- a. NDSU model of a remote technician working with a Central Pharmacist;
- b. Remote dispensing cabinetry controlled by a Central Pharmacist;
- c. Remote consultation sites where prescriptions are filled at a traditional Pharmacy and picked up by the client at the remote site; Pharmacists are connected to the client via video/audio connection for counseling;
- d. NDSU Hospital Telepharmacy model using Pharmacist remote order entry and a “tech check tech” system for product verification;
- e. Central Hospital Pharmacist controlling a remote ADMU (Automated Dispensing Medication Units); and
- f. Patient kiosks to order medication or obtain information that can be located remotely or within traditional Pharmacy to control line queues.