

Bill 41 Regulations – Issue and Options Analysis

Issue #7: Central Fill Component



September 8, 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 other five issues discussed at the Retreat.

The five issues that will be discussed in a series of Focus Groups are the following:

- Tele-pharmacy;
- Pharmacy Technicians;
- Pharmacists Prescribing, which will be discussed in combination with Extended Practice Pharmacists & Specialty Care Practice; and
- Inducements.

The seven issues for which an action plan was agreed at the Retreat are as follows:

- Central Fill Component;
- Personal Health Information Number (“PHIN”);
- Practice Directions / Standards of Practice;
- Professional Liability Insurance;
- Record Keeping;
- Pharmacy Manager Qualifications; and
- Pharmacist Profiles.

With the agreement of the Steering Committee, the information presented herein will be used to develop an implementation plan that could ready the issue for a member vote.

Overview of Issue

Central Fill typically refers to the practice of packaging a prescription at one location, for distribution at another location. The central fill facility does not interact directly with the patients for whom it fills prescriptions. In other jurisdictions, there are provisions which allow for some form of Central Fill service. Requirements for pharmaceutical distribution using Central Fill often include specific and detailed labeling requirements to ensure an audit trail for the pharmaceuticals and to enhance transparency to customers,

The definition of Central Fill service and its intended purpose are the primary issues arising from the Central Fill regulation. There is confusion over whether Central Fill facilities can distribute pharmaceuticals directly to patients or whether they only package and distribute prescriptions to pharmacies for distribution to patients.

Note: the following clarification regarding the intent and implementation particulars of the Central Fill Component was provided by the MPhA Council and the Registrar during the April 7, 2009 Retreat: (i) the purpose of the Central Fill Component is to realize efficiencies in drug packaging and distribution; (ii) a Central Fill facility can either deliver prepared prescriptions to a pharmacy that interacts with patients or directly to the patient; (iii) Central Fill Pharmacies cannot contact patients directly (e.g. counseling is the responsibility of the Pharmacy that interacts with the patient, not a responsibility of the Central Fill Pharmacy); and (iv) when prescriptions will be filled by a Central Fill Pharmacy, the use of a Central Fill Pharmacy must be disclosed to the Patient.

Options Paper

The remainder of this document provides information and background related to this issue. Specifically, the following information has been provided:

- **Suggested Course of Action:** A summary of the course of action which has been agreed to by the MPhA Council and the MSP Board;
- **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 opinions following a Retreat held with the MPhA Council, the MSP Board, and a representative of MHHL in April 2009;
- **Jurisdictional Comparison:** A high-level summary of how other jurisdictions in Canada have addressed and/or are addressing the issue; 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 other Canadian jurisdictions address the issue.

Suggested Course of Action

At the April Retreat, MSP and MPhA agreed upon the Action Plan outlined immediately below.

Proposed Action Plan:

MPhA will provide members with clarification of the rationale for Central Fill provision and the guidelines that currently exist; more specifically, MPhA will make it clear that the key purpose of the provision is to provide efficiencies in drug packaging and distribution, which are transparent to the patient (in the event that the prescription is dispensed at a location other than the pharmacy where the prescription was delivered).

MSP will assist MPhA dispel and clarify misunderstandings regarding Central Fill.

Issue # 6: Tele-pharmacy

Summary of Positions

MPhA Council	MSP Board	MHHL
<ul style="list-style-type: none"> ▪ Central fill can be implemented in one of two ways: the central fill location can distribute dispensed medication to a pharmacy or directly to a patient. ▪ Regulations require that patients be apprised of the (central fill) location where their prescriptions will be filled (disclosure). ▪ Central fill pharmacy cannot contact the patient directly. 	<ul style="list-style-type: none"> ▪ Members do not have sufficient understanding of what Central Fill is or the purpose for including this provision in the Regulations. ▪ MSP requests that MPhA provide a better definition of “Central Fill”, and provide clarification as to MPhA’s rationale for including a central fill provision in the Regulations. ▪ MSP would like to see MPhA commit to conducting a post-implementation impact study on Central Fill. 	<ul style="list-style-type: none"> ▪ MPhA should provide a better contextual explanation as to why the Central Fill provision has been included in the Regulations.

Note: the Action Plan that was agreed upon by MPhA Council and MSP Board at the April 7 Retreat is documented in the *Suggested Course of Action* section on the preceding page.

Jurisdictional Comparison

	Ontario	Saskatchewan	Alberta	British Columbia
Is Central Fill Utilized?	<ul style="list-style-type: none"> Yes. 	<ul style="list-style-type: none"> Indirectly through the use of Satellite Pharmacies. 	<ul style="list-style-type: none"> Indirectly through repackaging and compounding for another pharmacy. 	<ul style="list-style-type: none"> Yes.
Governing Regulation	<ul style="list-style-type: none"> Policy for the Use of Central Fill in Ontario. 	<ul style="list-style-type: none"> Satellite Proprietary Pharmacy Permit Criteria. 	<ul style="list-style-type: none"> Compounding and Repackaging Pharmacy Agreement. 	<ul style="list-style-type: none"> Centralized Prescription Processing (i.e., Professional Practice Policy).
Requirement to Disclose use of Central Fill	<ul style="list-style-type: none"> The label or auxiliary label must identify the name of the central fill pharmacy, indicate that the prescription was filled using central fill, and include the date filled and the transaction / prescription number used for cross referencing at the central fill pharmacy. 	<ul style="list-style-type: none"> Must use pharmacy specific prescription labels (i.e. address of satellite). 	<ul style="list-style-type: none"> Standards for Pharmacist Practice require the prescription label for all drugs processed by a compounding and repackaging pharmacy must include a unique identifier that allows identification of the compounding and repackaging pharmacy. 	<ul style="list-style-type: none"> A pharmacy can outsource aspects of prescription processing. All prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug.

Background

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Draft Pharmaceutical Regulations: Policy Document, December 3, 2007	
Central-fill component	<p>36(1) An applicant for a community pharmacy or hospital pharmacy license must specify that he or she is applying for a central-fill component if:</p> <ul style="list-style-type: none"> (a) the pharmacy will provide services to other pharmacies; and (b) the nature of the services will be storing and preparing drugs for dispensing.
Requirements for central-fill component	<p>36(2) In addition to the requirements of s.64(2) of the Act, and s. 29 of these regulations, an applicant for a central-fill component must provide evidence satisfactory to the Registrar that:</p> <ul style="list-style-type: none"> (a) the facility will be suitable for a central-fill pharmacy; (b) the hours of operation will meet the needs of the pharmacies served by the central-fill pharmacy; (c) reasonable arrangements have been made to protect personal and personal health information; provided; (d) the pharmacy will not interact directly with the patient for whom the prescriptions services are provided (e) records are being kept in compliance with sections 58 and 61 of these regulations; and (f) the facility has a quality assurance program relating to work performed at the facility, and the pharmacies to which it provides services.
Requirements for pharmacies using central-fill services	<p>36(3) Except for drugs being dispensed for a hospital, a pharmacy which uses the services of another pharmacy with a central-fill component, must disclose to a patient, prior to drugs being dispensed, that:</p> <ul style="list-style-type: none"> (a) the drugs will be prepared for dispensing at another facility; and (b) the name of the central-fill pharmacy.
Relevant Regulation: Separate applications	<p>29(6) An applicant must make application for separate pharmacy licences where the facility used as a pharmacy is not in the same or adjoining building.</p>

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Positions	
MPhA Council Position / Comments¹	<p>Meeting: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ Central fill can be implemented in one of two ways: the central fill location can distribute dispensed medication to a pharmacy or directly to a patient. ▪ Regulations require that patients be apprised of the (central fill) location where their prescriptions will be filled (disclosure). ▪ Central fill pharmacy cannot contact the patient directly.
MSP Board Position / Comments¹	<p>Meeting: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ Members do not have sufficient understanding of what Central Fill is or the purpose for including this provision in the Regulations. ▪ MSP requests that MPhA provide a better definition of “Central Fill”, and provide clarification as to MPhA’s rationale for including a central fill provision in the Regulations. ▪ MSP would like to see MPhA commit to conducting a post-implementation impact study on Central Fill. <p>Document: MSP Position Statement – December 9, 2008</p> <p>The Manitoba Society of Pharmacists requires further information before finalizing a position on the Central Fill Component. To date this issue has not received sufficient attention and before any positions are adopted, the Manitoba Society of Pharmacists wants to review the impact the Central Fill Component has had on the practice of pharmacy in Canada and North America.</p> <p>Central Fill initiatives have been introduced in institutional settings with some success; however, the appropriateness of a central fill component in community pharmacy practice is not fully understood.</p> <p>The Society encourages all members to cautiously review section 36 as set out in the December 3rd, 2007 MPhA Discussion Document.</p>
MHHL¹	<p>Meeting: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ MPhA should provide a better contextual explanation as to why the Central Fill provision has been included in the Regulations.
Surveys	Document: Questionnaire 7 – Central Fill Component

¹ See the Suggested Course of Action section on Page 3 for a summary of the Action Plan that was agreed upon by MPhA Council and MSP Board at the April 7 Retreat.

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	<p>Stakeholder Survey (70 Responses): All questions received a majority of support in MPhA’s survey, although questions were posed as to the term “satisfactory to the Registrar” as it can be considered subjective.</p> <p>April 2007: MPhA Discussion Document Membership Response²</p> <ul style="list-style-type: none"> • 88% (201) approval rate for this section.
Current Central Fill Guidelines	<p>Guidelines for Manitoba Pharmacies wishing to participate in a Centralized Prescription Filling Process</p> <ol style="list-style-type: none"> 1. This Document does not apply to hospital inpatients and does not pertain to the issue of manufacturing versus compounding. 2. “Centralized prescription processing,” permitted under this guideline means the processing by a “central fill pharmacy” of a request, from another pharmacy, to prepare a drug order or to perform processing functions such as packaging medication to be dispensed pursuant to a prescription, performing drug utilization review, completing claims adjudication, obtaining refill authorizations and initiating therapeutic interventions. 3. The “patient contact pharmacy” is the pharmacy that bears the responsibility, under The Pharmaceutical Act, for receiving the order from the patient or their agent and delivering the medication to the patient and providing patient care. 4. The “central fill pharmacy” is responsible for packaging the medication and performing any other aspect of the prescription process under a contract or policy that binds it to the “patient contact pharmacy”. 5. The agreement binding the two pharmacies may take the form of a corporate policy if both pharmacies have a common ownership. The agreement must be a duly signed contract between pharmacies with different owners. 6. The agreement referred to in No. 5 must address the manner in which the process being undertaken complies with Canadian and Manitoba laws and regulations including The Personal Health Information Act and The Personal Information Protection and Electronic Documents Act. The agreement must also describe an audit trail identifying all individuals involved in the processing of each prescription. 7. Pharmacies involved in a centralized filling process must maintain a quality assurance program which objectively and systematically monitors the quality and appropriateness of patient care and continuously reviews this data to improve, maintain and support patient care. 8. Centralized prescription processing can only occur in and between Manitoba licensed pharmacies.

² It is noteworthy that the surveys conducted by MPhA asked members whether they were in favor of the *intent* of the referenced section.

	<p>9. The label of a medication filled by a centralized prescription process must provide all the prescription label information as required by Pharmaceutical Regulation 19(1) and 19(2) for the “patient contact pharmacy”. The prescription label, an auxiliary label, a pamphlet included with the prescription or a code on the prescription label must inform that the prescription was packaged at a central fill pharmacy and indicate the name of the central fill pharmacy.</p> <p>10. The “patient contact pharmacy” must inform the patient that prescriptions may be processed by a “central fill pharmacy”.</p> <p>MPhA Council January 26, 2004</p>
Sub-Committees	N/A.
The Central Fill Component in Other Jurisdictions	
Ontario	<p>The Ontario College of Pharmacists has issued a <i>Policy for the Use of Central Fill</i> in Ontario under the following principals:</p> <ol style="list-style-type: none"> 1. The patient accesses and receives prescription and other pharmacy services from the “originating pharmacy”. 2. The prescription must be received, dispensed and filled from a pharmacy accredited in Ontario. 3. Pharmacists involved in the central fill process must maintain all Standards of Practice. 4. Written consent from the patient is required for any personal health information data transfer. 5. The designated manager and owner of both the originating pharmacy and the central fill pharmacy are responsible for the security of all data transmission. 6. The prescription authority and all documentation relating to the prescription and the patient remains in the originating pharmacy. 7. The designated manager and owner of both the originating pharmacy and the central fill pharmacy must report to the Ontario College of Pharmacists in writing that they participate in a central fill arrangement. 8. The designated manager and owner of both pharmacies are responsible for accurate record keeping, labeling and all legislative requirements. <p>Ownership Requirements, Responsibility of the Originating Pharmacy, Responsibility of the Central Fill Pharmacy, Quality Control, and Policies and Procedures are also addressed in the Policy.</p>
Saskatchewan	<p>A national proposal was issued in 2002, with the Registrars generally supporting the principals and recommendations enunciated for implementation on a province-by province basis.</p> <p>Per review of the Standards, Guidelines & Policy Statements of</p>

	<p>the SCP it would appear that the Province chose not to implement the Central Fill Component. However Satellite Pharmacies are permitted in communities in rural Saskatchewan with no conventional pharmacy services, which contain an element of the Central Fill Component as the prescriptions are filled off-site.</p> <p>Refer to SCP Policy Respecting the Direct Delivery of Extended Pharmacist Services in Rural Saskatchewan under Distance Care.</p>
<p>Alberta</p>	<p>No specific mention of a Central Fill Component in Alberta. Closest match found was Compounding and Repacking.</p> <p>Compounding and Repacking Pharmacy</p> <p>A Compounding and Repackaging license is need for pharmacies that provide services for patients of other pharmacies, not their own patients. Pharmacies that prepare compounds and sell them to other pharmacies must have an agreement (Compounding and Repackaging Pharmacy Agreement) in place with each pharmacy they sell to, otherwise they may be deemed to be manufacturing under the terms of the <i>Food and Drug Regulations</i>.</p>
<p>British Columbia</p>	<p>Pharmacy Operations and Drug Scheduling Act (PODSA) Bylaws: Outsourced Prescription Processing</p> <p>12.(1) A pharmacy may outsource aspects of prescription processing provided:</p> <ul style="list-style-type: none"> (a) all locations involved are licensed pharmacies; (b) all prescriptions dispensed are labeled and include an identifiable code that provides a complete audit trail for the dispensed drug; and (c) a notice is posted informing patients that the preparation of their prescription may be outsourced to another pharmacy. <p>(2) The manager of an outsourcing pharmacy must ensure that all applicable Standards of Practice are met in processing prescriptions at all licensed locations.</p> <p>(3) For the purpose of this bylaw, “pharmacy” includes a hospital pharmacy.</p> <p><i>The Professional Practice Policy – Centralized Prescription Processing addresses the above noted requirements.</i></p>