

Bill 41 Regulations – Issue and Options Analysis

Issue # 13: Record Keeping



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

A number of mandatory requirements for Record Keeping were defined in the December 2007 Draft Regulations. The Record Keeping regulations reflect a professional requirement for Pharmacists to maintain adequate records of their work. Record Keeping requirements are currently in effect in several other Canadian jurisdictions; however, they are typically included in the respective Standards of Practice or Council By-laws.

Although the concerns that have been raised by Manitoba Pharmacists regarding Record Keeping are specific to each particular record, the overriding concerns regarding the Record Keeping requirements from the December 2007 Draft Regulations are as follows:

- 1) Some of the requirements will increase a Pharmacist's workload without yielding a commensurate patient safety/care benefit, and

- 2) The collective impact on a Pharmacist's workload that is attributable to the Record Keeping regulations may be so great that it has a detrimental impact on patient care and safety.

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 following Action Plan.

Proposed Action Plan:

MPhA will provide clarification of record keeping requirements; MPhA will create a process flow diagram (picture) that clearly identifies which events require documentation and when the documentation must be created.

MPhA Council will review MSP's recommendations in detail, differentiate between business requirements and public safety requirements, and share the results of the analysis with MSP. MPhA and MSP will then form a joint subcommittee to review the differentiated requirements.

MPhA has committed to complete the above action items within 30 days (by May 7).

PwC expects that the deliverable that is produced by the above-mentioned joint committee will be a revised draft of the Regulations pertaining to Record Keeping; accordingly, it is expected that both MPhA Council and the MSP Board would fully support the revised draft wording that is prepared by the joint committee.

PwC reviewed the Record Keeping policies that are in effect in other Canadian jurisdictions and thereby determined that it is common practice for pharmacy regulating bodies to have mandatory requirements for record keeping; however, specific Record Keeping requirements differed between jurisdictions. PwC did not compare the requirements for keeping specific records from the December 2007 Draft Regulations to requirements for specific records in other jurisdictions (i.e., the jurisdictional review was not conducted at a record-specific level of detail). Other jurisdictions have taken different approaches and used different wording for specific regulations, policies, and procedural documents relating to record keeping, which makes it difficult to evaluate whether Manitoba's Draft Regulations for record keeping are either more stringent or more extensive than in other jurisdictions. PwC did not find any examples of documented record keeping policies in other jurisdictions that were more detailed than the Draft Regulations in Manitoba; however, this does not constitute confirmation that such detail does not exist in other jurisdictions.

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Accordingly, the jurisdictional review did confirm that implementation of Record Keeping requirements is in general alignment with the policies and practices of other Canadian jurisdictions (e.g., the maintenance of records for a specific term, the documentation of a patient record, labeling of pharmaceuticals, etc.), but it did not confirm that the level of detail required for specific records aligns with common policies and practices.

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Summary of Positions

MPhA Council	MSP Board	MHHL
<ul style="list-style-type: none"> ▪ It is too drastic to remove all requirements (for record keeping) from the Regulations; pharmacists perform many functions and certain events need to be document. ▪ Overall, MPhA does not support the recommendations of the subcommittee. Council feels the request for change (proposed by MSP) is too drastic, but acknowledge concerns with pharmacists' workload. A review of the Regulation is necessary, but MPhA does not accept all of the subcommittees recommendations ▪ Most of the requirements for record keeping can be delegated to a pharmacy technician. 	<ul style="list-style-type: none"> ▪ MSP advocates that the recommendations made by the subcommittee be accepted as a template. ▪ MSP is seeking to gain a better understanding of the requirements and definition of record keeping. ▪ MPhA counselor was on the subcommittee and participated in the discussions. ▪ Proposes that the current three day limitation on "triplicate" prescriptions be extended to seven days. 	<ul style="list-style-type: none"> ▪ Lack of complete record keeping limits the ability for management of the supply chain of drugs. Manufacturers and wholesalers have to keep records of the drugs, some integrity of the supply chain has been eroded by the recommendations MSP has put forward. ▪ Need to assess the recommendations from two perspectives: business and public safety.

Jurisdictional Comparison

	Ontario	Saskatchewan	Alberta	British Columbia
Record Keeping Requirements?	<ul style="list-style-type: none"> ▪ Yes. 	<ul style="list-style-type: none"> ▪ Yes. 	<ul style="list-style-type: none"> ▪ Yes. 	<ul style="list-style-type: none"> ▪ Yes.
Documentation	<ul style="list-style-type: none"> ▪ Documentation guidelines explicitly state record keeping requirements. ▪ Documentation is recognized as a critical component of the Standards of Practice. 	<ul style="list-style-type: none"> ▪ There is an indirect reference to record keeping requirements within the SCP Bylaws. 	<ul style="list-style-type: none"> ▪ Record keeping requirements are noted throughout the Health Professions Act. ▪ The Standards for Pharmacist Practice No. 18 states the obligations of a pharmacist to create and maintain a patient record. 	<ul style="list-style-type: none"> ▪ Record keeping requirements are noted throughout the Bylaws of the College of Pharmacists of BC.

Background

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Draft Pharmaceutical Regulations: Policy Document, December 3, 2007	
Records required	57 The records set out in this part are required to be made and kept by the member as it applies to his or her practice.
Authorization Record	<p>58(1) No drug may be approved for dispensing unless a record of the following is made and retained:</p> <ul style="list-style-type: none"> (a) the date and the signature of the authorizing member under section 86(1), or 68(1.1) 86 (4) or 90 of these regulations; or (b) the date and the authorization by he practitioner or extended practice pharmacist for dispensing the medication pursuant to a prescription, indicating: <ul style="list-style-type: none"> I. where the prescription is a written prescription, by the signature of the practitioner or extended practice pharmacist; or II. where the prescription is a verbal prescription, the name of the practitioner or extended practice pharmacist issuing the verbal order and the signature or initials of the person receiving the prescription; and III. the number of refills authorized by the practitioner or extended practice pharmacist issuing the prescription.
Approval Record	<p>58(2) No drug may be prepared for dispensing unless an approval record of the following is made and retained</p> <ul style="list-style-type: none"> (a) the prescription number and the signature or initials of the member approving the prescription for filling or refilling as required under section 50(d).
Counselling Record	<p>58(2.1) Not including inpatients of a hospital, no drug may be dispensed unless a counselling record of the following is made and retained:</p> <ul style="list-style-type: none"> (a) the applicable standards of practice and practice directions related to the counselling of the patient, or their agent, have been met, indicated by: <ul style="list-style-type: none"> I. the signature or initials of the member or intern providing the counselling; and

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	<p>II. where the person counselling is a student, the signature or initials of the member supervising the student.</p> <p>(b) where the counselling has been refused by the patient or their agent, the name of the person refusing counselling and the signature or initials of the member being advised of the refusal.</p>
Additional Counselling Record	<p>58(2.2) Notwithstanding section 58(2.1), the counselling record for:</p> <ul style="list-style-type: none"> (a) an inpatient of a personal care home; (b) a resident of a group home; or (c) a person who is not capable of comprehending the information and making a decision regarding their care must be made and retained indicating the name(s) of the caregiver being provided the information.
Prescription record	<p>58(3) In addition to the authorization, preparation and counselling record, no drug may be dispensed unless a prescription record of the following is made and retained:</p> <ul style="list-style-type: none"> (a) the date the prescription and each refill of the prescription was dispensed; (b) the name of the patient for whom the drug is prescribed; (c) the address of the patient for whom the drug is prescribed; (d) the name of the drug, as prescribed; (e) the manufacturer of the drug, as dispensed; (f) strength (where applicable) and quantity of the prescribed drug; (g) the directions for use, as prescribed; (h) the price charged; (i) the name and address of the practitioner or extended practice pharmacist issuing the prescription; and (j) the signature or initials of the person preparing the drug for dispensing or of the member, intern, student or pharmacy technician doing the final check where the person who prepared the drug for dispensing was not a member or intern.
Method of keeping records	<p>58(4) The information required by subsections (1), (2),</p>

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	<p>and (3) may be recorded and retained electronically or in written form, except:</p> <ul style="list-style-type: none"> (a) where a signature is required, it must be an original signature or an electronic signature; and (b) where initials are required, it must be original initials or an electronic signature.
Hospital records	<p>58(5) Notwithstanding section 58(3), the prescription record for a drug prescribed to an in-patient in a hospital under The Health Services Insurance Act, must show:</p> <ul style="list-style-type: none"> (a) name and location of the patient; (b) the person that authorized the prescription as described under section 58(1) and by substituting section 86 (1.1) for 86 (1); (c) who prepared the medication for dispensing and performed the final check; (d) the date the drug was dispensed; and (e) The drug name, strength and identification of the manufacturer.
Food and Drugs Act applies	<p>58(6) This section is subject to the requirements of the Food and Drugs Act (Canada) and regulations regarding the retention of written records.</p>
Medication label	<p>59(1) No drug may be dispensed pursuant to a prescription unless the container in which a drug is dispensed is marked with the following information:</p> <ul style="list-style-type: none"> (a) the name of the patient for whom the drug is prescribed; (b) the prescription number; (c) the business name of the pharmacy; (d) the address and telephone number of the pharmacy, or where applicable, the tele-pharmacy remote site or satellite; (e) the name of the drug; <ul style="list-style-type: none"> I. where a single entity drug, by its generic name and manufacturer; or II. where a multiple entity drug, by its trade name. (f) strength (where applicable) and quantity of the drug; (g) the name or initials of the member approving

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	<p>the prescription for filling or refilling;</p> <p>(h) the date the drug is dispensed;</p> <p>(i) the name of the person authorizing the prescription under section 58(1);</p> <p>(j) the directions for use, as prescribed;</p> <p>(k) the price charged; and</p> <p>(l) the number of refills, part-fills or doses remaining.</p>
Method of keeping prescription label record	59(2) The record required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.
Hospital in-patient records exempt	59(3) Section 59(1) does not apply for a drug dispensed for an inpatient of a hospital or resident of a personal care home under The Health Services Insurance Act.
Hospital and personal care home medication labels	59(4) No drug may be dispensed pursuant to a prescription for an inpatient of a hospital or resident of a personal care home, under The Health Services Insurance Act unless the container in which a drug is dispensed is marked in accordance with any pertinent Standards of Practice or practice direction.
Patient profile	<p>60(1) No drug may be dispensed pursuant to a prescription, unless a patient profile of the following is made and retained:</p> <p>(a) the name of the patient;</p> <p>(b) the address of the patient;</p> <p>(c) where the patient is a Manitoba resident and a PHIN is assigned, the PHIN of the patient, as required under the appropriate practice direction;</p> <p>(d) a reference to the prescription number for each prescription filled for the patient;</p> <p>(e) any written medical history or information collected regarding the patient;</p> <p>(f) any declaration waiving of the use of a child resistant container, and the name of the person waiving its use; and</p> <p>(g) any written authorization forms, order forms, terms of purchase and sale, or other agreements between the pharmacy and the patient.</p>

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Method of keeping patient profile	60(2) The records required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.
Central-fill pharmacy records	<p>61 Where the pharmacy from which the drug is dispensed to a patient is other than the pharmacy in which the drug was prepared for dispensing:</p> <ul style="list-style-type: none"> (a) the pharmacy dispensing to the patient is responsible for retaining the prescription record, prescription label record, and patient profile required under this part; (b) the pharmacy preparing the drug for dispensing must retain the prescription record and the prescription label record required under this part; (c) the prescription label must, in addition to the requirements of s.59.(1), be marked with the name of the pharmacy in which the medication was prepared for dispensing; (d) the prescription record must, in addition to the requirements of s.58(3), contain the name of the pharmacy in which the medication was prepared for dispensing; (e) the patient profile must, in addition to the requirements of s.60(1), include written authority from the patient to share the patient's personal and personal health information with the pharmacy in which the medication is to be prepared for dispensing; and (f) the involved pharmacies must meet any other requirements of the standards of practice, or applicable practice directions.
Acquisition and sales records	62(1) In addition to section 58(3), every pharmacy manager shall keep a record of all acquisitions and sales of drugs for a period of seven years.
Return to inventory	62(2) A drug must not be accepted for return to inventory if it has been previously dispensed.
Exceptions on returns	<p>62(3) Notwithstanding subsection (3), a drug may be accepted for return to inventory if:</p> <ul style="list-style-type: none"> (a) the lot numbers and expiry dates of the drug, where applicable, are directly attached to the dispensed container; (b) the drug has not expired; (c) where each dose of the drug or the container of the drug is sealed and the seal is intact at the

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	<p>time of the return to the pharmacy;</p> <ul style="list-style-type: none"> (d) the patient has not been in possession of the dispensed drug; (e) the conditions under which the drug has been stored between the time of dispensing and the time of return are known and appropriate; and (f) it is reasonably safe to do so. <p>62(4) Where a drug is returned to inventory, the acquisition record must include;</p> <ul style="list-style-type: none"> (a) the name of the drug returned; (b) the drug identification number or name of the manufacturer of the drug returned; (c) the strength (where applicable) and quantity of the drug returned; (d) the date of the return; and (e) the prescription number of each drug returned where applicable.
Method of keeping acquisition records	62(5) The records required by this section may be recorded and retained in a readily retrievable manner electronically or on paper.
Drug destroyed	<p>63(1) Not including drugs that have been previously dispensed, or any drug provided for an in-patient of a hospital, where a drug is destroyed, the disposal record must include:</p> <ul style="list-style-type: none"> (a) the signature of the member authorizing the destruction; (b) the lot number and the name of the manufacturer's product destroyed; (c) the reason for destruction; (d) the strength (where applicable) and quantity of the drug destroyed; and (e) the date and manner of destruction or, where the destruction was performed by a person other than the pharmacy, the name, address and telephone number of the person who destroyed the drug and the date the drug was released to the person.
Method of keeping disposal records	63(2) The records required by this section may be recorded and retained in a readily retrievable manner electronically or in written form.
Manitoba Prescribing Practices	65(1) The council may create the M3P Schedule of

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Program Schedule	drugs.
M3P Prescription requirements	<p>65(1.1) A prescription for a drug listed on the M3P schedule must:</p> <ul style="list-style-type: none"> (a) be dated and signed by the authorized practitioner on a form specified in the by-laws; (b) contain only one drug product prescribed on the form; and (a) contain all of the other information required under s.58(3).
Limits on dispensing	<p>65(2) A drug listed in the M3P schedule must not be dispensed unless:</p> <ul style="list-style-type: none"> (a) the person dispensing the drug has taken reasonable steps to satisfy himself or herself that there are no questions or issues as described in s.68(4) of these regulations; (b) the prescription meets all the requirements of subsection (1); (c) the prescription is entered into DPIN in accordance with any applicable practice directions; and (d) the prescription is dated by the authorized practitioner within three days of the date it is presented at the pharmacy for filling. <p>65(3) Subject to subsection (4), before dispensing a drug on the M3P schedule, prescription and patient information must be entered into DPIN in accordance with any applicable practice directions.</p> <p>65(4) If the requirements of subsection (2) are not met, the person requested to dispense must:</p> <ul style="list-style-type: none"> (a) refuse to fill the prescription and advise the patient or his or her designate and the authorized practitioner or other person who issued the prescription, of the refusal; (b) record the refusal to fill the prescription <ul style="list-style-type: none"> I. on the prescription form, and II. in DPIN, in accordance with any applicable practice directions; (c) retain the prescription form, unless the patient or that patient's designate requests the prescription be returned, in which case a copy of the prescription form must be retained. <p>65(5) This section does not apply to a prescription for a drug that is listed on the M3P schedule, if it is to be</p>

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	<p>administered to:</p> <ul style="list-style-type: none"> (a) a patient in a hospital; or (b) a resident in a personal care home; <p>if the facility is designated under The Health Services Insurance Act.</p>
Patient access to records	<p>66 Upon request by a patient, a member must provide a copy of the information on:</p> <ul style="list-style-type: none"> (a) the prescription record; (b) the prescription label record; (c) the patient profile; and (d) any other record maintained by the pharmacy, as it relates to the patient making the request and is consistent with the requirements under the Personal Health Information Act.
Retention of records	<p>67(1) Subject to sections 58(5) and 59(3), a member or owner must retain the following records for a period of not less than seven years after the circumstances giving rise to the creation of the record:,,</p> <ul style="list-style-type: none"> (a) authorization record; (b) approval record; (c) counselling record; (d) prescription record; (e) prescription label; (f) patient profile; (g) acquisition and sales record; (h) destruction of drugs; (i) prescriptions which were refused to be filled, under s.68(4); (j) prescribing record; (k) drug administration record; (l) test interpretation record; and (m) test ordering and results record.
Access to retained records	<p>67(2) A member or owner must make all records it is required to retain available within a reasonable time, during an investigation under Part 6 or an inspection under Part 10 of the Acts.</p>
Location of records	<p>67(3) The records required to be retained by a pharmacy need not be stored in the pharmacy, as long as the location of the records is reported under section</p>

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	29, the records are secure, and access is available pursuant to subsection (2).
Positions	
MPhA Council Position / Comments	<p>Meetings: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ It is too drastic to remove all requirements (for record keeping) from the Regulations; pharmacists perform many functions and certain events need to be document. ▪ Overall, MPhA does not support the recommendations of the subcommittee. Council feels the request for change (proposed by MSP) is too drastic, but acknowledge concerns with pharmacists' workload. A review of the Regulation is necessary, but MPhA does not accept all of the subcommittees recommendations ▪ Most of the requirements for record keeping can be delegated to a pharmacy technician.
MSP Board Position / Comments	<p>Meetings: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ MSP advocates that the recommendations made by the subcommittee be accepted as a template. ▪ MSP is seeking to gain a better understanding of the requirements and definition of record keeping. ▪ MPhA counselor was on the subcommittee and participated in the discussions. ▪ Proposes that the current three day limitation on "triplicate" prescriptions be extended to seven days. <p>Document: MSP Position Statement (February 27, 2009)</p> <p>The Manitoba Society of Pharmacists supports the recommendations of the MPhA Record Keeping Sub-Committee, and compliments the Committee in achieving unanimous support for all votes. The concerns identified through the Society's questionnaire are consistent with many of the Sub-Committee's recommendations.</p> <p>The Bill 41 regulation consultation process throughout 2009 will provide opportunities for extensive consultation on regulations which apply to record keeping. Significant progress is foreseeable should the relevant stakeholders be brought together for meaningful discussion and debate.</p>
MHHL	<p>Meetings: Retreat April 7, 2009</p> <ul style="list-style-type: none"> ▪ Lack of complete record keeping limits the ability for management of the supply chain of drugs.

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	<p>Manufacturers and wholesalers have to keep records of the drugs, some integrity of the supply chain has been eroded by the recommendations MSP has put forward.</p> <ul style="list-style-type: none"> ▪ Need to assess the recommendations from two perspectives: business and public safety.
Surveys	<p>Document: Questionnaire 5 – Prescriptions and Records</p> <p>The results of the questionnaire suggest that pharmacists supported the majority of the proposed regulations which address record keeping. Certain sections received the support of more than 80% of respondents, while other sections were not supported by the majority, some of these areas include:</p> <ul style="list-style-type: none"> ▪ 47 percent of respondents support the requirements in section 58(2.1) Counselling Record; ▪ 56 percent of respondents support the requirements in section 60(1) Patient Profile; ▪ 35 percent of respondents support the requirements in section 62(4) Exceptions on Returns; and ▪ 50 percent of respondents agree with the requirements in section 63(1) Drug Disposal. <p><i>Document: April 2007 MPhA Discussion Document Survey reported the following percentages of support by the members:¹</i></p> <p>Section 57 97% (189) Section 58 73% (143) Section 59 94% (187) Section 60 89% (179) Section 61 94% (180) Section 62 65% (128) Section 63 78% (154) Section 65 95% (188) Section 66 96% (189) Section 67 93% (186)</p>

¹ It is noteworthy that the surveys conducted by MPhA asked members whether they were in favor of the *intent* of the referenced section.

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	<p>Document: July 2007 MPhA Discussion Document Survey reported the following percentages of support by the members:²</p> <p>Section 58(1) 71% (70) Section 58(2) 85% (84) Section 58(2.1) 60% (61) Section 58(2.2) 60% (58) Section 58(3) 90% (87) Section 59(1) 95% (93) Section 62(1) 93% (93) Section 63.3 64% (64) Section 65 (1) 100% (98) Section 65(2) 96% (92) Section 66 79% (78) Section 67 67% (67)</p>
MPhA Subcommittees – Record Keeping	<p>Document: Bill 41 Records Subcommittee Report</p> <p>The MPhA Subcommittee on Recording Keeping conducted a detailed review on all relevant sections of the draft regulations. The approach adopted by the Committee in analyzing the record keeping sections was to identify additional documentation requirements and then determine if enhanced patient care would be achieved. Where it was determined health benefits would not result, the Committee either recommended amendments or removal of the applicable sections of the draft regulations. In total the MPhA Subcommittee recommended the following changes:</p> <p>58.2.1: Remove 58.2.1 and 58.2.2; 58(3): Strikeout “preparation and counselling record” add “approval record”; 60(1) Patient Profile;</p> <ul style="list-style-type: none"> ▪ (c) would add only under extreme circumstances can a prescription be filled without a PHIN; and ▪ (g) Remove as this is a business issue, not a patient care issue. <p>62(1): Remove all; 62(4): Remove all; 62(5): Remove all;</p>

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

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	<p>63(1): Remove as requirement is too time consuming. Narcotics and Controlled Drugs would be covered under CDSA;</p> <p>63(2): Remove all;</p> <p>65(2): Change (d) from “within 3 days” to “within 7 days”;</p> <p>67(1): Make the following changes:</p> <ul style="list-style-type: none"> ▪ Remove (c), (g), and (h); ▪ Remove (k), (l), (m) with approval of other committees; ▪ Accept (j) with the exclusion of schedule 2, 3 drugs; and ▪ Change 7 years to three years.
Record Keeping in Other Jurisdictions	
Ontario	<p>Documentation Guidelines for Pharmacists are set forth by the OCP.</p> <p>Documentation is recognized as a critical component of the Standards of Practice.</p> <p>Guidelines:</p> <ul style="list-style-type: none"> ▪ Documentation must be accurate and true. It should be clear, concise, and patient focused, including a number of key elements listed in the guideline. ▪ Documentation should not contain unfounded opinions or conclusions. Whenever drawing conclusions or making recommendations, supporting data should be recorded. ▪ Documentation should be completed promptly after providing care. It should be well organized and chronologically recorded. ▪ All documentation must be legible and non-erasable. Written entries should be made in ink, not in pencil. Electronic entries should be non-alterable. <ul style="list-style-type: none"> – Changes to any recorded information should include the source of the information to allow a complete audit trail; – In a manual record, cross out errors with a single line and initial; and – Notes should not be deleted or removed from any files or records. ▪ Documentation must be kept confidential and be

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	<p>readily retrievable.</p> <ul style="list-style-type: none"> - Protect information from unauthorized access; - Establish a policy on information access in compliance with the Code of Ethics and privacy legislation; and - Ensure the security and confidentiality of information that is transferred or released.
Saskatchewan	<p>Saskatchewan College of Pharmacists By-laws include indirect references to record keeping requirements. For example:</p> <p>14.5.5 Patient profiles (either manual or electronic) must be maintained;</p> <p>14.13.2 When the prescription for a Schedule I drug is written, the pharmacist selling the drug shall retain the prescription for at least two years from the date of filling. Where the prescription for a Schedule I drug is verbal, the pharmacist to whom the prescription is communicated by the practitioner shall forthwith reduce the prescription to writing and the pharmacist selling the drug shall retain that written record of the prescription for a period of at least two years from the date of filling.</p> <p>14.13.9 The pharmacist filling or refilling a prescription for a Schedule I drug shall enter on the original of the prescription or in a suitable record of prescriptions kept under the name of each patient:</p> <ul style="list-style-type: none"> (a) the date of filling; (b) the date of each refill, if applicable; and (c) the quantity of drug dispensed at the original filling and each refill; and name. <p>14.13.10.3 When a pharmacist:</p> <ul style="list-style-type: none"> (a) sells a Schedule I drug pursuant to section 14.13.10.2, he shall make a written record containing the following information: <ul style="list-style-type: none"> (i) the date and file reference number for the sale; (ii) the name and address of the person for whose benefit the drug is given; (iii) the proper name, common name or brand name of the specified drug and the quantity thereof; (iv) his name; (v) the direction for use;

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	<p>(vi) the name of the medical practitioner if designated by the patient; and</p> <p>(vii) the reasons and circumstances under which the sale is made.</p>
Alberta	<p>Indirect references to record keeping requirements are found throughout the Health Professions Act Standards for Pharmacist Practice.</p> <p>Standard 18 specifically states the obligations of a pharmacist to create and maintain a patient record:</p> <p><u>Transaction Record</u></p> <p>18.1 A pharmacist must ensure that a written transaction record is created each time a Schedule 1 drug is dispensed that includes:</p> <ul style="list-style-type: none"> (a) the name of the patient for whom the drug was dispensed; (b) the name of the prescriber of the drug; (c) the date the drug was dispensed; (d) the name, strength, and dosage form of the drug dispensed; (e) the DIN of the drug dispensed; (f) the quantity of drug dispensed; (g) route of administration and directions for use; and (h) a unique prescription and transaction number. <p><u>Duty to enter information in a patient's record</u></p> <p>18.2 A pharmacist who:</p> <ul style="list-style-type: none"> (a) dispenses a Schedule 1 drug or blood product; (b) sells a Schedule 2 drug; (c) prescribes a Schedule 1 drug or blood product; (d) administers an injection; or (e) establishes a follow-up plan or other patient care plan must ensure that an appropriate entry is made in the patient's record. <p><u>Requirements of a patient record</u></p> <p>18.3 A patient record must include:</p> <ul style="list-style-type: none"> (a) patient demographics; (b) a profile of drugs provided; and (c) a record of care provided. <p>18.4 In addition to the requirements set out in this</p>

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	<p>standard a patient record must meet the requirements of appendix A.</p> <p><u>Patient record to be current</u></p> <p>18.5 A pharmacist must keep the patient record accurate and current.</p> <p><u>Form of patient record</u></p> <p>18.6 The patient record must be kept:</p> <ul style="list-style-type: none"> (a) in a clear, concise and easy-to-read format; and (c) in a manner that facilitates sharing, ease of use and retrieval of patient information by authorized individuals. <p>18.7 Despite the requirements outlined in Standard 18, a pharmacist who works in an institution pharmacy, as defined in the Pharmacy and Drug Act, may:</p> <ul style="list-style-type: none"> (a) document the pharmacist’s activities in the institution’s medical record for the patient; and (b) rely upon documentation within the drug distribution system and the institution’s medical record if the pharmacist is satisfied that the information required in standards 18.1, 18.3 and 18.4 is available to the pharmacist.
British Columbia	<p>Indirect references to record keeping requirements are found throughout the Bylaws of the Council of the College of Pharmacists of British Columbia.</p> <p>Direct References</p> <ul style="list-style-type: none"> ▪ Bylaw 5 Community Pharmacy - Section 35 Records, Section 43 Patient Records; ▪ Bylaw 7 Residential Care Facilities and Homes – Section 61 Patient Records, Section 62 Resident Medication Administration Record; and ▪ Bylaw 8 Hospital Pharmacy – Section 84 Patient Record and medication order review. <p><u>Section 35 Records</u></p> <ol style="list-style-type: none"> 1. All patient records must be stored on the premises in a secure manner to protect patient confidentiality. 2. All information contained on prescriptions shall be considered privileged and confidential and shall not be released to any person without the express consent of the practitioner or patient, and prescriptions shall not be subject to perusal by any person other than those exempted in section 39

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	<p>(6).</p> <ol style="list-style-type: none">3. Without restricting the generality of subsection 35(2), no registrant may, for commercial purposes, release or permit the release of information or an abstract of information obtained from a prescription, which would permit the identity of the practitioner or the patient to be determined.4. Subsection 35 (3) does not apply to the release of information when it is done for non-commercial purposes in accordance:<ol style="list-style-type: none">(a) with the requirements of the Act and these bylaws; or(b) with the express written consent of the practitioner, the patient and the pharmacy manager.5. All prescriptions and patient records must be retained for a period of not less than three years.6. Notwithstanding subsection 35 (5), a registrant must not destroy prescription or patient records until any audit or investigation is completed.7. A registrant must dispose of community pharmacy records in a manner that preserves patient confidentiality<ol style="list-style-type: none">(a) paper records must be shredded or incinerated; and(b) computerized records must be rendered unreadable through the use of an appropriate mechanical, physical or electronic process and converted into such a form that they can not be reconstructed in whole or in part.8. A registrant must ensure that individual records are not lost or removed during the destruction process and that the resulting waste does not include fragments of readable personal information. <p><u>Section 43 Patient Record</u></p> <ol style="list-style-type: none">1. A patient record must be prepared and maintained for each patient for whom a Schedule I drug is dispensed.2. The patient record must include the following information.3. When a registrant obtains a drug history from a patient, he or she must request the following information:<ol style="list-style-type: none">(a) medical conditions and physical limitations;

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	<ul style="list-style-type: none">(b) adverse drug reactions, including allergies;(c) past and present prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy;(d) compliance with prescribed drug regimen; and(e) Schedule II and III drug use. <p>4. A pharmacist must review the patient record before the release of a drug in order to identify and take appropriate action, where applicable, for:</p> <ul style="list-style-type: none">(a) appropriateness of therapy;(b) drug interactions;(c) allergies;(d) therapeutic duplication;(e) contraindicated drugs;(f) degree of compliance;(g) correct dosage, route, frequency and duration of administration and dosage form; and(h) any other deviation from contemporary pharmaceutical care which may adversely affect the patient.