

Bill 41
Records Subcommittee
Report

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Introduction

Committee mandate - review Part 8 Prescriptions and Records of the regulation document dated Dec 3, 2007 and recommend changes which consider patient safety, legal issues, and the future of the profession of pharmacy.

Initially the scope of the committee included only Part 8 Prescriptions and Records but this was subsequently expanded to include any part of the regulation document with reference to record keeping. As such the records component of Parts 12, 13, 14, and 15 are also considered. The committee consisted primarily of retail pharmacists with representation from both local and international serving pharmacies. There was no representation from hospital pharmacy.

There was general agreement between committee members to maintain a reasonable level of record keeping balancing safety and patient care. There was unanimous agreement that an excessive record keeping requirement may impact patient safety due to reduced pharmacist resources in the area of pharmaceutical care.

The results of the committee review are presented as text from the December 3, 2007 document followed immediately by recommendations and comments.

The committee referred to numerous documents during the process all of which are included in this report.

Final approval of the report was made via email.

Committee Recommendations and Comments

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PART 8 – PRESCRIPTIONS & RECORDS

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.

No changes

Authorization Record

58(1) No drug may be approved for dispensing unless a record of the following is made and retained:

(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 the practitioner or extended practice pharmacist for dispensing the medication pursuant to a prescription, indicating:

(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.

No changes

58(2) No drug may be prepared for dispensing unless an approval record of the following is made and retained:

(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)

There was concern about the wording “no drug can be prepared for dispensing” It was felt in the retail practice model the pharmacist doesn’t always start the dispensing process and in a single pharmacist setting (s)he can’t be counseling patients while the technician waits for the approval to fill a prescription. As a pharmacist must at some point before releasing the prescription to the patient approve the prescription process it is recommended to change “no drug can be prepared for dispensing” to “no drug maybe dispensed”

Counselling Record

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:

(a) Removed –confirmation of the drug being dispensed and that the applicable standards of practice and practice directions related to the counselling of the patient, or their agent, have been met, indicated by:

(i) the signature or initials of the member or intern providing the counselling; and

(ii) where the person counselling is a student, the signature or initials of the member supervising the student.

(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.

Additional Counselling Record

58(2.2) Notwithstanding section 58(2.1), the counselling record for:

(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.

Remove 58(2.1 & 2.2) - This could become a paper nightmare trying to keep all these records. Not all prescriptions are picked up on the same day and excessive paper trail may result. It was felt by all committee members that patient counseling is valued, spending time with the patient or agent counseling is more important then documenting that which is mandatory by the Pharmacy Act. Patient care would not be enhanced and may even suffer.

Prescription record

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:

(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.**

Strike out "preparation and counseling record" add "approval record"

Method of keeping records

58(4) The information required by subsections (1), (2), and (3) may be recorded and retained electronically or in written form, except:

- (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.**

No changes

Hospital records

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:

- (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.**

No changes

Food and Drugs Act applies

58(6) This section is subject to the requirements of the Food and Drugs Act (Canada) and regulations regarding the retention of written records.

No changes

Medication label

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:

- (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:
 - (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 the prescription for filling or refilling**

- (h) the date the drug is dispensed;***
- (i) the name of the person authorizing the prescription under section 58(1);***
- (j) the directions for use, as prescribed;***
- (k) the price charged; and***
- (l) the number of refills, part-fills or doses remaining.***

No changes - Compounds need to be defined how to be labeled and that brand name referencing may be included on label. Example "furosemide" and "generic for Lasix" would be considered appropriate.

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.

No changes

59(3) Hospital in-patient records exempt

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.

No changes

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.

Committee Recommendation - No changes

Patient profile

60(1) No drug may be dispensed pursuant to a prescription, unless a patient profile of the following is made and retained:

- (a) the name of the patient;***
- (b) the address of the patient;***
- (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;***
- (d) a reference to the prescription number for each prescription filled for the patient;***
- (e) any written medical history or information collected regarding the patient;***
- (f) any declaration waiving of the use of a child resistant container, and the name of the person waiving its use; and***
- (g) any written authorization forms, order forms, terms of purchase and sale, or other agreements between the pharmacy and the patient.***

Under (c) would add only under extreme circumstances can a prescription be filled without a PHIN.

Remove (g) it was felt that these agreements are a business issue not a patient care issue and therefore it should be removed. Patient care issues would be covered under (e)

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.

No changes

Central-fill pharmacy records

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:

(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.

No changes

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.

Remove all - discussions took place on what records of acquisitions and drug sales really involves. If this means records of invoices and hard/electronic copies of prescriptions for a period of seven years this is already covered under the Income Tax Act and also under 67(1). If it means creation of a perpetual log for every drug in the pharmacy as for narcotics presently, committee members felt this would be excessive administration. The results would not lead to better patient care or safety.

Return to inventory

62(2) A drug must not be accepted for return to inventory if it has been previously dispensed.

No changes

Exceptions on returns

62(3) Notwithstanding subsection (3), a drug may be accepted for return to inventory if:

(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 time of the return to the pharmacy;

(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.

No changes

62(4) Where a drug is returned to inventory, the acquisition record must include;

- (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.**

Remove since deleted acquisition record in 62(1)

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.

Remove since deleted acquisition record in 62(1)

Drug destroyed

63(1) Not including drugs that have been previously dispensed New – or any drug provided for an in-patient of a hospital, where a drug is destroyed, the disposal record must include:

- (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.**

Remove section - it was felt this requirement would be too time consuming for pharmacists and would not enhance patient safety. Committee members felt Narcotics and Controlled drugs would be covered under CDSA. Destruction records would have to be kept for these drugs.

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.

Remove since deleted acquisition record in 63(1)

Manitoba Prescribing Practices Program Schedule

65(1) The council may create the M3P Schedule of drugs.

No changes

M3P Prescription requirements

65(1.1) A prescription for a drug listed on the M3P schedule must:

- (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**

(c) contain all of the other information required under s.58(3).

No changes

Limits on dispensing

65(2) A drug listed in the M3P schedule must not be dispensed unless:

(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.

Change (d) from “within 3 days” to “within 7 days” to reduce voided prescriptions. This would also benefit people traveling long distances for care, giving them the option of having the prescriptions filled in their regular pharmacy.

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.

65(4) If the requirements of subsection (2) are not met, the person requested to dispense must:

(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

(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.

No changes on 65(3 & 4) – There is a concern that some dispensing software may not easily accommodate “refused to fill” prescriptions.

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 administered to:

(a) a patient in a hospital; or

(b) a resident in a personal care home;

if the facility is designated under The Health Services Insurance Act.

No changes

Patient access to records

66 Upon request by a patient, a member must provide a copy of the information on:

(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.

No changes

Retention of records

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:

- (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.**

Remove sections (c) ,(g) and (h) and, subject to other committees review (k),(l) and (m), accept (j) with the exclusion of schedule 2,3 drugs and accept (a),(b),(d),(e),(f),(l) and change “seven years” to “3 years”

Access to retained records

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 Act.

No changes

Location of records

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 29, the records are secure, and access is available pursuant to subsection (2).

No changes

PART 12 – PRESCRIBING BY MEMBERS

Prescribing record

89(1) A member who issues a prescription must make and retain a record of:

- (a) the name and address of the patient;**
- (b) date of birth of the patient**
- (c) where the patient is a Manitoba resident and a PHIN is assigned, the PHIN of the patient;**
- (d) the name of the drug prescribed;**
- (e) the strength (where applicable) and quantity of the prescribed drug;**
- (f) the directions for use;**
- (g) the number of refills available to the patient;**
- (h) the name of the member issuing the prescription;**
- (i) the date of the prescription; and**
- (j) the treatment goal, diagnosis or clinical indication when issuing the**

prescription.

Method of keeping prescribing records

89(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

Continued care prescriptions

Prescribing record not required

90(4) A member prescribing under section 90 is not required to keep the prescribing record described in section 89(1).

No changes - There is concern about the possibility that this may include everyday "recommendations" by pharmacists. This should be specifically excluded as excessive documentation may actually do more harm than good.

PART 13 – ADMINISTRATION OF DRUGS

Administration of drugs by members

Drug administration record

92(1) A member who administers a drug to a patient must make and retain a record in the pharmacy of:

- (a) the name of the patient;***
- (b) the address of the patient;***
- (c) the name of the drug and total dose administered;***
- (d) the identification of the manufacturer, lot number and expiry date of the drug;***
- (e) the route of administration;***
- (f) the name of the member administering the drug;***
- (g) the date and the time of the administration;***
- (h) any adverse events, and***
- (i) the price, where there is a charge for administration.***

Method of keeping drug administration records

92(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

The committee did not have a definition of administration. Overall it was felt the section was good but members were concerned about having to document common services such as opening a pill bottle for somebody at the pharmacy so they can take a dose or other services that could be performed by a lay person.

PART 14 – TEST INTERPRETATION

Test interpretation record

94(1) A member who interprets and makes a recommendation to a patient regarding a patient administered test must make and retain a record in the pharmacy of:

- (a) the name of the patient;***
- (b) the address of the patient;***
- (c) the nature of the test interpreted;***
- (d) the results of the test;***
- (e) the nature of the advice given to the patient;***
- (f) the name of the member interpreting the test; and***
- (g) the date of the test.***

Method of keeping test interpretation records

94(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

Recommend deleting 94(1 & 2) - documentation requirements could prove excessive if we have to document every time somebody self-administers a BP test or BG test and asks our opinion.

PART 15 – ORDERING AND RECEIPT OF TEST REPORTS

Ordering tests by members

Test ordering and results record

96(1) A member who orders and receives the results of a screening or diagnostic test must make and retain a record in the pharmacy of:

(a) the name of the patient;

(b) the address of the patient;

(c) the nature of the test ordered or recommended;

(d) the health professional to whom the results were forwarded or the recommendation was made;

(e) the name of the member requesting the test;

(f) the date the test was ordered or recommended;

(g) the date the results were received;

(h) the date the results were communicated by the member to the health professionals responsible for the patient's care.

Method of keeping Test ordering and results records

96(2) The information required by subsection (1) may be recorded and retained in a readily retrievable manner electronically or in written form.

No changes