College of Pharmacists of Manitoba

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Practice Direction
Standard of Practice # 12 – Records and Information

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning documentation and records through the authority of *The Pharmaceutical Regulations* to *The Pharmaceutical Act* and *The Pharmaceutical Act.*

1.2 Document Jurisdiction (Area of Practice)

Compliance is expected from all licensed pharmacists in Manitoba practice.

1.3 Regulatory Authority Reference

Section 56 of *The Pharmaceutical Regulations* to the *Pharmaceutical Act* empowers the Council to create a practice direction for documentation and information.

2.0 Practice Direction

2.1 **Documentation:**

2.1.1 A licensed pharmacist shall document and keep all required records according to the legislation and any other applicable practice directions.

2.1.2 All documentation shall be in a clear, concise and easy to read format that facilitates sharing, ease of use and retrieval of information.

2.1.3 All records maintained by the pharmacy shall be current and accurate with respect to the pharmacist's or pharmacy's activities.

2.1.4 In hospital practice, documentation unique to the pharmacy standards shall be maintained; however, information already appearing in the patient's chart need not be duplicated.

Prescription Information:

2.1.5 All original, new prescriptions, or new transaction hardcopies must contain the following information:

2.1.5.1 Documentation as a verbal order, copy or transfer, continued care, partial fill or similar designation referring to how the authority to supply the prescription was obtained, if not written or faxed. If more than one

pharmacist is involved in obtaining the authorization and filling the prescription, the documentation must clearly demonstrate the responsibility of the pharmacist involved;

2.1.5.2 Documentation as a "deferred" "unfilled", "logged", or similar designation when the prescription information is pre-entered into the pharmacy computer software and the prescription is not filled;

2.1.5.3 Documentation as "Prescriptions not filled", (NF), ward stock, or similar designation when a prescription product based on a prescription and not filled as a prescription, is provided from the front store stock (OTC), or from ward stock;

2.1.5.4 Documented reference to the original prescription number on a new hardcopy when an old prescription number is updated;

2.2 **Amending a Record:**

When a record under section 79 of the Regulations is amended to correct an error after the fact the following must be identifiable:

2.2.1 the original entry,

2.2.2 the identity of the pharmacist or other staff member who amended the record,

2.2.3 the date on which the record was amended.

2.3 **Electronic Records:**

2.3.1 A pharmacy license holder must ensure that the pharmacy's computer equipment, system and software has the ability to:

2.3.1.1 Store and report the information required in a patient record and prescription transaction;

2.3.1.2 Identify each user who is granted access, control the access granted to the users and create an accurate audit trail of access;

2.3.1.3 Generate reports of prescription information chronologically and by drug name and strength, patient name and prescriber name;

2.3.1.4 Store and report the information required for the time required by the appropriate legislation and standards.

2.3.2 A pharmacy license holder must ensure that the pharmacy's computer equipment, system and software :

2.3.2.1 Facilitates the sharing, ease of use and retrieval of necessary data to facilitate continuity of patient care;

2.3.2.2 Have sufficient security to ensure that only authorized users have access to the system;

2.3.2.3 Requires a deliberate and auditable procedure to be carried out by the pharmacy license holder or their delegate prior to purging any information from the system;

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2.3.2.4 Has adequate backup and recovery systems.

2.3.3 A pharmacy license holder must ensure that the back up of electronic records:
- 2.3.3.1 occurs once daily;
- 2.3.3.2 is tested for recovery on a regular basis;
- 2.3.3.3 is retrievable in the event the system malfunctions or is destroyed.

2.4 **Security of Records:**

2.4.1 Pharmacy records, including back-ups, stored either on- or off-site must have adequate security to protect the records from unauthorized access, theft, use, or loss.
- 2.4.1.1 Security measures include appropriate physical, administrative and technical safeguards.

2.5 **Access to Records:**

2.5.1 If a patient or their agent requests access to their records, the pharmacy license holder must provide a response as soon as reasonably practical, but no longer than 30 days from the date the record was requested.
- 2.5.1.1 In responding the pharmacy must either:
  - 2.5.1.1.1 Make the record (or a copy) available to the individual
  - 2.5.1.1.2 Indicate that no record exists (if a record is found later, then the individual must be notified)
  - 2.5.1.1.3 Indicate that access is denied pursuant to a specific section of the *Personal Health Information Act (PHIA).*

2.6 Destruction of Records:

2.6.1 A licensed pharmacist must ensure the appropriate destruction of records in one or more of the following manners:
- 2.6.1.1 Physical destruction using a shredder or complete incineration;
- 2.6.1.2 Erasure or destruction of electronic records in such a manner that the information cannot be reconstructed.

2.7 Remedying a Security Breach:

2.7.1 A pharmacy license holder must take appropriate measures to remedy a security breach as soon as reasonably possible after discovery of unauthorized access, use, disclosure, or disposal of personal patient information. These measures include:
- 2.7.1.1 Recovering personal information or ensuring disposal of such information if it cannot be recovered;
- 2.7.1.2 Ensuring the security of remaining personal information;

2.7.1.3 Notification of affected persons, the College, and legal authorities (if breach is a result of a criminal activity);
2.7.1.4 Modifying security measures to prevent a re-occurrence.

2.8 **Transfer of Patient Records**:

2.8.1 The pharmacy manager is responsible for patient records until such time as the records are transferred to another trustee.
2.8.2 The pharmacy must make reasonable efforts to notify the patients whose records are being transferred and must make those records available to the patients during the transfer.
2.8.2.1 Where it is not reasonable to notify patients individually, pharmacies shall use a minimum of 2 methods of providing notice including but not limited to: notice on pharmacy website, posting of notice in/on pharmacy, message on pharmacy answering machine.
2.8.3 In the event of a permanent store closure, where no other party takes ownership, patients must still have access to their records for the time specified in any applicable regulations and:
2.8.3.1 The pharmacy is responsible for ensuring the secure storage or transfer of patient records.
2.8.3.2 The College of Pharmacists of Manitoba must be notified in writing of the disposition of such records.

2.9 **Delegation to external document storage or destruction companies**:

2.9.1 The pharmacy license holder must ensure the company is bonded and the service arrangement is compliant with PHIA.
2.9.2 The pharmacy retains responsibility for the safety and security of patient records even if the storage or destruction is contracted out to a third party.

3.0 Compliance Adjudication

3.1 All records must be readily accessible and open to regulatory review.

4.0 Appendices

4.1 Not applicable

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