



College of Pharmacists of Manitoba

200 Taché Avenue, Winnipeg, Manitoba R2H 1A7
Phone (204) 233-1411 | Fax: (204) 237-3468
E-mail: info@cphm.ca | Website: www.cphm.ca

Practice Direction – Standards of Practice #9: Medication Incidents and Discrepancies or Near-Miss Events

1.0 Scope and Objective:

1.1 Expected Outcome

This document is a practice direction by Council concerning medication incidents and discrepancies or near-miss events 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

Sections 56(1) and 56(2) of *The Pharmaceutical Regulations to the Pharmaceutical Act* empowers the Council to create a practice direction for medication incidents and discrepancies or near-miss events.

2.0 Definitions:

2.1 Medication incident – a preventable occurrence or circumstance that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

2.2 Discrepancy or Near-Miss Event – an event or circumstance that took place, and could have resulted in an unintended or undesired outcome(s), but was discovered before reaching the patient.

3.0 Practice Direction

3.1 Policies and Procedures for medication incidents

The Pharmacy Manager will ensure that:

- 3.1.1** The pharmacy has written policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents. In the case of a pharmacy owned by a Regional Health Authority, the

*College of Pharmacists of Manitoba Mission:
To protect the health and well-being of the public by ensuring and
promoting safe, patient-centred and progressive pharmacy practice.*

Member of the National Association of Pharmacy Regulatory Authorities



College of Pharmacists of Manitoba

200 Taché Avenue, Winnipeg, Manitoba R2H 1A7

Phone (204) 233-1411 | Fax: (204) 237-3468

E-mail: info@cphm.ca | Website: www.cphm.ca

manager/director of the pharmacy will collaborate with the regional health authority to ensure that there are written policies and procedures for addressing, reporting, investigating, documenting, disclosing and learning from medication incidents.

- 3.1.2** Licensed pharmacists, pharmacy technicians, pharmacy assistants and employees of the pharmacy are trained and are required to comply with systems, policies and procedures related to medication incidents, discrepancies or near misses.

3.2 Community Pharmacies

- 3.2.1** Upon discovery of a medication incident, the pharmacist made aware of the incident must:

3.2.1.1 Determine if the patient has experienced harm or is at risk of possible harm

3.2.1.2 Provide care for the patient to the best of their ability to protect their health and safety

3.2.1.3 Ensure the patient receives the right medication in a timely manner

3.2.1.4 Acknowledge that something has happened and the distress the incident has caused the patient and express empathy and concern. Listen to the patient.

3.2.1.5 Take reasonable steps to ensure that the incorrect medication is quarantined and/or returned to the pharmacy to avoid risk of harm or further harm, if relevant.

3.2.1.6 Inform the patient that the medication incident will be reported to pharmacy manager, investigated transparently and steps taken to reduce the likelihood of the medication incident happening to others

3.2.1.7 Notify the prescriber about the medication incident and any other personnel deemed necessary.

3.2.1.8 Notify the pharmacy manager of the medication incident.

3.2.2 The Investigation

Upon discovery of a medication incident, the pharmacy manager must ensure that:

3.2.2.1 The staff member(s) involved in the incident are made aware of the incident.

3.2.2.2 The investigation of the factors associated with the medication incident is done in a transparent and timely manner.

3.2.2.3 Changes in processes or systems that may have led to the medication incident are identified, and a plan is developed and implemented to reduce the risk of the incident recurring.

*College of Pharmacists of Manitoba Mission:
To protect the health and well-being of the public by ensuring and promoting safe, patient-centred and progressive pharmacy practice.*



College of Pharmacists of Manitoba

200 Taché Avenue, Winnipeg, Manitoba R2H 1A7

Phone (204) 233-1411 | Fax: (204) 237-3468

E-mail: info@cphm.ca | Website: www.cphm.ca

3.2.2.4 Findings and changes to be implemented are shared with pharmacy staff and changes reflected in the policies and procedures manual if deemed necessary

3.2.3 Documentation

The Pharmacy manager must ensure that:

3.2.3.1 The pharmacist who discovered the incident initiates documentation of the medication incident, including information obtained in section **3.2.1** of this document

3.2.3.2 All medication incidents are documented promptly on a pharmacy incident report form (a sample template of a report is provided in the appendices of this practice direction).

3.2.3.3 The pharmacy incident report form shall include, at minimum, the date, prescription number, incident number and a brief summary of the incident.

3.2.3.4 Corrective action taken to mitigate the risk of the incident recurring is documented.

3.2.3.5 The documentation is collated internally and periodically assessed to determine if other changes must be made to pharmacy systems or processes as a result of the incident.

3.3 Hospital pharmacy, personal care home, and long term care facility

3.3.1 When the pharmacist discovers a medication incident, they must notify the pharmacy manager, the prescriber, as well as other healthcare providers as specified in the organization's policies and procedures.

As part of the healthcare team, pharmacists must:

3.3.2 Determine if the patient has experienced or is at risk of experiencing harm. Participate in providing care for the patient as appropriate that is required to protect their health and safety.

3.3.3 Adhere to the organizations/pharmacy's policies and procedures for patient disclosure, reporting, investigating, documenting, and sharing lessons learned.

3.3.4 Participate in a process to review medication incidents with a multidisciplinary team.

3.4 Incidents involving a breach of personal health information

3.4.1 Refer to Practice Direction # 12 Records and Information, section 2.7

3.5 Discrepancies or Near-Miss Events

3.5.1 Whether in community, hospital, personal care home, or long-term care facility the documentation of near-miss events should be considered since it can initiate

*College of Pharmacists of Manitoba Mission:
To protect the health and well-being of the public by ensuring and
promoting safe, patient-centred and progressive pharmacy practice.*

Member of the National Association of Pharmacy Regulatory Authorities



College of Pharmacists of Manitoba

200 Taché Avenue, Winnipeg, Manitoba R2H 1A7

Phone (204) 233-1411 | Fax: (204) 237-3468

E-mail: info@cphm.ca | Website: www.cphm.ca

changes to improve safety and reduce risk of future medication incidents and patient harm.

3.6 System-wide learning

- 3.6.1 Pharmacists can help prevent recurrences of near misses and medication incidents in other practice sites in Manitoba and Canada by confidentially and anonymously reporting to the Institute for Safe Medication Practices Canada (ISMP). Go to <http://www.ismp-canada.org/>
- 3.6.2 Sharing information on system changes being proposed should be considered, including to colleagues outside of the pharmacy, to promote wider shared learning and improvement while maintaining confidentiality (PHIA) principles.

4.0 Compliance Adjudication

- 4.1 All documentation must be readily accessible and open to regulatory review.

5.0 Appendices

- 5.1 Medication Incident and Discrepancy or Near-Miss Event Report Form

A Practice Direction is a written statement made by Council for the purposes of giving direction to members and owners about the conduct of their practice or pharmacy operations. Compliance with practice directions is required under the Pharmaceutical Act.

The process for development, consultation, implementation, appeal and review is been published on the College website.

Development Source:
Regulatory Reference:
Consultation Close:
Authorized by Council:
Effective Date:
Revised:
Review Due:

Standards of Practice Committee
Section 56(9) of *The Pharmaceutical Regulations*
March 13, 2015
June 20, 2016
July 8, 2016

*College of Pharmacists of Manitoba Mission:
To protect the health and well-being of the public by ensuring and
promoting safe, patient-centred and progressive pharmacy practice.*

Member of the National Association of Pharmacy Regulatory Authorities