# College of Pharmacists of Manitoba

**200 Taché Avenue, Winnipeg, Manitoba R2H 1A7**
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## Practice Direction –
## Standards of Practice #9: Medication Incidents and Near-Miss Events

**1.0 Scope and Objective:**

**1.1 Expected Outcome**
This document is a practice direction by Council concerning medication incidents and 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 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 human factors, environmental factors, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

**2.2** Near-Miss Event (discrepancy) – 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.

**2.3** Continuous Quality Improvement (CQI) - a structured process used within the pharmacy which allows for continual review and improvement of all aspects of the medication dispensing process, in order to improve patient safety.

**2.4** Safety self-assessment (SSA) – a proactive assessment of pharmacy processes by the pharmacy manager and staff to identify areas of improvement.

**2.5** Safety IQ – a standardized continuous quality improvement (CQI) program approved by Council for community pharmacies which includes elements of reporting, analyzing, documenting and shared learning from medication incidents and near miss events with the objective to improve patient safety.

**2.6** National medication incident database – a single national data repository that is independent of a reporting platform and has the ability to accept anonymous reporting data from multiple platforms using a common set of standards. Contribution to a national database allows for population of national aggregate data in which learnings arising from trends and patterns can be communicated across the profession.

**2.7** Medication incident reporting platform – a system that pharmacies and pharmacy professionals use to record data on medication incidents and near misses and then exports the anonymous data collected to the national medication incident database. The system must meet the data standards and platform criteria set by Council and satisfy the requirements of the College's standardized continuous quality improvement program, Safety IQ.

**2.8** Anonymous report– A reported medication incident with no identifying information about the patient, reporter or individual staff members involved in the medication incident transmitted to the CMIRPS National Incident Data Repository for Community Pharmacies.

## 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 and near-miss events. In the case of a pharmacy owned by a Regional Health Authority, the 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 and near-miss events.

**3.1.3** In the case of a community pharmacy, ensure that the pharmacy meets and follows the requirements of the College's standardized continuous quality improvement (CQI) program - Safety IQ. This includes but is not limited to utilizing specific tools for recording and reporting medication incidents and near-miss events, proactively identifying any safety issues within the pharmacy, and documenting improvement plans to ensure medication safety within the pharmacy.

**3.1.4** In the case of a community pharmacy, ensure that all dispensary staff are trained in the elements of the Safety IQ program.

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### 3.2 Community Pharmacies

#### 3.2.1 Discovery

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** 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.

**3.2.1.5** Notify the pharmacy manager of the medication incident.

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

#### 3.2.2 Disclosure Process and Apology

**3.2.2.1** Acknowledge that a medication incident has occurred and apologize for the distress the incident has caused the patient.

**3.2.2.2** Listen to the patient, Express empathy and concern, do not minimize what happened

**3.2.2.3** Advise the patient of the potential consequences (both short and long term) from the incident.

**3.2.2.4** Provide a description of the facts that are known about the incident and update the patient as new information is obtained

**3.2.2.5** Inform the patient that:

- **3.2.2.5.1** the medication incident will be reported to pharmacy manager,
- **3.2.2.5.2** the pharmacy will anonymously report the medication incident to a national medication incident database to enable other pharmacies to learn from this incident
- **3.2.2.5.3** an investigation will take place and based on the investigation, that changes to systems or processes will be developed and implemented to minimize recurrence of a similar medication incident or near miss

**3.2.2.6** Notify patient of any changes to systems or processes made after analysis of the incident

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**3.2.3 Investigation**

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

**3.2.3.1** The staff member(s) involved in the incident are made aware of the incident and are provided access to support if needed.

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

**3.2.3.3** Inform the patient of the action plan implemented to prevent further incidents

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

**3.2.4 Report**

**3.2.4.1** Medication incidents are promptly and anonymously reported by pharmacy staff member(s) to a medication incident reporting platform which will export the report details to a national medication incident database

**3.2.4.2** Near misses that are recurrent or could potentially cause harm if not corrected are also reported to identify trends and preventive recommendations.

**3.2.5 Analyze for Improvement**

The pharmacy manager must ensure that:

**3.2.5.1** Incidents and recurrent or potentially harmful near misses are reviewed and analyzed by pharmacy staff to identify contributing factors. The pharmacy manager or designate should review individual near-misses and incidents to identify contribution factors and opportunities for improvement. Review of aggregate data should happen on a quarterly basis to look at trends or opportunities for improvement and compare to national data.

**3.2.5.2** Changes to systems or processes are developed and implemented to minimize recurrence of a medication incident or near miss

**3.2.5.3** A pharmacy-specific safety self-assessment (SSA) is completed during the first year of the Safety IQ program, and every three years thereafter. For new pharmacy openings, the safety self-assessment should be completed within the first year of operation. The safety self-assessment can be completed more frequently if deemed appropriate by the pharmacy manager.

**3.2.5.4** A formal Continuous Quality Improvement meeting be conducted with pharmacy staff at a minimum annually with informal huddles occurring as medication incidents occur and as deemed necessary.

**3.2.6 Documentation**

The Pharmacy manager must ensure that:

**3.2.6.1** Medication incidents, CQI improvement plans and formal CQI meetings are documented and accessible for regulatory review.

**3.2.6.2** In addition to information reported to the medication incident reporting platform, all communication with the patient and prescriber must be documented.

**3.2.6.3** All CQI improvement plans and outcomes, as a result of medication incidents and near misses are documented.

**3.2.6.4** All CQI improvement plans and outcomes, as a result of completion of the safety self-assessment (SSA) are documented.

**3.2.6.5** All formal CQI meetings with pharmacy staff are documented including date, staff present and topics of discussion.

**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 necessary 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.

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### 3.4 Incidents involving a breach of personal health information

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

## 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
**5.2** Community Pharmacy Safety Culture Toolkit
**5.3** Safety IQ Guidance Document

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*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.*

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