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New Brunswick College of Pharmacists
Ordre des pharmaciens du Nouveau-Brunswick

Mandatory Medication Incident Reporting Practice Directive

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DEFINITIONS

Medication Error	Medication incidents that are identified after their release to the patient (or administering health care professional) and therefore have greater potential for harm.
Medication Incident	An all-encompassing term that includes medication errors (mistakes that are released from the pharmacy) and near miss events (mistakes intercepted prior to release from the pharmacy).
Near Miss Event	Medication incidents that are identified and resolved prior to the release of medication from the pharmacy.
Pharmacy Professional	Pharmacist, Certified Dispenser and Pharmacy Technician
Quality	The extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be safe (minimize risks and harms to service users), effective, timely, efficient, equitable, and people-centered. ¹

GLOSSARY OF ABBREVIATIONS

CIHI	Canadian Institute for Health Information
CMIRPS	Canadian Medication Incident Reporting and Prevention System
COMPASS	Community Pharmacy Professionals Advancing Safety in Saskatchewan
CPhIR	Community Pharmacy Incident Reporting
CPhM	College of Pharmacists of Manitoba
CQI	Continuous Quality Improvement
ISMP Canada	Institute of Safe Medication Practices Canada
MSSA	Medication Safety Self-Assessment
PPC	The NB College of Pharmacists' Professional Practice Committee
QMP	Quality Management Program
SCPP	Saskatchewan College of Pharmacy Professionals

AUDIENCE

This practice directive applies to New Brunswick pharmacy professionals (pharmacists, pharmacy technicians and certified dispensers) and students practicing in all patient care environments.

INTRODUCTION

Medication incidents are among the most common and harmful patient safety incidents. Deaths resulting from patient safety incidents rank third in Canada behind cancer and heart disease. In 2013, just under 28,000 deaths were attributable to patient safety incidents. The costs (morbidity and mortality) to the healthcare system are estimated at \$2.75 billion (2017) per year. Medication incidents are recognised as a significant component of patient safety incidents² and merit concerted harm reduction efforts.

Non-maleficence (doing no harm) is a bioethical principle that pharmacy professionals consider in the course of meeting their duty to promote and protect the health, well-being, safety and interest of the public.³ The New Brunswick College of Pharmacists (the College) and its members are ethically obligated to minimise the risks of harm to the public associated with medication incidents. In order to fulfill this obligation, incidents must be captured and analysed so that appropriate preventative measures may be taken.

Medication incidents encompass:

1. Medication errors (or dispensing errors) and
2. Near miss events

Approximately 85 per cent of medication incidents are considered to be near misses and 15 per cent are estimated as being medication errors.^{4,5} Additional statistical analysis of reported medication errors estimates approximately one (1) per cent result in some degree of harm to the patient.⁵

Due to the human component in the current process of verifying and dispensing medications, it is not possible to achieve a medication incident rate of zero and therefore, the primary objectives of Mandatory Medication Incident Reporting are to:

1. Collect medication incident reports using a common central database: Professionals require a low-risk (i.e., anonymous), simple, accurate and efficient process for reporting.
2. Identify incident patterns and trends: Analysis of a centralized database of medication incident reports allows for identification of strong and weak signals of trends and patterns.
3. Learn from the trends so that as a profession, pharmacy may reduce the probability that these incidents recur: Communication of trends and patterns and risk-reduction strategies to professionals contributes to learning and action.

BACKGROUND

In 2017, the Professional Practice Committee (PPC) evaluated the risk of medication incidents to the public and assigned it the highest possible priority. In developing this practice directive the following was considered:

- Medication incident reporting is or will be mandatory in all Canadian provinces
- Other pharmacy regulatory authorities' experience with similar mandatory requirements for medication incidents.
- Reporting platforms to identify both benefits and areas of improvement of existing systems
- Challenges faced by pharmacists with respect to processes and time management
- Strategies adopted by pharmacy managers to promote reporting and facilitate a culture of safety within the practice^{6,7} site or pharmacy
- Hospital pharmacy reporting mechanisms

Pharmacies' Quality Management Program (QMP) includes medication incident reporting as a component of an overall plan. The New Brunswick College of Pharmacists' Regulations regarding quality management state⁸:

14.2 The manager must ensure and document ongoing quality management including, but not limited to; evaluating staff performance, equipment and facilities and adherence to Standards of Practice including the following:

(a) anonymous medication error reporting to an external Canadian database for those errors that reach patients

(b) response to individual errors and trends

(c) maintenance of a culture of safety within the practice

This practice directive provides guidance to pharmacy practitioners in order to successfully comply with part (a), (b) and to some extent, (c) of Regulation 14.2.

MANDATORY MEDICATION INCIDENT REPORTING PRACTICE DIRECTIVE

1. Reporting

Pharmacy managers must ensure that pharmacy professionals anonymously report medication errors (medication incidents that reach the patient) to an external, central Canadian database.

- **Anonymous** means that the individual reporting the medication error and those involved in making the error cannot be identified. Anonymity reduces the barrier of practitioner-perceived risk to reporting. Evidence has shown that adopting an anonymous error reporting system leads to higher reporting rates across healthcare professions.⁷ Furthermore, reports have identified that "confidentiality of medication incident reporting is a high priority for staff because of aversion to blame, embarrassment, and humiliation, as well as concerns regarding firm reputation and job security".⁶ The culture of the practice also contributes to whether pharmacy professionals feel safe and supported in reporting [Regulation 14.2 (c)].
- **Errors that reach the patient must be reported** as specified in Regulation 14.2.

- Near miss events must minimally be described and logged internally. [Appendix 1](#) contains samples of near miss reporting log sheets. The reporting of near misses to the external database is at the discretion of the pharmacy professional. Please refer to the Frequently Asked Questions (FAQs) section for more information.
- Documentation of all medication incidents should be retained (electronically or on paper) for five (5) years.
- **External database** means a repository of medication incident reports that resides outside of the pharmacy and corporate/institutional organization to which the pharmacy belongs, if applicable. The database must facilitate the receipt of reports and data analysis from pharmacy professionals. The database must maintain a quality standard that all reports meet so as to allow analysis and maximise learning on the part of pharmacy professionals, managers, government, industry, the public and regulators.
- **Central/common database** means a repository of medication incidents that is administered by an independent pan-Canadian program. The program established by Health Canada to provide this service is the Canadian Medication Incident Reporting and Prevention System (CMIRPS).
- **Canadian database** means medication incident reports can be received from pharmacy professionals in all Canadian provinces and territories. The database will meet federal and provincial legislation regarding the physical location of the server within Canada and aggregation of Canadian data for the purposes of improving medication safety.

2. Responding

Pharmacy managers must ensure pharmacy professionals respond to individual medication incidents and trends. Response includes **recovering** and **learning** from internal incidents as well as medication incidents and trends that are shared from external organizations (other pharmacies and external Canadian database). In an effort to ensure continuous monitoring and feedback at the practice level on error trends and outcomes, a reporting and learning cycle similar to that used in Saskatchewan's standardised continuous quality improvement (CQI) program, [COMPASS](#), will be utilised ([Appendix 2](#))⁹. Pharmacy managers must ensure responses to medication incidents are **documented**.

- **Recovery** encompasses activities such as contacting the patient, physician and other stakeholders³ involved as well as investigating the event(s). Medication incidents (errors and near miss events) should be analysed internally using root cause analysis. Only with this process can a practice address the multiple factors that contribute to a given or series of medication incidents. The recovery period allows for reflection, discussion and regrouping within the pharmacy practice and for knowledge gained secondary to the medication incident to be shared with other pharmacy professionals within a practice or organization. Practice or organizational policy may change quickly during this recovery phase.
- **Learning** occurs at a provincial and national level through analysis of medication error trends from all reporting practices. The findings are widely distributed by organizations that analyse data from the Canadian database and regularly disseminate patient safety newsletters and bulletins. This information also influences regulation. On a practice level, professionals learn of potential risk of medication incidents through internal analysis of their own medication incidents as well as review and discussion of information published in

patient safety newsletters and bulletins. Learning is facilitated through regular meetings to share and address individual events (and/or near misses) and trends. While some pharmacies may find it easier to make time for longer, more infrequent meetings, these meetings must occur at minimum on a quarterly basis.

- **Documentation.** The response to individual medication errors and identified trends of near-miss events must be clearly documented. This includes outcomes and initiatives discussed at the quality-related meetings. Discussion of findings during meetings should result in clear action plans and subsequent changes to pharmacy policies and procedures. A monitoring plan must be implemented and documented in order to measure ongoing quality improvement.

3. **Maintaining a Culture of Safety**

Attitudes and systems within the pharmacy practice contribute to a **culture** that is non-punitive and supportive of individuals reporting medication incidents. Nurturing such a culture is the basis for generating policy and processes that improve patient safety. In practice, “factors influencing medication error reporting, recovery, and learning not only originate from the individual staff members but also ... pharmacy as a whole”⁶ and thus must also be addressed by pharmacy as a profession.

CONCLUSION

While the implementation of a mandatory medication incident reporting system is a step in the right direction with respect to promoting patient safety, the act of reporting in and of itself is not enough. Individual pharmacies, corporations and regulatory bodies must effectively respond to- and learn from- trends in reported medication incidents and adjust policies, procedures and regulation accordingly. Provincial and national findings will inform changes to this practice directive and potential new initiatives to increase effectiveness of medication incident reporting as a component of the pharmacy quality management program (QMP). Additionally, quality outcomes will be tracked to determine whether mandatory medication incident reporting results in measurable improvements to public health and safety in New Brunswick.

FREQUENTLY ASKED QUESTIONS

1. How do I report medication incidents given time constraints in my current practice?

There are many avenues to explore when finding time to report medication incidents. It will take time, managerial commitment, possible culture change and the input of all pharmacy staff to establish consistent, valuable and complete incident reporting within your work environment.

Some measures might include:

- Managers are responsible for the implementation of a quality management program (QMP) however managers might consider delegation of some QMP tasks. Consider delegating the lead role of medication incident reporting to a particular pharmacy technician. Pharmacy technicians can champion reporting of medication incidents. Their role in final product checks and understanding the steps of the medication dispensing process provides a sufficient skill set for this task.
- Near miss events can be tracked as they occur using a paper log or an electronic document if these documents remain open on the computer terminal.
- If immediate reporting is not possible then schedule time at the end of each shift to document medication incidents.
- Barriers to reporting “include lack of feedback on action taken as a result of reporting, system design (e.g. form takes too long to fill out, not enough time to complete the forms), incident too trivial, delaying filling out a report and ultimately forgetting, and lack of justification for reporting a near miss.”⁶ In addressing these barriers to reporting, pharmacy managers may need to reorganise human resources and adapt existing reporting technology. For example, pharmacy managers may elect to use a given platform to transmit data to the external, central Canadian database but because corporate or institutional risk management requires different information, the reporting platform is used to generate a document that may be appended or edited and subsequently submitted to corporate management for their internal purposes.
- If corporations and institutions require internal reporting of medication errors, the organization is encouraged to implement technology that allows for simultaneous anonymous reporting to an external central Canadian database. This would allow for the most efficient use of professionals’ time and resources while achieving mandatory medication incident reporting.

2. How can pharmacy managers best meet this new regulation?

In addition to challenges with reporting as outlined above, recovery-related challenges identified include finding time to schedule the required meetings, ensuring all pharmacy staff is involved in reporting and maintaining positive staff relationships following reporting.⁷ Multisite studies of community pharmacies conducting QMP found that managers showing visible commitment to medication incident reporting helped address apprehension relating to reporting and minimised disruption to the staff network.⁷ Furthermore, some managers found it useful to plan after-hours quality-related meetings and compensate for staff time in the interest of maximizing staff engagement.¹⁰

3. What reporting platforms are available that comply with Regulation 14.2 that specifies reporting to an external Canadian database?

Professionals must determine whether their current medication incident reporting platform links with organizations within the [CMIRPS](#) program to ensure compliance with this Regulation. The intent is that a single pool of medication incident data securely exists and grows. New Brunswick's small population could result in our data only becoming meaningful in aggregate when combined with other regions. Pooling data from all provinces creates a sufficiently large sample size where trend identification is possible. New Brunswickers will ultimately benefit from our ability to analyse medication incident data on a national scale.

4. What is CMIRPS?

The Canadian Medication Incident Reporting and Prevention System [CMIRPS](#) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada. At time of publication of this practice directive, both the CIHI National System for Incident Reporting ([NSIR](#)) and the ISMP Canada Community Pharmacy Incident Reporting ([CPhIR](#)) programs contribute to the CMIRPS database.

5. What **must I report to the external database?**

All medication errors that leave the custody of the pharmacy (reached the patient or the medication was transferred to another health care provider for administration), regardless of harm, must be reported.

6. What **should I report to the external database?**

In addition to medication errors that reach the patient, situations where a near miss should be reported include:

- A medication incident that had the potential to cause harm if not intercepted
- Recurrent near misses
- Any medication incident a pharmacy staff member believes is important should be reported to the external centralised Canadian database.¹¹
- A medication incident that is identified/intercepted by another health care professional prior to patient administration (i.e., in long-term care or hospital)

It is acceptable to only track the above examples within the internal near miss events log according to the pharmacy professional's judgement.

7. With respect to near miss events, what is the benefit of recording it if it didn't make it to the patient?

Near miss incidents should be recorded in a manner that allows trends to be identified in aggregate within your practice environment. Evaluating themes and patterns of near misses will allow the pharmacy team to identify opportunities for improvement. The team can develop and implement strategies to reduce the likelihood of a medication incident eventually occurring. This practice directive specifies that documentation of all medication incidents should be retained for five years for optimal pattern and trend identification. It is shorter than the standard 15 years

specified in Regulation [17.22](#) because the purpose of retention is for learning purposes.

8. Do hospital pharmacies also have to report medication incidents?

Yes. Hospitals must comply with this practice directive. At time of publication, the College is working with New Brunswick's regional health authorities to ensure medication incident reports are channeled to the Canadian Institute for Health Information national System for Incident Reporting (CIHI NSIR). Until such time as external reporting can be integrated into the reporting platform, it is the pharmacy's responsibility to ensure that anonymous error reports are transmitted anonymously to an external central Canadian database.

9. Can I be the subject of a complaint as a result of making an error?

The College takes a systems approach to analysing an error so that the multiple causes are identified and addressed rather than attributing responsibility to an individual professional. It is unusual but not impossible for a member to be the subject of a complaint as a result of a medication error. In the 24 formal cases dealt with by the Complaints and the Discipline and Fitness to Practice Committees (from 2010 to 2018) there were two instances related to medication errors that caused harm to a patient. Details of the most current complaints and discipline decisions are published on the College website.

Conversely, a member could be subject to a complaint as a result of **not reporting** a medication error. It is in everyone's best interest to report medication errors for the purposes of identification of systems issues and widespread (not just a single pharmacy) learning.

10. If I've discovered a medication incident that was made at another pharmacy, who should report this?

You must notify the pharmacy of the medication incident and they should report the incident to the external database through their usual channels. They will be able to provide the greatest possible amount of information about factors (root cause analysis) that led to the incident. You can request the pharmacy follow up with you to ensure the medication incident is recorded, analyzed and responded to.

11. What is the cost of a subscription to a medication incident reporting program that meets the requirements of Regulation 14.2?

The subscription for the ISMP Canada medication incident identification and reporting (CPhIR) program and medication safety self-assessment tool (MSSA) is \$340 (June 2018) per community pharmacy per year. The cost of an institutionally-based platform would be much higher as they are generally integrated into an overarching risk management platform that captures all incidents (not just medication-related) within the institution.

12. What resources exist for my pharmacy team regarding patient safety and medication incidents?

SCPP COMPASS Safety Resources; <http://www.saskpharm.ca/site/compass/safety?nav=sidebar>

CPhM Safety IQ Resources for Pharmacy Professionals:

<https://mpa.in1touch.org/site/safetyiq/resourcesforpharmacyprofessionals> and

CPHM Safety IQ Resources for Patients at
<https://mpha.in1touch.org/site/safetyiq/resourcesforpatients>

Canadian Medication Incident Reporting and Prevention System:
<https://www.cmirps-scdpim.ca/?p=14&lang=en>

Canadian Institute for Health Information (CIHI)
<https://www.cihi.ca/en>

Medication Safety Culture Indicator Matrix (MedSCIM): New Brunswick Results
<https://www.youtube.com/watch?v=Cy-xTkgz00c&feature=youtu.be>

Institute for Safe Medication Practices Canada (ISMP Canada): <https://www.ismp-canada.org/>

Medication Safety Culture Indicator Matrix (MedSCIM): New Brunswick Results [Video]
<https://www.youtube.com/watch?v=Cy-xTkgz00c&feature=youtu.be>

Analysis of Medication Incidents Associated with Patient Harm in New Brunswick using the Medication Safety Culture Indicator Matrix [Poster]
<https://www.ismp-canada.org/download/posters/AFPCCPERC2018-MedSCIM.pdf>

Multi-Incident Analysis on Incidents Involving Patients: Lessons Learned from a Provincial Pilot Study in New Brunswick [Article]
<https://www.ismp-canada.org/download/PharmacyConnection/PC2016-LessonsLearnedProvincialPilotStudy.pdf>

APPENDICES

Appendix 1: Near Miss Tracking Tools:

A. Royal Pharmaceutical Society Document:

<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/near-miss-error-log-and-table.pdf>

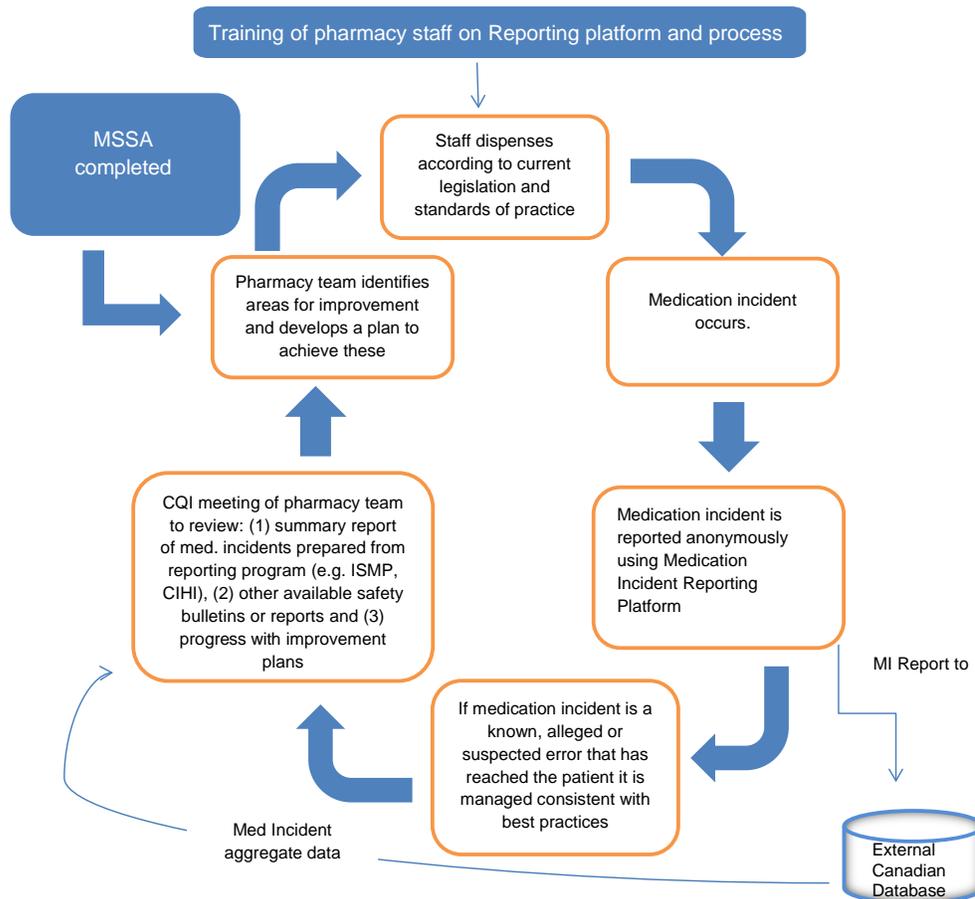
B. Basic Tracker for Near Misses

The Canadian Patient Safety Institute defines near misses as events with the potential for harm that did not result in harm due to timely intervention or good fortune.

Date Discovered	Point of Discovery	Rx/Tx Number (optional)	Type of Error	Point of Error	Error Reviewed	Action Taken
Example:						
Aug 27/14	Dispensing	123456	Wrong sig	Entry	Aug 28/19	Independent double check for Rx with high-alert medications sigs"

Appendix 2: Reporting and Learning Cycle

CQI Cycle for Medication Incidents



Abbreviations: CIHI - Canadian Institute for Health Information
 CQI – Continuous quality improvement
 ISMP Canada - Institute for Safe Medication Practices Canada
 MI - Medication Incident
 MSSA - Medication Safety Self-Assessment

SCPP COMPASS Safety Resources; <http://www.saskpharm.ca/site/compass/safety?nav=sidebar>

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MONITORING FREQUENCY:
MONITORING METHOD:
REVIEW FREQUENCY:
RESPONSIBILITY: