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

# STANDARDS OF PRACTICE: MANDATORY MEDICATION INCIDENT REPORTING

## ACKNOWLEDGEMENT

The New Brunswick College of Pharmacists gratefully acknowledges the Nova Scotia College of Pharmacists for their invaluable contribution in developing the original policy document on *Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies,* and the *SafetyNetRx Continuous Quality Assurance Guide for Community Pharmacies*. We are grateful for their willingness to share their work, which has provided a solid foundation for our policy framework and guide on mandatory medication incident reporting.

## DEFINITIONS

The definitions below are based on the Model Standards for Continuous Quality Improvement and Medication Incident Reporting by Pharmacy Professionals, developed by the National Association of Pharmacy Regulatory Authority (NAPRA)[1].

**Anonymized reports**

Reports that do not include any information that could be used to identify the individual who completed and/or submitted the report, nor any pharmacy personnel involved in the incident or near miss, in accordance with federal and/or provincial/territorial privacy laws.

**Contributing factor**

A circumstance, action or influence that is thought to have played a part in the origin or development of an incident or near miss, or to increase the risk of an incident or near miss.

**Continuous Quality Assurance (CQA*), also known as quality management program (QMP) in the NB Pharmacy Act, 2014 section 18 (a) (iv)***

A structured process that ensures pharmacy practices are consistently safe, effective, and compliant by using a systematic approach to monitor, assess, and improve all aspects of the medication dispensing process, to improve patient safety.

**Culture of patient safety**

A component of organizational culture, which includes the shared beliefs, attitudes, values, norms and behavioural characteristics of employees, and influences staff member attitudes and behaviours in relation to their organization's ongoing patient safety performance. An enabling patient safety culture is characterized by leadership that leads by example, transparent communication, psychological safety facilitating reporting of errors, patient and family engagement, and a commitment to ongoing improvement.

**De-identified report**

A report that does not include any information that could be used to identify patients, in accordance with federal and/or provincial/territorial privacy laws.

**A Just culture**

The environment of a workplace in which consideration is given to wider systemic issues when things go wrong, enabling professionals and those operating the system to learn without fear of retribution. To encourage reporting of safety issues, inadvertent human error, freely admitted, is generally not subject to sanction. However, people are held to account where there is evidence of unprofessional conduct or deliberate acts.

[1] https://www.napra.ca/publication/model-standards-for-continuous-quality-improvement-and-medication-incident-reporting/

**Medication incident**

Any preventable event that may cause or lead to inappropriate medication use or patient harm that has reached the patient. 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.

**Medication safety self-assessment**

Medication safety self-assessment is a structured tool designed to identify gaps in current medication safety systems, highlight areas for improvement, and monitor progress over time.

**National database**

A repository of medication incident and near miss reporting data submitted from across Canada. The data contained in a national database is de-identified and anonymized.

**Near miss**

An event that could have resulted in unwanted consequences but did not because, either by chance or through timely intervention, the event did not reach the patient. This may include but not limited to errors in medication selection, dosage, labeling, patient identification, or administration of drug at the wrong time.

**Pharmacy manager**

The pharmacy professional recognized as being in charge of the operations of a specific pharmacy and who is held accountable by the pharmacy regulatory authority for the operations of that pharmacy.

**Pharmacy professional**

A person authorized to practice as a pharmacist or pharmacy technician by a pharmacy regulatory authority in one of the provinces or territories of Canada. This term includes pharmacy managers. For the purposes of this document, a pharmacy manager would be expected to meet the standards of practice for pharmacy professionals in addition to the standards for pharmacy managers.

**Reporting platform**

The computer software used by pharmacy professionals for recording medication incidents and near misses at the pharmacy level and reporting them to a national and/or provincial database.

**Root cause**

The most fundamental reason (or one of several fundamental reasons) a suspected failure, a medication incident, a near miss, or a situation in which performance does not meet expectations has occurred.

**Root-cause analysis/Incident Analysis**

An objective analytical process that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

**Quality-related events (QREs)**

This includes known, alleged or suspected medication incidents that reach the patient **as well as** those that are intercepted (near miss) prior to dispensing.

## INTRODUCTION

The role of pharmacy professionals in ensuring medication safety and identifying learning opportunities within the medication management system is vital to the overall quality of patient care. Pharmacists and pharmacy technicians play a critical role in identifying, reporting, managing, and investigating incidents to minimize the risk of recurrence and learn through the process for an improvement in medication safety practices.

The New Brunswick College of Pharmacists (the College) recognizes the importance of establishing standards of practice on medication incident reporting and the continuous learning of pharmacy professionals to encourage transparency and contribute to patient trust in the safety of pharmacy practice. The mandatory reporting of medication incidents and adherence to a Quality Management Program (QMP) encourages a Just culture where pharmacy professionals can report incidents without fear of disproportionate consequences while providing valuable information for learning opportunities that improve patient safety.

This policy document provides a comprehensive framework for reporting and continuously learning from medication incidents and near misses to ensure the highest level of medication safety and professional accountability. It is the responsibility of the pharmacy manager to ensure that the pharmacy develops, maintains, and enforces policies and procedures to comply with these standards of practice. The pharmacy manager may identify a staff member who will act as a quality assurance (QA) coordinator and oversee the activities described in these standards.

## PURPOSE

To provide a standard for an effective Continuous Quality Assurance (CQA) process for pharmacies that ensures pharmacies engage in active enhancement of the safety and quality of their professional services and practices both on a regular, ongoing basis as well as in response to medication incidents or near misses.

## TERMINOLOGY CLARIFICATION: QMP AND CQI

The ***NB Pharmacy Act, 2014*** and Regulations currently use the term QMP. However, in this document and in the Guide to Continuous Quality Assurance (CQA), we will use QMP interchangeably with continuous quality improvement (CQI) and continuous quality assurance (CQA). These terms are grounded in the same principles and objectives, aiming to ensure high-quality standards and continuous improvement[2] in pharmacy practices.

[2] https://qualizeal.com/quality-assurance-in-healthcare-what-why-how/

## STANDARDS

In accordance with sections 13.5(g) and 14.2 in the *Regulations of the New Brunswick College of Pharmacists* , a pharmacy must establish and maintain a comprehensive QMP. The QMP constitutes a well-structured policy and procedure manual that must be readily accessible to all pharmacy staff, who must have a thorough understanding of its contents. The quality assurance coordinator is responsible for regularly reviewing and updating the manual when necessary. The QMP manual must include information that:

**Standard 1:** Monitors and documents staff performance, adequacy of staffing levels, and adherence to standards of practice.

**Standard 2:** Manages known, alleged and suspected medication incidents that reach the patient consistent with the best practices for this activity undertaken by others in the profession, including:

i. Taking necessary action to optimize patient care, including prompt consultation with the patient's other health-care providers to minimize negative impact.
ii. Ensuring that the patient is adequately informed about the management of medication incidents.
iii. Ensuring the management of an incident minimizes undue stress and frustration for the patient.
iv. Ensuring the management of an incident includes an apology (see the CQA guide for details) in which the pharmacist acknowledges the negative impact on the patient and commits to taking appropriate steps to minimize the likelihood of the incident recurring.
v. Promptly analyzing the incident for causal factors (also call root cause analysis).
vi. Communicating the causal factors of the incident to the patient when appropriate and explaining the actions taken to reduce the likelihood of recurrence.
vii. Documenting promptly and thoroughly the details of any known, alleged, or suspected incident or near miss, including statements from all pharmacy staff involved and the steps taken to resolve the problem.
viii. Communicating all details of the medication incident or near miss to pharmacy staff, including the causal factors and actions taken to reduce the likelihood of recurrence.

**Standard 3:** Requires reporting of medication incidents or near misses (also referred to as quality-related events (QREs)[3] to a database that contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) National Incident Data Repository (NIDR) for Pharmacies and enables this reporting to be anonymous.[4] [5]

[3] The extent to which intercepted incidents/near misses are reported will be a professional judgment decision of the pharmacy manager in consideration of the nature of the near miss, its implication for patient safety and the extent to which it is recurring.

[4] Enabling anonymous reporting means that the pharmacy must have a process by which practitioners have the ability to report all QREs anonymously (no identifying information about the patient, reporter, or individual staff member(s) involved is collected) and that this process is as equally promoted and supported as the in-house reporting system.

[5] Any data that is transmitted to the CMIRPS National Incident Data Repository for Pharmacies must be anonymized so that no identifying information about the patient, reporter, or individual staff member(s) involved in the QRE is transmitted.

**Standard 4:** Encourages open dialogue on QREs between pharmacy staff and management through, at a minimum, quarterly review of the pharmacy's aggregate QRE data (e.g., total number of incidents, type of incidents, etc.).

**Standard 5:** Documents process improvements made as a result of quarterly CQI meetings with staff.

**Standard 6:** Requires annual completion of a medication safety self-assessment and monitoring the progress of the resulting enhancement plan at quarterly QMP meetings.

**Standard 7:** Includes provisions to protect the confidentiality of information relating to specific patients.

**Standard 8:** Achieves the purposes of an effective QMP as described at the beginning of this policy document through ongoing education of pharmacy staff on the current best practices in QRE management and adoption of these practices to discourage punitive identification or other approaches that are detrimental to reporting and learning.

## FREQUENTLY ASKED QUESTIONS (FAQS)

### Why is Mandatory Medication Incident Reporting (MMIR) important?

MMIR is crucial for enhancing patient safety and quality of care. By systematically reporting and analyzing medication incidents, pharmacies and staff members can identify patterns and root causes of errors. This information is used to develop preventative strategies, training programs, and policies to mitigate the risk of future incidents.

### Why does the College mandate the reporting of medication incidents?

The College mandates reporting medication incidents to improve patient safety, ensure accountability and transparency, and encourage a culture of ongoing improvement within the pharmacy profession. These reports offer valuable educational opportunities to identify the root causes of incidents and develop quality management initiatives to prevent future occurrences.

### Who is responsible for reporting medication incidents in the pharmacy?

Pharmacy staff members must promptly and anonymously report medication incidents to a medication incident reporting platform, which will export the report details to the national medication incident database. The pharmacy manager must ensure the pharmacy's policies and procedures clearly define the steps for documenting and reporting these incidents.

### How should medication incidents and near misses be communicated within the pharmacy team?

The pharmacy manager must promptly inform the staff involved of any medication incidents and provide necessary support. Additionally, all incidents and potentially harmful near misses must be reviewed and analyzed by the pharmacy team to identify root causes and improvement opportunities, ensuring overall safety and preventing future incidents.

### How can reporting medication incidents improve pharmacy practice?

Reporting medication incidents offers pharmacy professionals valuable insights and educational opportunities by analyzing pharmacy-specific and nationwide data. The goal is to reduce the occurrence of medication incidents, minimize risks to patients, enhance the quality and safety of patient care, and strengthen patient confidence in the safety of pharmacy practices.

### How should a medication incident be reported?

Medication incidents must be reported through any reporting platform that meets the following requirements:

- Reporting platform must submit medication incidents/near misses to the National Incident Data Repository (NIDR).
- Reporters must have the option to be anonymous when reporting to the platform.

- Reporting platform must allow more than one user to add medication incident/near miss details as often more than one person has information regarding a medication incident/near miss.

The report must include detailed information about the incident, including the nature of the error, the circumstances surrounding it, and any actions taken in response. Timely and accurate reporting is essential for effective incident analysis and follow-up.

**When should near misses be reported?**

The pharmacy manager must develop, document, and implement a pharmacy-specific policy outlining when a near miss should be reported through the reporting platform to the National Incident Database Repository (NIDR).
The following is a sample criterion that could be used to determine whether a near miss should be reported:

- If it were to reach the patient, the near miss may cause harm.
- The near miss has been a recurrent issue in the pharmacy.
- The nature of the near miss, and if it provides a learning opportunity for pharmacy practice in general.

Reporting recurring near misses or those that could potentially cause harm allows for prompt review and analysis to prevent future incidents by addressing vulnerabilities and improving safety protocols.

**Is the information that is submitted to NIDR confidential?**

The NIDR, which is managed by the Institute for Safe Medication Practices (ISMP) Canada, gathers anonymously reported medication incidents from pharmacies across Canada. The confidentiality of the reported information guarantees that medication incidents and near misses can be reported without fear of retributive actions, thus promoting a culture of safety and continuous improvement.