



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

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# Guide to Continuous Quality Assurance (CQA)

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*Companion to the MMIR Standards of Practice*

## **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.

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## **DISCLAIMER**

The information contained in this guide is intended to serve as a reference for informational purposes only. It is not intended as a complete guide to a quality management program (QMP) as set forth by the New Brunswick College of Pharmacists (the College). This information is intended for use by pharmacy staff within the scope and standards of their professional practice. Having this information does not ensure that you comply with the Mandatory Medication Incident Reporting (MMIR) Standards of Practice; staff must be actively engaged in the quality assurance processes to be compliant.

If you have any questions regarding the content of this guide, please email the College at [info@nbpharmacists.ca](mailto:info@nbpharmacists.ca).

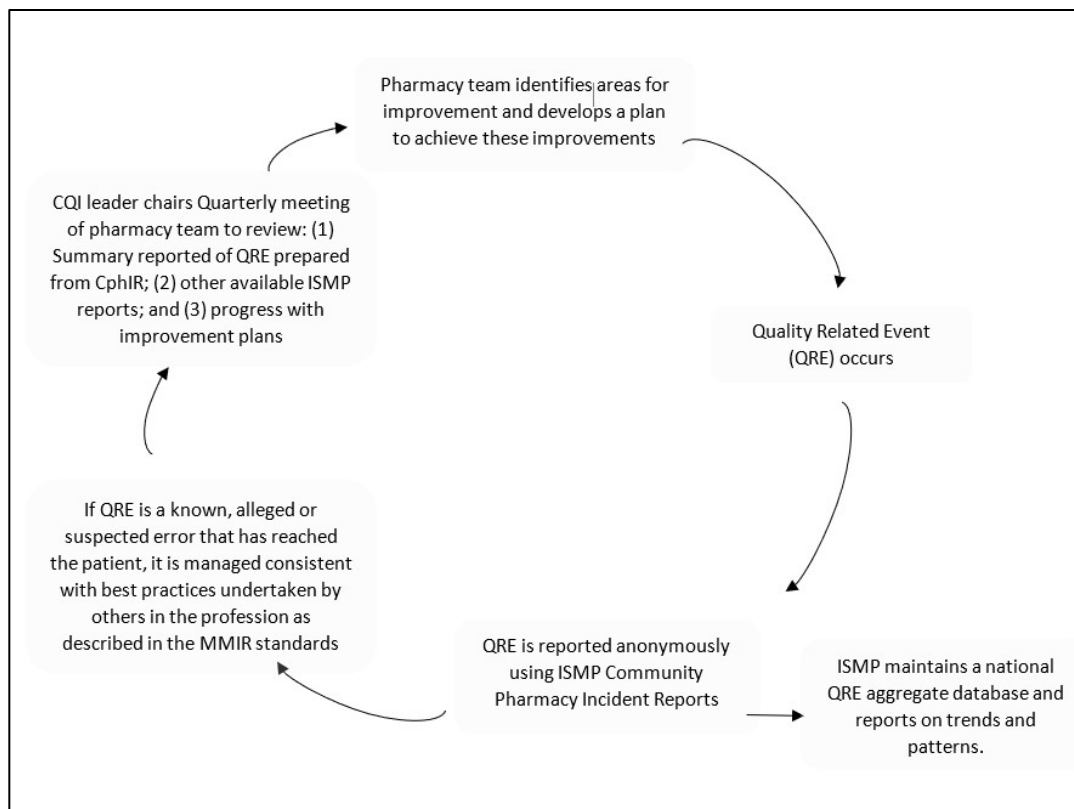
## HOW TO USE THIS GUIDE

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

It is recommended that you thoroughly acquaint yourself with the contents of this guide. The resources included in this guide have been selected to help you better understand the Standards of Practice: Mandatory Medication Incident Reporting (MMIR Standards) as set forth by the New Brunswick College of Pharmacists (the College). The MMIR Standards outline the criteria for assessing your practice and ensuring that your Continuous Quality Assurance (CQA)/Quality Management Program (QMP) complies. Resources from the Institute for Safe Medication Practices (ISMP) Canada, which can assist pharmacies in meeting the MMIR Standards, are also included.

Once you have read through the guide, you are encouraged to meet with staff members to review the documents and to discuss how best to implement the MMIR Standards, as a component of QMP, in your pharmacy.

Below is the Continuous Quality Improvement (CQI) Cycle for pharmacies (Figure 1). This provides a visual description of the process by which the standards and their associated practices should be integrated into your pharmacy practice. Its purpose is to help you better understand when and how to use the forms included in this guide.



**Figure 1. CQI Cycle for Pharmacies**

Source: *Continuous Quality Assurance: A Guide for Pharmacies* (Nova Scotia College of Pharmacists, 2019).

## RESOURCES

Some documents included here are mandatory for your pharmacy records, while others are suggested resources. They are presented in the following sections:

### SECTION 1: MANDATORY DOCUMENTS

The **Quality Related Events (QRE) Quarterly Meeting Agenda** has been included to ensure CQA/QMP coordinators and pharmacy managers prioritize QMP topics when quarterly staff meetings are conducted. By following a standard agenda, quarterly meetings will consistently address required content and provide staff members with a predictable, structured flow. Time is allocated for review of old business, review of new quality-related events and announcements to staff. It is important that the improvement plan is reviewed and amended as needed at each meeting. Attention to quality-related events at quarterly meetings will help the pharmacy achieve requirements set by the College.

The **QRE Quarterly Meeting Report Form** is to be filled out for each quarterly meeting. The form encourages discussion and analysis of QREs based on a number of dimensions, including workflow, staffing and environment issues. The creation of action plans in each of these areas assist in the effort to reduce the likelihood of the QRE reoccurring. These forms also aid in the discussion of “old

business” during quarterly QRE meetings to ensure follow through on the action plans.

The **Quality Management Tool (Site assessment)** will be used by pharmacy practice advisors to help ensure the pharmacy has achieved the standard of practice. The document is also included as a “self-audit” for pharmacies to ensure they are meeting the requirements being assessed by the College. Please ensure this document is filled out completely and accurately. It may be useful to fill this document out monthly to help keep track of the number of QREs reported and when quarterly meetings take place.

The **Medication Safety Self-Assessment survey** assists pharmacies by allowing pharmacy professionals to self-rate on a variety of safe practice characteristics across the spectrum of pharmacy activities. The tool must be completed by each pharmacy annually. Completing a medication safety self-assessment annually will fulfill Standard 6 of the MMIR Standards.

## Quality Related Events (QRE) Quarterly Meeting Agenda

Date: \_\_\_\_\_

1. Attendance
2. Old Business
  - a. Review of QRE statistics from the last meeting
  - b. Review of action plans made
  - c. Discuss Progress (continue/change action plans as needed)
3. New Business
  - a. Presentation of QREs for consideration
  - b. Discussion and analysis of QREs
    - i. Summarization of issues
    - ii. Identify solutions
    - iii. Create action plan (use fishbone diagram or other tool if appropriate)
4. Announcements

*Adapted from Florida Pharmacy Continuous Quality Improvement (CQI) Manual, 2002.*

**QRE Quarterly Meeting Report Form**

	Quarterly Meeting 1	Quarterly Meeting 2	Quarterly Meeting 3	Quarterly Meeting 4
Date				
Pharmacists present				
Pharmacy Technicians present				
Non-regulated staff present				
Pharmacy manager present (Y/N)				
Number of QREs reviewed				

**QRE Quarterly Meeting Report Form (Cont.)**

Meeting 1 Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Meeting 2 Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Meeting 3 Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Meeting 4 Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**QRE Quarterly Meeting Action Report Form**

Planned Action	QRE Meeting 1 (Date & Discussion)	Follow-Up		
		QRE Meeting 2 (Date & Discussion)	QRE Meeting 3 (Date & Discussion)	QRE Meeting 4 (Date & Discussion)
e.g., Place Rxs to be picked up in red basket	May 19, 2011 Confusion surrounding which Rxs to be picked up vs. waited for. Will use colour-coded baskets.	August 19, 2011 Not adopted by all staff. Discussed again to ensure everyone is on same page.	November 19, 2011 Working well. Less confusion and reduced near misses.	February 19, 2012 Trained new staff on procedure. Still working well.

## Quality Management Tool (Site Assessment)

Quality Management		
	Yes	No
Process for documenting <b>near misses</b>		
Process for documenting <b>medication errors</b>		
All <b>errors</b> being reported to external platform		
Data Sharing Agreement in place		
Process for discussing CQI plans (i.e., staff meetings/communication, at least quarterly)		
Staff appraisals being done		
Written job descriptions		
Health and safety checks of facility are being done (at least yearly)		
Equipment calibration:		
- Scales		
- Pill counters		
- Blood <b>pressure</b> machine		
- Other:		

## SECTION 2: ADDITIONAL RESOURCES

The following documents are intended as resources to aid pharmacies in topics related to the MMIR Standards.

**FAQs** have been provided as a quick reference on a number of topics related to the MMIR Standards and this document. Additional documents included in this guide are intended as resources to aid pharmacies with topics related to the CQA/QMP standards.

A sample **Confidentiality Agreement** has been included to aid in adhering to confidentiality provisions as stated in Standard 7.

**Root Cause Analysis Instructions** provide pharmacies with direction on how to employ root cause analysis techniques when analyzing QREs during quarterly and staff meetings. A **Fishbone Diagram** is also included to help staff visually discuss root causes and identify solutions. Pharmacy professionals should consider the root cause analysis tools available within their chosen reporting platform; this technology may make the root cause analysis more efficient.

The **Suggested Protocol for Handling Medication Incidents** provides an easy-to-follow policy when a QRE that has reached the patient has occurred or is suspected to have occurred in the pharmacy. The protocol is generic enough to use in all instances where a QRE has reached a patient and provides direct advice on how to proceed. This protocol or something similar should be placed on a shared notice space for all pharmacists, pharmacy technicians and locum staff to view and reference.

Finally, the **New Brunswick Effect of Apology Act** is to serve as a reference when preparing for disclosure to patients. For relevant sections of the Act, please see the last page of this guide.

## Confidentiality Agreement

Patient/client health records and personal information (including demographic information) are privileged and confidential.

I understand that I may become aware of patient information in the course of performing my duties at \_\_\_\_\_ and I am prohibited from divulging or communicating this information both during and after my employment or throughout and following my contract to conduct work for the pharmacy.

I agree to respect the patient's right to confidentiality and privacy.

If it is not part of my duties, I agree not to access patient's personal health information.

I agree to preserve the confidentiality of all clinical or patient information and to not divulge this information in any form, except where authorized by the patient or required by law. Any breach or violation, on or off duty, of this Agreement can or may result in legal or disciplinary action including dismissal.

I acknowledge that I have read this Confidentiality Agreement and understand my responsibilities as they pertain to confidentiality of personal information. I agree to be bound by the provisions of this Agreement both during and after my employment or throughout and following my contract to conduct work for the pharmacy.

Signature	Date	Position
Signature	Date	Position
Signature	Date	Position
Signature	Date	Position
Signature	Date	Position
Signature	Date	Position

**\*This Agreement is to be signed by anyone who has access to or who may come into contact with patient information.**

## Root Cause Analysis Steps and Instructions

Root Cause Analysis is a method of problem-solving techniques with a purpose of determining the root cause or causes of a QRE in order to prevent the QRE from occurring again in the future. Root Cause Analysis views every QRE as an opportunity to learn and improve a process by determining the root cause of a QRE so that the issue can be addressed in order to take appropriate action in your pharmacy to improve the overall process.

When determining the root cause of a QRE it can be helpful to use a fishbone diagram with your pharmacy staff for brainstorming purposes. The fishbone diagram will list various possibilities to where the root cause of the QRE lies. There are other root cause analysis tools available beyond a fishbone diagram, and this may include root cause analysis tools imbedded within your reporting platform.

The steps to Root Cause Analysis can be described as follows<sup>1</sup>:

**Step 1:** Define and describe the QRE that occurred in your pharmacy.

When defining the QRE that occurred in your pharmacy it is important to be specific about the incident that occurred (e.g. what drugs were involved). You may also want to categorize the QRE that occurred in your pharmacy as well during this step (e.g. wrong dose; wrong drug).

**Step 2:** Detail as much information about the QRE as possible.

Gather as much detail about the situation as possible on your own and from pharmacy staff who were working at the time of the QRE. Asking questions such as “when did the QRE happen?” and “what else was going on in the pharmacy at the time?” are some examples. You may want experienced staff, who may be knowledgeable of why exactly the QRE happened, to speak at your brainstorming session to determine the root cause of the problem.

**Step 3:** Determine all possible causes of the QRE using the Fishbone Diagram and sort based on the categories of causes in the diagram.

During your brainstorming session with your pharmacy staff, start by using the Fishbone Diagram on a whiteboard or where everyone can see it and contribute. Fill in the QRE defined in Step 1 in the head of the fishbone where it says QRE. The back of the fishbone diagram contains categories where causes of the QRE may lie. Brainstorm all the possible causes of the QRE with your staff and fill them in on the lines under the appropriate categories. The categories listed in the diagram are only a suggestion so feel free to add any categories that you feel are appropriate for your pharmacy.

Also, it is not required to fill all of the categories, it is only important for you and your staff to do a thorough brainstorming session here and to consider all of the categories on the Fishbone Diagram so that no potential causes of the QRE are missed.

**Step 4:** Define relationships between the potential causes of the QRE identified in Step 3 by asking why repeatedly.

Now that your Fishbone Diagram is filled out, look at each of the causes of the QREs that you’ve

listed under the categories individually. For each cause ask the team to brainstorm why it happened. For example, if you've determined that the QRE was that the wrong medication was given out and one potential cause was that the staff member was not trained correctly, ask why.

When you've determined the potential cause of the staff member not being trained correctly ask why again and keep going with this process until the question why cannot be answered. Continue this process for each of the potential causes that you have listed in your Fishbone Diagram.

**Step 5:** Brainstorm which potential cause would eliminate the QRE in the pharmacy if it was fixed and identify potential solutions to eliminate the potential cause.

When brainstorming possible solutions to decrease the risk of the QRE recurring, the solution must meet three important criteria. First, the solution to eliminate the cause of the QRE must eliminate the QRE if it is implemented. Second, if eliminated, the root solution cannot result in more QREs within the pharmacy. Third, the solution must also be possible within the pharmacy. When conducting the brainstorming session there should be discussion among the pharmacy staff why a potential strategy for the removal of the cause of the QRE does or does not meet the specified criteria. This process could leave you with only one possible solution, or several.

**Step 6:** Rank solutions that will best eliminate the QRE in the pharmacy.

If Step 5 leaves you with only one possible solution, then there is no need to determine the best solution as there is only one choice. If there are several possible solutions from Step 5, then the team should be asked to rank each solution based on effectiveness of eliminating the QRE and feasibility of the solution. The averages of the two scores should be calculated and the solution with the best score should be chosen for implementation.

**Step 7:** Implement the solutions determined in Step 6 into your pharmacy's process and monitor to ensure the solutions have been effective.

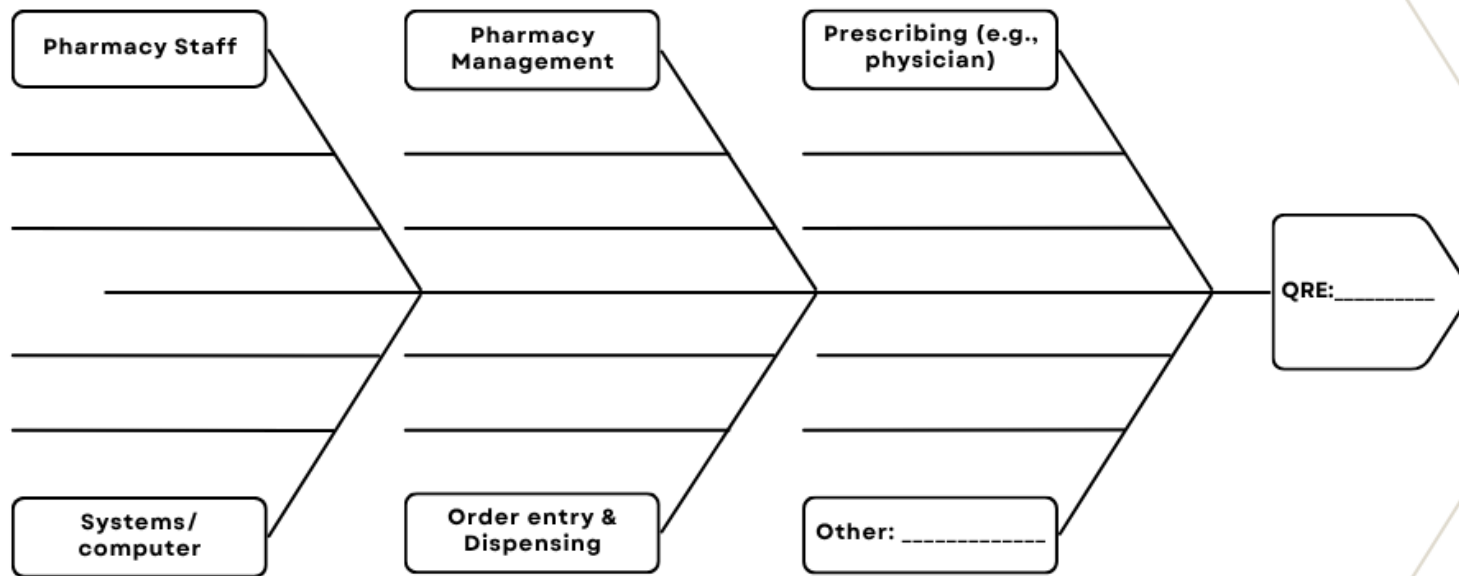
Upon implementation of the chosen solution, it is important to monitor to ensure the solution has had the desired effectiveness. If the solution has not resulted in the desired effectiveness, it could be because the root cause of the QRE was incorrect or because the best possible solution to remove the root cause was not chosen.

**Step 8:** If the QRE continues to occur, repeat the Root Cause Analysis process.

If you determine that the solution implemented has not had the desired effectiveness it may be necessary to complete the Root Cause Analysis again to determine a different root cause to the QRE that may have been incorrectly defined previously, or to brainstorm a better solution to remove the root cause from the process. Because it may be necessary to repeat the Root Cause Analysis in your pharmacy for the same QRE if the solution is not effective, it is important to keep all notes and information gathered about the QRE until the solution has been deemed to be a success.

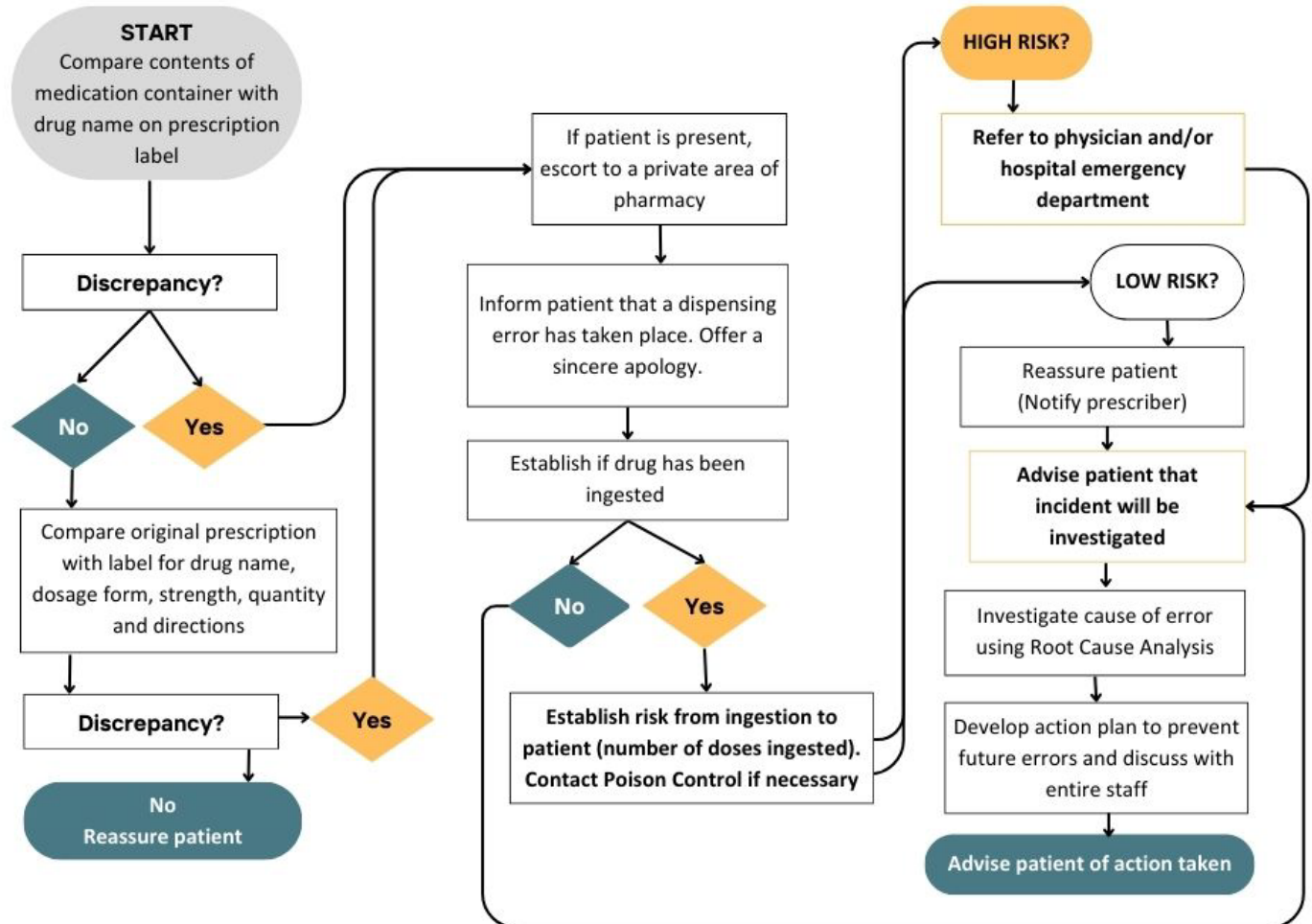
**QRE Fishbone Diagram**

Meeting Date: \_\_\_\_\_  
Version: \_\_\_\_\_



## Protocol for Handling Medication Incidents

### Incident is discovered or patient alleges dispensing error



## **Effect of Apology**

79(1) An apology made by or on behalf of a person in connection with any matter that is or may become the subject of a complaint:

(a) does not constitute an express or implied admission of fault by the person in connection with that matter;

(b) does not, despite any wording to the contrary in any contract of insurance or indemnity and despite any other Act or law, void, impair or otherwise affect any insurance or indemnity coverage for any person in connection with that matter; and

(c) shall not be taken into account in any investigation or determination of fault in connection with that matter.

79(2) Despite any other Act or law, evidence of an apology made by or on behalf of a person in connection with any matter that is or may become the subject of a complaint, including the factual admissions made in the document containing the apology, is not admissible in any civil or administrative proceeding, in a criminal prosecution or in an arbitration as evidence of the fault, liability or culpability of any person in connection with that matter.

79(3) Notwithstanding subsection (2), if a person makes an apology while testifying at a civil proceeding, including while testifying at an out of court examination in the context of the civil proceeding, at an administrative proceeding, in a criminal trial or at an arbitration, this section does not apply to the apology for the purposes of that proceeding or arbitration.

*Source: New Brunswick Pharmacy Act, 2014.*

## Schedule of QMP Audits

Process	Jan	Feb	Mar	April	May	June	July	Aug	Sept	Oct	Nov	Dec
<b>1. Staff Performance (Annually)</b>												
<b>2. Drug Inventory (minimum every 3 months)</b>												
<b>i.</b> Check & Removal of outdated stock												
<b>ii.</b> Documentation of notices to pharmacies of drug recalls, drug warnings and adverse drug reactions (ADRs)												
<b>iii.</b> Documentation of reporting of ADRs by pharmacists to Health Canada												
<b>iv.</b> Narcotic Reconciliation (minimum every 3 months)												
<b>3. Equipment and Facilities (minimum annually; more frequently as per equipment requirements)</b>												
<b>i.</b> Valid certification of equipment (e.g. fridge, automated tablet counter, sterile hood, compound equipment, blood pressure monitor, scale, etc.)												
<b>ii.</b> Facility safety (refer to Occupational Health and Safety requirements in New Brunswick) <sup>1</sup>												
<b>4. Adherence to Standards of Practice (record at quarterly staff meetings)</b>												
<b>i.</b> Ensuring ongoing adherence to all NBCP deficiency correction action plan(s) of pharmacies												
<b>ii.</b> Monitoring process of documented CQI plan(s)												
<b>iii.</b> Documentation of staff meetings (quarterly: standard)												
<b>iv.</b> Completion of medication safety self-assessments (annually)												

<sup>1</sup> <https://www.worksafenb.ca/employers/health-safety/employer-responsibilities/>

<b>5. An audit of Quality Related Events</b> <b>i. Documentation of the reporting of QREs to an independent, third-party organization (quarterly)</b>												
<b>ii. Documentation of medication incidents (quarterly)</b>												

## **Annual Medication Safety Self-Assessment Improvement Plan Form**

Below are resource links to the ISMP version of medication safety self-assessment improvement plan form, along with a supporting document from SaskPharm that provides guidance on completing the ISMP MSSA

- Community Pharmacy: <https://mssa2.ismp-canada.org/comm-pharm-ii>
- Hospital Pharmacy: <https://mssa2.ismp-canada.org/hospital>

### Guide

- [https://saskpharm.ca/document/4246/MSSA%20Quick%20Start%20Guide%20ISMP%20Canada\\_201805](https://saskpharm.ca/document/4246/MSSA%20Quick%20Start%20Guide%20ISMP%20Canada_201805)

## Frequently Asked Questions (FAQs)

### **What is a Quality Related Event (QRE)?**

As defined in the MMIR Standards, “QREs include alleged or suspected medication incidents that reach the patient **as well as** those that are intercepted (near miss) prior to dispensing.”

### **Do all QREs need to be reported?**

As stated in the MMIR Standards, “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 intercepted medication incident, its implication for patient safety, and the extent to which it is reoccurring.” However, as per Standard 2, all medication incidents that reach a patient must be recorded both anonymously online, as well as being readily retrievable records in their entirety within the pharmacy.

### **What is a coordinator?**

Each store will ideally select at least two coordinators, preferably one pharmacist (which may be the pharmacy manager) and one pharmacy technician (if there is one on staff). These coordinators will be responsible for training their staff by creating an open dialogue on QREs. These individuals are responsible to bring the pharmacy team together annually to complete a medication safety self-assessment survey, train staff to use their reporting platform, and to schedule and facilitate quarterly QRE review meetings.

### **Is it mandatory to have a CQA/QMP binder?**

No, the College does not require a particular format, whether that is a binder or an electronic format, as long as that format is accessible to all pharmacy team members. Additionally, the CQA/QMP materials are to be organized, complete, and easily retrievable when requested by Practice Advisors.

### **Why do pharmacies have to complete a medication safety self-assessment survey annually?**

Annual completion of a medication safety self-assessment survey will provide pharmacies with the ability to assess their pharmacy services with the goal of working towards ongoing improvement, independent of any QREs. This is considered a proactive CQA activity. By completing a medication safety self-assessment each year, a pharmacy can produce reports to monitor their progress in improvement.

### **Is there a fee for the use of a medication safety self-assessment and a reporting platform?**

Yes. Both reporting platforms and medication safety self-assessment tools are associated with fees for use.

**Is there a paper form that can be used in place of the online form?**

Participants can choose to use paper forms to collect incident reports if they prefer. Paper forms can be collected from staff and entered manually into the online reporting system in a timely manner after discovery of the QRE, to ensure that all information is captured for the production of QRE reports.

**Is the information that is submitted to my reporting platform confidential?**

Yes, the information submitted to your reporting platform does not include identifiers for either the individual entering the data or the patient affected by medication incidents or near misses. This ensures anonymity of all individuals involved in the incident. The specific information submitted by individual pharmacies can only be viewed by that particular pharmacy by logging in using their username and password.

**What are quarterly QRE reviews?**

At least once every 90 days, teams within each pharmacy, including pharmacy managers, staff pharmacists, pharmacy technicians and other staff, are to meet to discuss the previous quarter's QREs and to formulate strategies to reduce the likelihood of them occurring in the future. Pharmacy managers may decide that such meetings may take place more frequently.