



Complaint Resolution Process Map and Risk Assessment Tool

2021

Introduction

The College of Pharmacists of Manitoba (College) protects the health and well-being of the public by ensuring and promoting safe, patient-centred, and progressive pharmacy practice. One of the mechanisms that allow the College to fulfil this mission is the Complaints and Discipline Process. *The Pharmaceutical Act (The Act)* grants authority over this process to the Complaints Committee and the Discipline Committee. This process map documents the pathways available to these committees in achieving a resolution satisfactory to the complainant, to uphold the trust and protection of the public.

Who is the Complaints Committee?

The Committee is made up of five members; three licensed pharmacists who are appointed by the College Council, and two public representatives who are appointed by the Minister of Health. This ensures that the public is well represented in all complaint matters, and supports the mandate of the College to ensure that the interests and safety of the public remain secure.

How are Complaints Resolved?



All seven phases of the complaint resolution process are represented above. While an investigation, and subsequent review of the outgoing investigation report, are not always necessary steps in every complaint, all other phases occur in the resolution of every complaint.


Receiving Complaints

Complaints can be submitted by anyone, but must be done in writing (email or formal correspondence) as a requirement of *The Act*. Upon receipt, all complaints are reviewed and risk assessed for patient safety before being forwarded to the Complaints Committee for review. Should a complaint rank as high risk, the College will take protective measures to ensure the safety of the public prior to review by the Complaints Committee. High risk complaints are rare. Typically, complaints follow the established process for review and consideration.


Notice of Complaint

The complaint resolution process is not anonymous. The involved pharmacist and/or pharmacy manager are provided with a copy of the complaint, and provided two weeks to submit a written response for consideration by the Complaints Committee. The involved pharmacist(s) are advised not to contact the complainant specific to the complaint, but are required to continue providing pharmacy services and communication as necessary for continuity of care as applicable.


Initial Review

 The Complaints Committee will review the complaint and the response and consider if any additional information is required in order to make a decision in the matter. If the Committee has all of the necessary information, the Complaints Committee will make the decision at that time. When additional information is required, an investigation will be ordered and a College investigator is appointed.


Investigation

 The investigation process can be lengthy. Evidence and statements are gathered from multiple pharmacy staff and the complainant. An unbiased report is written and submitted to the Complaints Committee for consideration. The investigator does not make recommendations to the Complaints Committee as their role is simply to gather the facts of the matter for the Complaints Committee to consider.

Review of Investigation Report

 The Complaints Committee will then review the investigation report and determine a decision from there.

Decisions of the Complaints Committee


 The Complaints Committee is empowered to make several decisions by *The Act*, including a decision that no further action is necessary. Some examples of complaints that may result in this decision include ones that are outside the jurisdictional scope of the College or identify that the matter is a customer service issue where no professional misconduct has occurred.

In many cases, the Committee will send a formal letter of guidance to the pharmacy/pharmacist for them to implement independently to improve practice. These letters are valuable learning opportunities for improving patient care and communication.

The Committee may censure the investigated person. A censure is a remedial and educational caution about practice(s) that may put the public at risk. Entering into a voluntary agreement is also an option available to the Committee and the investigated person.

Finally, the Complaints Committee may refer the matter to the Discipline Committee, which would hold a hearing to determine appropriate action. Following a hearing, and a finding of professional misconduct, the Discipline Committee may reprimand the registrant, suspend a licence or registration, cancel a licence or registration, accept an undertaking to limit practice, impose conditions, or require treatment or counselling to be taken by the investigated person. The investigated person may appeal the decision of the Discipline Committee.

Appeal

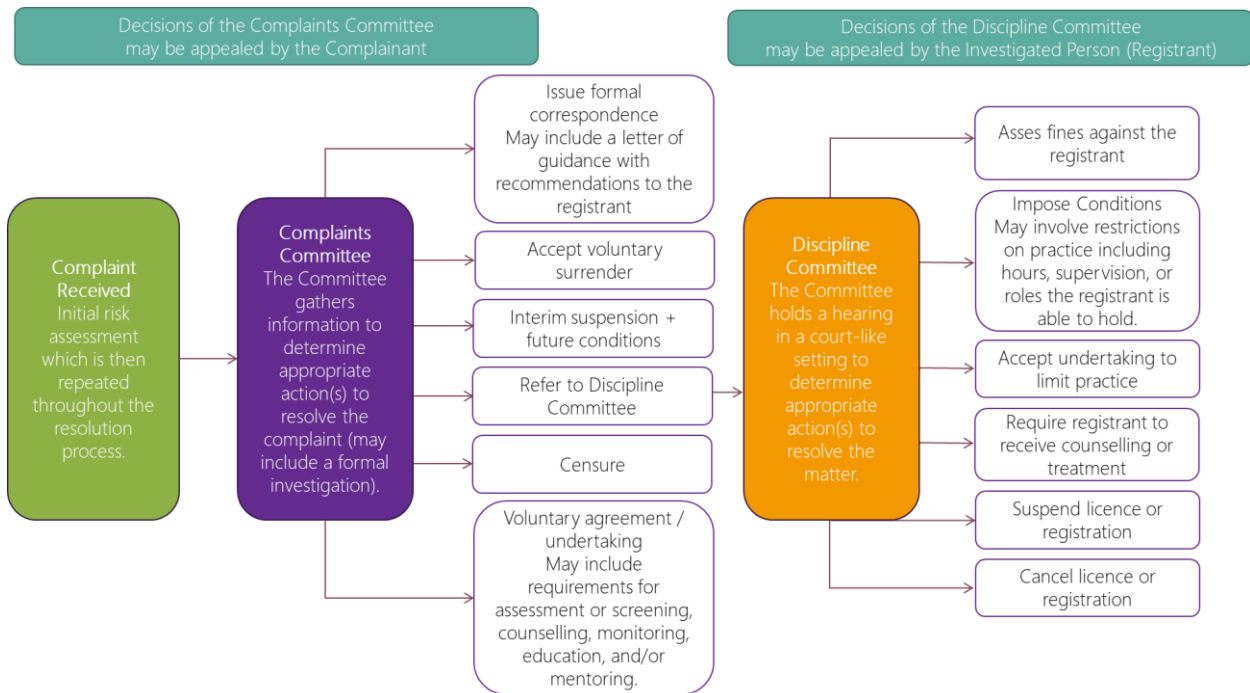
 A complainant may appeal decisions of the Complaints Committee to an appeal panel.

How is Risk Assessed?

Throughout the complaint resolution process displayed on the following pages, risk assessment is critical and continual until the matter is concluded. If the concern or conduct of a registrant (typically a pharmacist) or pharmacy presents or is likely to present a serious risk to the public, their licence may be suspended on an interim basis pending the outcome of the matter. Decisions on interim suspensions are made using a Risk Assessment framework on pg. 3.

Risk assessment is a continual practice applied throughout the resolution process. This means that the possibility of an interim suspension remains until the matter is closed. Interim suspensions are typically followed by conditions placed on the licence that was suspended, before a full return to practice is allowed. This applies to both a pharmacist's practicing licence and a pharmacy's licence.

What Decisions can the Complaints and Discipline Committees Make?



Risk Assessment Framework

A pharmacist's practicing licence or a pharmacy licence may be suspended on an interim basis either by the Registrar when the College becomes aware of the concern(s), or by the Complaints Committee during the resolution process. Before a licence is suspended, the concern(s) are reviewed to determine if the concern/conduct presents, or is likely to present, a serious risk to the public.

(1) Does the pharmacist's conduct expose, or is it likely to expose, patients to serious harm?

Consider the severity of the harm involved and whether any terms, conditions or limitations short of an interim suspension would be sufficient in preventing the seriousness of harm.

Yes

No – Interim suspension is not required

(2) Is the pharmacist likely to continue conduct that places patients at risk of serious harm?

Consider whether you can trust the pharmacist to comply with measures already in place. Consider the pharmacist's relevant prior history.

Yes

No – Interim suspension is not required

(3) What intervention would prevent the potential harm?

The principles of "Right Touch Regulation" include proportionality, whereby regulators should only intervene when necessary and with remedies appropriate to the risk and with minimized costs. In other words, regulators should ask – what is the minimum intervention needed?

An interim suspension or voluntary surrender of licence is necessary to prevent the potential harm to patients

What terms, conditions and limitations would prevent the potential harm?

If there are terms, conditions or limitations short of an interim suspension that would prevent potential harm, these should be employed rather than an interim suspension.

Risk Analysis Tool

Risk Assessment	Definition	Potential Outcome
No/Minimal Risk	Does not support taking regulatory actions	No action
Low Risk	Unlikely to have direct impact on patient care, safety, or the public interest	Guidance letters
Moderate Risk	Clinical issues requiring remediation OR concerns related to a registrant's conduct that may have direct impact on patient care, safety, or the public interest	Censure, focused remediation, undertaking, supervision, conditions, discipline referral
Serious/High Risk	Serious concerns regarding registrant's conduct or practice likely to have direct impact on patient care, safety, or the public interest OR concerns that cannot be addressed through remediation OR issues that require removal from practice	Discipline referral, referral to other agencies (if needed), undertaking

How to Use this Tool

Using the definitions in the table above, indicate the type of risk posed by applicable areas of concern in the table below. The type of risk posed then guides the decision-maker to potential outcomes available in the table above.

Area of Concern	N/A	No/Minimal Risk/Concerns	Low Risk/Concerns	Moderate Risk/Concerns	Serious/High Risk/Concerns
Patient Harm/Safety					
Ethics					
Professional Judgement					
Documentation/ Recordkeeping					
Patient-Informed Consent					
Communication or Conflict Management					
Practice Management Protocols					
Billing or Financial					
Personal Health Information Breach					
Conflict of Interest					
Fitness to Practice					
Sexual Abuse					

Area of Concern	N/A	No/Minimal Risk/Concerns	Low Risk/Concerns	Moderate Risk/Concerns	Serious/High Risk/Concerns
Boundary Violations					
Professionalism					
Non-Compliance with Previous Order from the College					
Other:					

What are mitigating factors and aggravating factors that should be considered?

Mitigation Factors:

- No prior history/one-time incident
- No intent to harm
- No intent to deceive
- Honesty
- Willingness to address the issue
- Cooperation/governability
- Reflection/remorse
- Extenuating circumstances requiring action
- Good character/reputation
- No harm to patient or public
- Voluntary admission
- Open to remediation
- Low number of concerns/allegations
- No financial gain
- Low likelihood of recurrence

Aggravating Factors:

- Prior history/pattern of behaviour
- Intentional actions
- Deception or dishonesty
- Lack of willingness to address the issue
- Lack of cooperation/governability
- Lack of reflection/remorse
- Poor character/reputation
- Harm to patient or public
- Lack of admission of guilt
- Lack of rehabilitation potential
- High number of concerns/allegations
- Financial gain
- High likelihood of recurrence

References

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- College of Licensed Practical Nurses of Manitoba. «Investigation Decision Making Pathway.»
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- Russell, Kathleen A, and Beth K Radtke. «An Evidence-Based Tool for Regulatory Decision Making: The Regulatory Decision Pathway.» *Journal of Nursing Regulation* 5, no. 2 (July 2014).