Ontario College of Pharmacists
Putting patients first since 1871

Risk Assessment Framework

Purpose: *This framework applies to all complaints, reports and other information received by the College about a registrant's conduct or capacity. It provides a consistent way for the College to determine the level of risk of the concern. Then the assigned level of risk is used to prioritize work.*

Three Levels of Risk

LOW RISK

No practice concerns are identified, or the concerns are mild and unlikely to have a direct impact on patient care, safety, or the public interest.

MODERATE RISK

Concerns are likely to have an impact on patient care, safety, or the public interest.

HIGH RISK

Concerns are serious and likely to have a significant impact on patient care, safety, or the public interest.

How to Determine the Level of Risk

STEP 1:
IDENTIFY THE CATEGORY OF THE CONCERN(S)

For every concern, the College will identify a category (or categories) based on the details provided. Each category has been assigned a general level of risk.

LOW	MODERATE	HIGH
• Communication/Service • Confidentiality • Non-Practice Related • Recordkeeping/ Documentation	• Billing • Business Practices • Expanded Scope • Other Conduct/ Behaviour • Charges/Findings • Dispensing • Narcotic/ Controlled Drugs • Supervision/ Training • Therapeutics	• Boundary Violation • Failure to Fulfill a College Requirement • Health Concerns • Sexual Abuse • Sexual Harassment • Unauthorized Practice

Note: If multiple categories apply to the concern, the category with the highest risk level is used. Category definitions are provided on page 4.

STEP 2:
IDENTIFY ANY FACTORS THAT MAY INCREASE THE RISK

The level of risk may be higher than the one assigned to the concern's category if certain factors are present.

For example, risk level may increase if the concern involves any of the following:

- Registrant has similar past concerns
- Red flag drug
- Red flag patient
- High risk practice
- Actual harm or risk of harm

- Risk of eroding public trust
- Governability of registrant
- General disregard for ethical principles
- Reckless or intentionally risky behaviour

Note: Please see the definitions provided on page 6.

STEP 3:
IDENTIFY ANY FACTORS THAT MAY DECREASE THE RISK

The level of risk may be lower than the one assigned to the concern's category if certain factors are present.

For example, the risk level may decrease if the concern involves any of the following:

- No actual harm or risk of harm
- Registrant no longer practicing

- No urgent public safety issues
  - E.g., The registrant has already identified the problem and taken steps to address it.

STEP 4:
ASSIGN LEVEL OF RISK AND PRIORITIZE

The initial risk level is assigned as low, moderate, or high based on the assessments in steps 1-3 and the information available to the College at the time. The risk level can change as more information is collected or as an investigation continues.

Once we know the risk level, College staff uses it to prioritize our work. For example, we may focus our resources first on an investigation into a concern that is assigned a high level of risk.

STEP 5:
REASSESS LEVEL OF RISK AS MORE INFORMATION IS AVAILABLE

As we get further information while looking into the concern, we will repeat steps 1-4 and adjust the risk level if needed.

An Example of How the Risk Assessment Framework Is Applied

STEP 1:
IDENTIFY THE CATEGORY OF THE CONCERN(S)

A complaint is recieved about a dispensing incident. This would fall under the Dispensing category, which is listed as a **Moderate risk**.

STEP 2:
IDENTIFY ANY FACTORS THAT MAY INCREASE THE RISK

The incident involved an elderly patient who was dispensed hydroxyzine instead of hydralazine. The patient experienced side effects and was hospitalized.

The patient is a red flag patient and experienced severe harm. These are relevant factors that may increase risk. Therefore, the level of risk is changed to **High risk**.

STEP 3:
IDENTIFY ANY FACTORS THAT MAY DECREASE THE RISK

There are no relevant factors that may decrease the level of risk. Therefore, the complaint remains **High risk**.

STEP 4:
ASSIGN LEVEL OF RISK AND PRIORITIZE

Based on steps 1-3, the complaint is classified as **High risk** during the intakes process. Therefore, the intakes team prioritizes the complaint and proceeds to request records and information from the pharmacy where the incident occured.

STEP 5:
REASSESS LEVEL OF RISK AS MORE INFORMATION IS AVAILABLE

The College receives the pharmacy's records. Based on the information provided, the category of concern, the increasing risk factors and the decreasing risk factors do not change from the initial assessment. Therefore, the complaint remains **High risk**.

College staff will continue to reassess the level of risk throughout the investigation.

Definitions

Categories of Concerns

CATEGORY	DESCRIPTION
Billing	Concerns related to a fee, billing or account submitted by or on behalf of a registrant. Examples include: • failure to disclose to a patient the fee for a service before the service is provided • failure to provide itemized accounting for services and/or products on request • a charge that does not align with the College's guidance on billing Relevant resource: Fees for Professional Pharmacy Services Policy
Boundary Violation	A boundary violation is when a relationship changes from professional and clinical to unprofessional and inappropriate. It occurs when a registrant does not establish and/or maintain the boundaries of a professional relationship with their patient and/or abuses their power. Boundary violations: • exploit the power imbalance inherent in the registrant-patient relationship • may be sexual or non-sexual in nature Relevant resource: Boundary Violations and Sexual Abuse Policy
Business Practices	Concerns related to the business practices of the pharmacy that may affect patient care. Examples include: • discontinuing professional services • entering into an agreement that restricts a person's choice of a pharmacist • soliciting or permitting the solicitation of an individual • returning to stock or re-selling or re-dispensing a drug that was previously sold or dispensed • practicing while in a conflict of interest Relevant resource: O. Reg. 130/17 Professional Misconduct
Charges/Findings	Registrant has been charged with or found guilty of an offence under the *Criminal Code* (Canada) or the *Controlled Drugs and Substances Act* (Canada).
Communication/ Service	Concerns related to the way a registrant communicates to a patient, which could include: • casual or uncaring attitude • disrespect • insensitivity • addressing nontherapeutic or culturally inappropriate matters Also includes concerns related to the service received by a patient from the registrant.
Confidentiality	Confidentiality concerns can include: • failing to keep a patient's personal health information or other personal information confidential • accessing a person's health record without a professional reason to do so Relevant resources: O. Reg. 130/17 Professional Misconduct
Dispensing	Dispensing concerns relate to the dispensing of a medication and can include: dispensing incidents* • labelling issues • expired products • issues related to compounded products Dispensing incidents: any preventable event or error that could cause or lead to inappropriate medication use or patient harm.

Definitions

Categories of Concerns (continued)

CATEGORY	DESCRIPTION
Expanded Scope	Expanded scope concerns are related to a registrant's practice involving expanded scope acts, including: • administering vaccines • adapting/renewing prescriptions • performing point of care tests • prescribing drugs for certain minor ailments
Failure to Fulfill a College Requirement	Concerns related to the failure to fulfill a College requirement can include: • failing to cooperate with an inspector of the College appointed for purposes of the *Drug and Pharmacies Regulation Act* • failing to reply within a reasonable time to a request from the College • failing to appear before the Inquiries, Complaints and Reports Committee for a caution • failing to carry out or abide by an undertaking given to the College or breaching an agreement with the College • contravening a term, condition or limitation on the registrant's certificate of registration Relevant resource: O. Reg. 130/17 Professional Misconduct
Health Concerns	Registrants may have substance use problems or suffer from a physical or mental condition or disorder that has the potential to interfere with their pharmacy practice. These concerns may be investigated to determine if the registrant is incapacitated, as that term is defined under section 1(1) of the *Health Professions Procedural Code*: "that the registrant is suffering from a physical or mental condition or disorder that makes it desirable in the interest of the public that their practice be subject to terms, conditions or limitations, or that they no longer be permitted to practise." Relevant resource: Health Inquiry Process
Narcotic/ Controlled Drugs	A registrant's conduct is in contravention of federal or provincial regulations for the provision and procurement of narcotics and controlled substances.
Non-Practice Related	Concerns outside of the scope of practice of pharmacy that do not fall under another category..
Other Conduct/ Behaviour	Conduct or behaviour that is not defined in any other category.
Recordkeeping/ Documentation	Concerns related to recordkeeping or documentation can include: • failing to keep patient or practice records as required • falsifying a record related to the registrant's practice • falsifying a person's health record. Relevant resource: O. Reg. 130/17 Professional Misconduct
Sexual Abuse	Sexual abuse of a patient is defined under section 1(3) of the *Health Professions Procedural Code* as: (a) sexual intercourse or other forms of physical sexual relations between the registrant and the patient, (b) touching, of a sexual nature, of the patient by the registrant, or (c) behaviour or remarks of a sexual nature by the registrant towards the patient. 1993, c. 37, s. 4.

Definitions

Categories of Concerns (continued)

CATEGORY	DESCRIPTION
Sexual Harassment	Sexual harassment concerns include: • engaging in a course of knowingly unwelcome vexatious comments or conduct because of sex, sexual orientation or gender identity • making a knowingly unwanted sexual advance
Supervision/ Training	Concerns related to supervision and training include: • failure to provide an appropriate level of supervision to a person whom the registrant was professional obligated to supervise • failure to adequately supervise the overall operation of the pharmacy Relevant resource: O. Reg. 130/17 Professional Misconduct Designated Manager – Professional Supervision of Pharmacy Personnel Policy
Therapeutics	Conduct involving inadequate or inappropriate care because of failing to perform a proper patient assessment.
Unauthorized Practice	Concerns related to unauthorized practice include: • performing acts outside of the registrant's scope of practice • practicing while their certificate of registration is suspended

Other Relevant Terms

CATEGORY	DESCRIPTION
Governability	Governability is the willingness of a registrant to accept the regulatory authority of the College. The level of risk of a concern may increase where a registrant is unwilling to accept this authority, as this may result in them being unlikely to fulfill their professional obligations or potentially harm the reputation and standing of the profession.
High Risk Practice	High risk practices are pharmacy activities that have an increased risk of causing adverse outcomes or potential patient harm. These activities require the use of strict quality assurance measures, enhanced monitoring and specialized training to mitigate the risks involved. Examples include opioid agonist therapy, sterile compounding and compliance packaging.
Red Flag Drug	Drugs that have a higher risk of causing significant patient harm when they are used in error. Relevant resource: ISMP List of High-Alert Medications
Red Flag Patient	A red flag patient is a patient that has an increased likelihood of experiencing adverse health outcomes or complications. These patients may require special attention, monitoring or interventions to ensure optimal care. Examples of red flag patients include seniors, infants and children, individuals with a greater chance of medical complications and individuals with compromised immune function.