Ontario College of Pharmacists

Putting patients first since 1871

Reporting Obligations for Pharmacy Professionals

This chart summarizes the statutory reporting obligations of pharmacy professionals, as mandated by legislation and/or College By-Laws.

It is a resource for information only and should not be considered legal advice. It does not address self-declarations made at the time of annual renewal nor the recording of medication events through the Assurance in Medication Safety (AIMS) Program. Voluntary reporting in situations *not* presented below is left to the discretion of the registrant.

When in doubt, registrants should file a report rather than risking potential legislative penalty.

Contents

Changes to personal information

Log into the OCP online account portal **within 30 days** to update your:

- Address and telephone number of your principal residence
- Preferred address, telephone number, and e-mail address for communications from the College
- Details about each place of practice, inside or outside of Ontario
- Designated Practice Assessment (DPA) site[1] in Ontario

Legislative reference(s)

College's By-Law No. 7

Additional resources

Practice Assessment

New Non-Accredited Workplace form

RegistrantServices @OCPInfo.com

Conduct of a registered personal support worker (PSW)

File a mandatory report to the Health and Supportive Care Providers Oversight Authority **within 30 days** if you have:

- Reasonable grounds to believe a registered PSW has sexually abused a patient

Legislative reference(s)

Health Professions Procedural Code (Schedule 2 of the *Regulated Health Professions Act,* s. 85.1[b])

Additional resources

Mandatory Reporting

Conduct of another registered pharmacy professional

File a mandatory report to OCP by fax to 416-847-8499 or by email to Concerns@ OCPInfo.com **within 30 days** if you have:

- Reasonable grounds to believe a registrant has sexually abused a patient
- Terminated, revoked, suspended, or imposed restrictions on the privileges of a registrant for reasons of professional misconduct, incompetence, or incapacity
- A registrant employee who has resigned or voluntarily relinquished or restricted their practice for reasons of (or, during an investigation into allegations of) professional misconduct, incompetence, or incapacity
- Dissolved a partnership, health profession corporation, or association with a registrant for reasons of professional misconduct, incompetence, or incapacity

[1] A practice site in Ontario where a registrant provides patient care and their practice assessment takes place, which may be or may not be their primary place of practice.

Legislative reference(s)

Health Professions Procedural Code (Schedule 2 of the *Regulated Health Professions Act,* s. 52[1], 85.1, 85.5)

Additional resources

Mandatory Reporting

Fitness to Practice – What Does Incapacitated Mean

Conduct of another regulated health professional (RHP)

File a mandatory report to the regulatory body for the health professional being reported **within 30 days** if you:

- Have reasonable grounds to believe that an RHP has sexually abused a patient
- Have terminated, revoked, suspended, or imposed restrictions on the privileges of an RHP for reasons of professional misconduct, incompetence, or incapacity
- Employ an RHP who has resigned, voluntarily relinquished or restricted their practice for reasons of (or, during an investigation into allegations of) professional misconduct, incompetence, or incapacity
- Have dissolved a partnership, health profession corporation or association with an RHP for reasons of professional misconduct, incompetence, or incapacity

Legislative reference(s)

Health Professions Procedural Code (Schedule 2 of the *Regulated Health Professions Act,* s. 85.1, 85.5)

Additional resources

Mandatory Reporting

Health Profession Regulators of Ontario

Incidents involving Class A precursors[2] (pharmacists and hospitals only)

File a report to the local police detachment or OPP **within 24 hours** upon discovery of:

- Unusual waste or disappearance of a Class A precursor that cannot be explained by normally accepted business practices

Report to the minister of Health (Canada)[3] **within 72 hours** after discovery of:

- Theft of a Class A precursor set out in column 1 of the schedule, if in a package not intended for retail sale and the quantity exceeds the maximum quantity specified in column 2 of the schedule

Legislative reference(s)

Precursor Control Regulations under the *Controlled Drugs and Substances Act* s. 91.96

[2] Class A precursor means any substance set out in Part 1, and any preparation or mixture referred to in Part 3, of Schedule VI to the *Controlled Drugs and Substances Act*.

[3] Include confirmation that the police have been notified.

Additional resources

Reporting loss or theft of controlled substances or precursors

ocs.reporting-rapporter.bsc@hc-sc.gc.ca

Incidents involving controlled substances (*pharmacists only*)

Report to the Minister of Health (Canada) **within 10 days:**

- Any loss or theft of **controlled substances**[4] (including dispensed prescription forgeries)
- If you are moving/transporting/transferring a controlled substance from one pharmacy to another (e.g., due to a relocation or permanent closure)

Legislative reference(s)

Narcotic Control Regulations, s. 42, s. 45(3)

Benzodiazepine and Other Targeted Substances Regulations, s. 56, s. 72(2) *(cont.)*

Food and Drug Regulations, Part G, G.03.012, G.03.016

Additional resources

Controlled Substances: Reporting Loss or Theft

Pharmacy Closing Statement

Office of Controlled Substances

Incidents involving therapeutic products *(hospitals only)*[5]

File a report to Health Canada (Canada Vigilance Program or MedEffect Canada) **within 30 days** about **serious adverse drug reactions (ADRs)**[6] involving therapeutic products regulated under the *Food and Drugs Act* such as:

- Pharmaceuticals (e.g., prescription and non-prescription drugs; drugs released in response to an urgent public health need)
- Biologic drugs (i.e., biotechnology products, blood products with a Drug Identification Number, and vaccines – except those administered under Ontario's routine immunization program)
- Radiopharmaceutical drugs
- Hard surface disinfectants[7] with a Drug Identification Number

[4] A drug named in the federal *Controlled Drug and Substances Act (CDSA),* Schedules I, II, III, IV, V. These drugs are also listed in the schedules to the regulations as narcotics, controlled drugs, benzodiazepines, and other targeted substances.

[5] Pharmacy professionals should follow the hospital's procedures for reporting. Outpatient clinics that are legally part of the hospital are subject to these obligations even if they are physically separate from the hospital. Pharmacy professionals in other practice settings should report these events, as per the Standards of Operation for Pharmacies.

[6] "Serious adverse drug reaction" is defined as a "noxious and unintended response to a drug which occurs at any dose and requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening, or results in death."

[7] "Disinfectant" is defined as "a substance, or mixture of substances, capable of destroying or irreversibly inactivating pathogenic (disease-causing) and potentially pathogenic (opportunistic) microorganisms, but not necessarily bacterial spores, present on environmental surfaces and inanimate objects due to the antimicrobial action of the active ingredient(s)."

Legislative reference(s)
Food and Drugs Act, s. 21.8
Food and Drug Regulations, *C.01.020.1*
Medical Devices Regulations

File a report to Health Canada (Canada Vigilance Program or MedEffect Canada) **within 30 days** about a **medical device incident (MDI)**[8] involving therapeutic products regulated under the *Medical Device Regulations* such as:

- Hospital beds, wheelchairs, leg prostheses
- Infusion sets, syringes, tracheostomy tubes, urethral catheters
- Infusion pumps, anesthesia gas machines, intrauterine devices
- Pacemakers, defibrillators, breast implants, bone grafts

Legislative reference(s)
Food and Drugs Act, s. 21.8
Medical Devices Regulations

Additional resources
Overview of Vanessa's Law and Mandatory Hospital Reporting Requirements
Health Canada guidance document: Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals

Prescription forgery

File a report to the Ontario Drug Benefit program by email (drugprogramsdelivery@ontario.ca) **as soon as possible after discovery** about a prescription forgery for a monitored drug[9] including the following information:

- The prescriber's name, address, phone/fax number *(cont.)*
- The name(s) of the drug(s)
- A copy of the prescription and any additional forged documents

If any quantity of the fraudulent prescription was dispensed, refer to the section on **incidents involving controlled substances.**

Legislative reference(s)
Narcotics Safety and Awareness Act (NSAA)
Ontario Regulation 381/11 – General

[8] "Medical device incident" is an incident related to a failure of a medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use that has led to the death or a serious deterioration in the state of health of a patient, user, or other person, or could do so were it to recur.
[9] "Monitored drug" means a controlled substance as defined in the *Controlled Drugs and Substances Act* and any drug that is an opioid.

Additional resources
Management and Reporting of Fraudulent Prescriptions
Tips for Identifying Fraudulent Prescriptions
Executive Officer Notice: Forgery Notification Alerts
Frequently asked questions

Privacy breach

Give written notice to the appropriate regulatory college **within 30 days** if, due to the **unauthorized collection, use, disclosure, retention, or disposal of personal health information**[10] (PHI), you have:

- Terminated, suspended, or taken disciplinary action toward a regulated health professional
- Revoked, suspended or restricted privileges of, or affiliation with, a regulated health professional
- Reasonable grounds to believe a regulated health professional has resigned or relinquished or voluntarily restricted their privileges or affiliation with you due to an investigation or other action with respect to an alleged privacy breach

Legislative reference(s)
Personal Health Information Protection Act (PHIPA), s. 12(3), s. 17.1, s. 55.5(7)(b)

Additional resources
Health Profession Regulators of Ontario

File a report with the Information and Privacy Commissioner of Ontario **as soon as possible after discovery** when:

- Personal health information is lost or stolen, used, or disclosed without authority[11]
- Written notice is given to a regulatory college of an event that relates to a loss, unauthorized use or disclosure of personal health information by a healthcare professional

Legislative reference(s)
Ontario Regulation 329/04 – General under the *Personal Health Information Protection Act*, s. 6.3, s. 6.4, s. 18.3

Additional resources
Responding to a Health Privacy Breach – Guidelines for the Health Sector
Reporting a Health Privacy Breach – Guidelines for the Health Sector
Report a Privacy Breach

File a report with the Information and Privacy Commissioner of Ontario at the Online Statistics Submission website **annually, by March 1,** if:

- You have statistics of privacy breaches related to PHI within your custody from the previous calendar year

[10] As defined in the *Personal Health Information Protection Act*, s. 4.
[11] This includes theft of physical and electronic health records, theft of a device containing records, and ransomware/malware attacks.

Legislative reference(s)

- *Ontario Regulation 329/04 – General* under the *Personal Health Information Protection Act*, s. 6.3, s. 6.4, s. 18.3

Additional resources

Annual Reporting of Privacy Breach Statistics to the Commissioner

Health Privacy Breach Statistical Report – FAQ - IPC

Sale of compounded antimicrobial preparations for veterinary use

File a report Health Canada (Veterinary Antimicrobial Sales Reporting) annually, by March 31, on annual sales of compounded preparations for veterinary use containing:

- Antimicrobial active pharmaceutical ingredients (API) on List A, even if sourced from a drug in dosage form and not the raw ingredient

Legislative reference(s)

Food and Drug Regulations, C.01.612 (1)

Additional resources

Guidance on veterinary antimicrobial sales reporting

vasr-vavr@hc-sc.gc.ca

Self-reporting

File a self-reporting form to OCP (by fax to 416-847-8499 or email to Concerns@ OCPInfo.com) **as soon as possible** if you:

- Have been charged with and/or found guilty of any offence[12] and any conditions of release (e.g., bail, restrictions)
- Have been the subject of a disciplinary finding or a finding of professional misconduct or incompetence[13] by another regulatory or licensing authority, in any jurisdiction
- Have had a civil court finding of professional negligence or malpractice *(cont.)*
- Are the subject of an investigation, review, or proceeding for professional misconduct, incompetence, or incapacity[14] with respect to the practice of pharmacy or any other profession or occupation, in any jurisdiction
- Are the subject of a civil court proceeding in any jurisdiction with respect to the practice of pharmacy or any other profession or occupation
- Are a member of another body that governs a profession in any jurisdiction
- Have failed to maintain personal professional liability insurance in Ontario
- Are no longer a citizen or permanent resident of Canada
- No longer have a valid work permit

[12] An offence defined under the *Criminal Code* or the *Controlled Drugs and Substances Act (CDSA)* of Canada.

[13] When the panel of a discipline committee finds the registrant's professional care of a patient displayed a lack of knowledge, skills, or judgment of a nature or to an extent that demonstrates that the registrant is unfit to continue to practice or that their practice should be restricted.

[14] Suffering from a physical or mental condition or disorder that makes it desirable in the interest of the public that the registrant's certificate of registration be subject to terms, conditions, or limitations, or that the registrant no longer be permitted to practice.

Legislative reference(s)

Ontario Regulation 256/24, s. 9 under the *Pharmacy Act*

Health Professions Procedural Code (Schedule 2 of the *Regulated Health Professions Act,* s. 85.6.1, 85.6.2, 85.6.3, 85.6.4)

Ontario Regulation 261/18 under the *Regulated Health Professions Act*

OCP By-Law No. 7

Additional resources

Self-Reporting

Personal Professional Liability Insurance

Canadian Citizenship or Legal Status in Canada

Fitness to Practice – What Does Incapacitated Mean

OCP Concerns: 1-800-220-1921, ext. 3800

Suspected harm to a child

File a mandatory report to the Children's Aid Society or Indigenous Child and Family Well-Being Agency **as soon as possible** if you have reasonable grounds to suspect that a child under the age of 16 years needs protection because:

- They have suffered, or are at risk of suffering, physical harm inflicted by their caregiver[15] or resulting from that caregiver's failure to adequately care for, provide for, supervise, or protect the child
- They have been sexually abused or exploited or are at risk for sexual abuse or exploitation, including child sex trafficking
- Their caregiver does not provide (or provide access or consent to) the service or treatment when they:
  - require treatment to cure, prevent, or alleviate physical harm or suffering
  - have suffered or are likely to suffer emotional harm[16] resulting from their caregiver's actions, failure to act, or pattern of neglect
  - are younger than 12 years old and have killed or seriously injured another person or caused serious damage to another person's property
  - suffer from a mental, emotional, or developmental condition that, if not remedied, could seriously impair their development
- They are younger than 12 years old and have more than once injured another person or caused loss or damage to another person's property either with the caregiver's encouragement or due to the caregiver's failure or inability to supervise the child adequately
- Their parent has died or is unavailable to exercise their rights of, or has not made adequate provisions for, the child's care and custody
- They are in a residential placement and their parent refuses or is unable or unwilling to resume the child's care and custody

Legislative reference(s)

Child Youth and Family Services Act (CYFSA), s. 74(2), s. 125

Additional resources

Yes, You Can. Dispelling the Myths About Sharing Information with Children's Aid Societies

Reporting Child Abuse and Neglect: It's Your Duty

[15] The *Child, Youth and Family Services Act, 2017,* does not define or differentiate between kinds of caregivers. The language used in the legislation is "parent" or "person having charge of the child."

[16] Emotional harm can be demonstrated by serious anxiety, depression, withdrawal, self-destructive or aggressive behaviour, or delayed development.

Suspected harm to a resident of a long-term care home[17]

File a mandatory report to the director of the long-term care home **as soon as possible** if you are an employee of the home or of their pharmacy service provider[18] and have reasonable grounds to suspect that any of the following has occurred or may occur:

- Improper or incompetent treatment or care that resulted in harm or a risk of harm to the resident
- Abuse of a resident by anybody or neglect by the licensee or staff that resulted in harm or a risk of harm to the resident
- Unlawful conduct that resulted in harm or a risk of harm to a resident
- Misuse or misappropriation of a resident's money
- Misuse or misappropriation of funding provided to a licensee

Legislative reference(s)
Fixing Long-Term Care Act (FLTCA), s. 28

Additional resources
Long-Term Care Home Complaint Process
Elder Abuse Prevention Ontario – Reporting
OntarioHealthAtHome.ca

Suspected harm to residents in a retirement home

File a mandatory report to the registrar of the Retirement Homes Regulatory Authority **as soon as possible** if you have reasonable grounds to suspect that any of the following has occurred or may:

- Improper or incompetent treatment or care[19] that resulted in harm or the risk of harm to the resident
- Abuse or neglect[20] by the licensee or staff that resulted in harm or risk of harm to the resident
- Unlawful conduct[21] that resulted in harm or risk of harm to a resident
- Misuse or misappropriation of a resident's money

Legislative reference(s)
Retirement Homes Act, s. 75

Additional resources
Reporting Harm
Elder Abuse Prevention Ontario – Reporting

[17] "Long-term care home" means a place licensed as a long-term care home under the *FLTCA,* and includes a municipal home, joint home or First Nations home approved under Part IX. May also be referred to informally as a "nursing home," "assisted living," "group home," etc. Check www.ontariohealthathome.ca to confirm that a home is licensed.
[18] Any person can report harm or neglect or make other complaints by calling the Long-Term Care ACTION Line toll-free at: 1-866-434-0144.
[19] Improper or incompetent treatment or care could include mishandling of a resident during care or a mistake/error in providing care (e.g., with medications).
[20] Abuse could be emotional, physical, sexual, verbal, and/or financial. Neglect could include failure to provide care or assistance to a resident.
[21] Unlawful conduct could include theft of medication by staff, unlawful fees being charged, unlawful eviction, or other illegal activity.

Vaccine-related incidents and reportable diseases
File an Adverse Event Following Immunization (AEFI) Reporting Form to the Medical Officer of the Public Health Unit[22] **as soon as possible** if you recognize the presence of a reportable event and form the opinion that it may be related to the administration of an immunizing agent (vaccine). Reportable events after administration include: • Persistent crying or screaming, anaphylaxis or anaphylactic shock occurring within 48 hours • Shock-like collapse, high fever, or convulsions occurring within 3 days • Arthritis occurring within 42 days • Generalized urticaria, residual seizure disorder, encephalopathy, encephalitis, or any other significant occurrence occurring within 15 days • Death occurring at any time following a symptom described above Legislative reference(s) *Health Protection and Promotion Act* (HPPA), s. 38 Additional resources AEFI Reporting Form AEFI Reporting Fact Sheet File a report with your local public health unit **as soon as possible** if you form the opinion that the person to whom you are providing professional services has or may have: • A disease of public health significance (DOPHS) listed in Column 1 of the Table in *O. Reg. 135/18*. Legislative reference(s) *Health Protection and Promotion Act* (HPPA), s. 25 *Ontario Regulation 135/18*: *Designation of Diseases* Additional resources Infectious Diseases Protocol 2023

Last updated: April 22, 2026

[22] In hospitals, the hospital administrator has the duty to report (s. 27) and pharmacy professionals should follow the hospital's procedures for reportable events.