

DRAFT: Not for Circulation



**Ontario College
of Pharmacists**

Putting patients first since 1871

STANDARDS OF OPERATION FOR PHARMACIES

STANDARDS OF OPERATION

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TERMS (Continued on next page)

Accredited Pharmacy: A pharmacy that has applied to the College and been granted a certificate of accreditation that permits the owner to operate a pharmacy.

Automated Pharmacy System: An automated pharmacy system is a mechanical system that performs operations or activities with respect to the storage and packaging of drugs or medications, and with respect to their dispensing or distribution directly to patients.

Cold Chain: A cold chain is a temperature-controlled supply chain. A cold chain is mandatory where products require a given temperature range during distribution and storage. Products that have not been maintained at the appropriate temperature are considered to be unsafe for distribution and sale.

Contact Person: The person(s) designated in a hospital pharmacy or an institutional pharmacy as the contact with the College.

Designated Manager: The pharmacist designated by the owner(s), in information provided to the College, as responsible for managing the pharmacy. The designated manager carries the same liability for the operation of the pharmacy as the owner(s).

Equipment: Healthcare devices used for diagnosis, monitoring, or treatment over an extended period, generally requiring greater investment, ongoing maintenance, and in some cases specialized training to operate safely and effectively.

Governance: There are clear definitions within the practice location of the rules, practices and processes in which the pharmacy is managed. Governance includes outlining the roles and accountabilities of the people involved in providing and managing pharmacy services.

Hospital Pharmacy Administrator: The person with oversight of the hospital pharmacy operation who is accountable for ensuring that all systems required to provide safe and effective pharmacy services are in place. The Administrator is not required to be a member of the College.

Medication Incident: A Medication Incident is defined as any preventable event that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, or systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Owner: The person or persons, who own the pharmacy, and where the owner is or includes a corporation, includes each director of the corporation. Every owner is responsible for ensuring the pharmacy is operated according to the law.

Pharmacy Professional Member: A regulated health professional registered with the College.

Pharmacy Services: ~~A framework of a services that augment drug therapy, including enhanced medication related services, expanded patient care services and core dispensing services.~~ Patient care activities provided by a pharmacy professional within the scope of practice of pharmacy and the authorized acts of the profession, as defined in the *Pharmacy Act*.

Pharmacy Staff: All individuals who perform activities, tasks, or functions within a pharmacy or that support the operation of a pharmacy, regardless of their employment status, professional designation, or level of regulation. This includes regulated pharmacy professionals and non-regulated personnel who contribute to the delivery of pharmacy services or the functioning of the pharmacy environment.

Remote Dispensing Location: A remote dispensing location means a place where drugs are

dispensed or sold by retail to the public and that is operated by, but is not at the same location as, a pharmacy whose certificate of accreditation permits its operation.

TERMS (continued)

Risk Assessment and Management: Risk assessment and management systems are those which provide a structured approach to identifying and managing errors associated with an area of practice that is high risk and, therefore, has a greater potential for patient harm. Examples of high risk practices include compounding, dispensing methadone, high volume dispensing, and dispensing blister packs; these are all practices that may be associated with a greater than normal risk to patient safety.

Supplies: Consumable items intended for immediate or short-term use that support assessment, treatment, or patient care, are typically simple to use, have limited durability, and require frequent replacement or disposal.

Safe Medication Practices: Safe medication practices prevent and reduce medication errors through established policies and procedures and continuous quality improvement. Components of a safe medication practice include providing access to current medication information, systems to identify high alert medications and procedures to store, count, administer, and dispose of medications. Wherever possible, an independent double check is used to verify products against prescriptions, and to check repackaged and labelled medications and volumes for reconstituted preparations prior to release.

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INTRODUCTION

The purpose of the Standards of Operation for Pharmacies is to facilitate the creation of the optimal environment for the safe and effective practice of pharmacy and to support the regulation of pharmacies in Ontario within the context of the outcome-based regulations under the *Drug and Pharmacies Regulation Act, 1990 (DPRA)*.

The standards apply to all accredited pharmacies to facilitate the creation and sustaining of the optimal environment for the safe and effective practice of pharmacy and should be read in conjunction with the requirements established through legislation, College policies and guidelines, Standards of Practice for Pharmacists and Pharmacy Technicians, and the Code of Ethics. Members of the College, hospital pharmacy administrators, owners and directors, including non-pharmacist directors, are responsible for meeting these standards.

The College holds pharmacists, pharmacy technicians, designated managers, directors (on behalf of corporations), and hospital administrators (on behalf of hospitals) fully accountable where professional obligations, expectations and responsibilities are not met, and equally enforces the clearly outlined responsibilities accorded to each role.

All regulated health professionals working in the pharmacy should be familiar with these standards, and pharmacists and pharmacy technicians must understand that they are expected to raise concerns with the management of the pharmacy if they believe these standards are not being met and/or there is a perceived risk to patients related to pharmacy operations.

These standards address topics related to:

- Governance and legal compliance;
- Management and employee relations;
- Pharmacy premises and environment;
- Delivering services;
- Equipment and technology;
- Information management; and
- Quality improvement and medication safety.

The pharmacy environment includes the premises of the pharmacy along with the equipment, systems and staffing required to protect against and mitigate risks associated with the delivery of services, and as importantly, the culture established by the management of the pharmacy to support pharmacy professionals to meet the standards of professional practice.

In a hospital, the College has oversight over any location deemed to be a pharmacy in the regulations, anywhere drugs are compounded, dispensed or supplied for hospital patients, and any other location where drugs are stored or supplied from. In the case of the hospital pharmacy, access is secured and drug storage areas are protected with the appropriate security measures.

PRINCIPLES

This document is organized according to principles and standards. The principles provide the foundation on which the outcomes outlined in regulations to the *Drug and Pharmacies Regulation Act* are met.

GOVERNANCE AND LEGAL COMPLIANCE:

Pharmacies are operated in compliance with the law, according to the requirements set by the College, and in keeping with the Code of Ethics.

MANAGEMENT AND EMPLOYEE RELATIONS:

Pharmacy professionals ~~Members~~ are empowered to exercise independent authority within their scope of practice to optimize patient care, fulfill professional obligations, and protect the health, safety and wellbeing of patients and the public.

PHARMACY PREMISES:

The pharmacy environment is appropriate for the services provided, and organized and maintained to support patient and staff safety.

DELIVERING SERVICES:

Policies and procedures are developed and implemented to support service delivery in accordance with accepted policies, guidelines and standards of professional practice.

EQUIPMENT AND TECHNOLOGY:

The equipment and technology used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients, the public and staff.

INFORMATION MANAGEMENT:

Pharmacy professionals have access to the information systems and technological support that enables them to meet the standards of practice of the profession.

SAFE MEDICATION MANAGEMENT SYSTEM AND QUALITY IMPROVEMENT:

The pharmacy has implemented a safe medication management system and quality improvement program to support patient safety.

1 **GOVERNANCE AND LEGAL COMPLIANCE**

2 **Pharmacies are operated in compliance with the law, according to the requirements**
3 **set by the College, and in keeping with the Code of Ethics.**

4
5 **STANDARDS**

6 The pharmacy is in compliance with relevant legislation and regulations governing pharmacy
7 accreditation, services and operations, privacy and security that are applicable in Ontario.

8 Pharmacies must also ensure that provincial and national standards, and all requirements established
9 by the College are met by the pharmacy and/or support professional practice.

10 **Option for new standards:**

11 Pharmacy staff are supported by policies, procedures, training, and monitoring practices to provide
12 pharmacy services in a manner that respects a person’s dignity and abides by provincial human rights
13 legislation.

14 Pharmacy services are delivered in a manner that is compliant with the relevant provincial legislation
15 on accessibility for persons with disabilities and associated regulations, including considering and
16 accommodating the patient’s physical, cognitive, and sensory abilities; level of health literacy; and
17 level of digital literacy up to the point of undue hardship.

18 Owners, shareholders, officers and directors, whether or not they are registered with the College,
19 understand their responsibilities and liabilities in regard to the operation and accreditation of the
20 pharmacy.

21 The designated manager/hospital administrator understands their role and responsibilities with respect to
22 the accreditation and management of the pharmacy, including medication procurement and inventory
23 management, supervision of pharmacy personnel, and required signage.

24 Pharmacy staff members receive orientation and have access to the policies and procedures
25 established by the owner and/or designated manager and understand their responsibilities to maintain
26 the standards of accreditation.

27 Mechanisms are in place that allow feedback and concerns about the pharmacy, services and staff to
28 be raised, and these are taken into account and action taken where appropriate.

29
30

31 **Additional Resources**

- 32 Code of Ethics
- 33 Policy – Medication Procurement and Inventory Management
- 34 Policy – Supervision of Pharmacy Personnel
- 35 Guidance – Accreditation and Operation of a Pharmacy

36 MANAGEMENT AND EMPLOYEE RELATIONS

37 **Pharmacy professionals** ~~Members~~ are empowered to exercise independent authority
38 within their scope of practice to optimize patient care, fulfill professional obligations,
39 and protect the health, safety and wellbeing of patients and the public.

40 STANDARDS

42 All pharmacy staff ~~members~~ are oriented to the regulatory framework that governs both the place and
43 the practice of pharmacy.

44 ~~The pharmacy has an adequate number of qualified and trained staff to maintain the accepted~~
45 ~~standards of professional practice, and to deliver safe and effective patient care.~~

46 **Options to replace above standard (lines 44-45):**

47 ~~The pharmacy is staffed at all times with the number of qualified and trained staff required for~~
48 ~~pharmacy professionals to maintain the standards of practice while providing pharmacy services.~~

49 ~~The pharmacy workflow is managed to permit pharmacy professionals adequate time to maintain the~~
50 ~~standards of practice and to support pharmacy professional wellbeing.~~

51 The pharmacy is operated within a culture of openness, honesty and learning. Staff and management
52 roles, responsibilities and accountabilities are understood and accepted.

53 Pharmacy staff ~~members~~ and trainees are provided with the appropriate level of supervision or
54 delegation.

55 Pharmacy professionals employed have the skills, qualifications and competence to provide patient
56 care and optimize health outcomes for patients.

57 Pharmacy professionals are provided access to the resources and training necessary to support
58 patient outcomes.

59 Management ensures that pharmacy professionals comply with their professional and legal
60 obligations and are empowered to exercise professional judgement in the interests of patients and the
61 public.

62 Incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or
63 the professional judgement of staff.

64 Pharmacy professionals are empowered to provide feedback and raise concerns about how pharmacy
65 services are organized and delivered.

66 Additional Resources

68 Code of Ethics

69 Standards of Practice

- 70 • Standards of Practice for Pharmacists
- 71 • Standards of Practice for Pharmacy Technicians

72 Policy – Medical Directives and the Delegation of Controlled Acts

73 Policy – Opioid Policy

74 Policy – Supervision of Pharmacy Personnel

78 PHARMACY PREMISES

79 The pharmacy environment is appropriate for the services provided, and organized and
80 maintained to support patient, public and staff safety.

81 82 STANDARDS

83 The pharmacy is designed, constructed and maintained to ensure the integrity and the safe and
84 appropriate storage of all drugs and medications; including, the proper conditions of sanitation,
85 temperature, light, humidity, ventilation, segregation and security.

86 The pharmacy is designed to permit optimal work flow management, mitigate risk, support patient care
87 and maintain safe and effective drug distribution while providing healthcare and services to patients.

88 **Option to replace lines 99-100 below:**

89 The pharmacy premises meet the requirements outlined in provincial accessibility legislation and
90 associated regulations, supporting patient's right to access pharmacy services and the human rights of
91 all pharmacy staff and patients.

92 The pharmacy is designed to protect the privacy, dignity and confidentiality of patients and the public
93 who receive pharmacy services.

94 **Option to expand lines 92-93 above:**

95 The pharmacy has a separate and distinct area for patient consultation where the provision of
96 pharmacy services may take place without being overheard by others and which respects the privacy
97 needs of each patient. This includes both acoustical and visual privacy, as appropriate for the pharmacy
98 service provided and determined to be acceptable by the patient.

99 The public areas of the pharmacy meet legislated standards for accessibility for persons with
100 disabilities.

101 There is a program to ensure the regular cleaning of the pharmacy, including all premises, furniture,
102 equipment and appliances, and automated pharmacy systems, if any.

103 **Option to replace above standard (lines 101-102):**

104 Procedures are in place that ensure appropriate infection prevention and control practices are
105 occurring. This includes cleaning the premises, furniture, equipment and appliances, and automated
106 pharmacy systems, if any, on a regular and as needed basis.

107 Controlled drugs and substances are stored and managed according to national guidelines and
108 provincial requirements.

109 There is a program for the safe return and disposal of prescription drugs according to national and
110 provincial guidelines.

111

112 113 Additional Resources

114 Code of Ethics

115 Standards for Pharmacy Compounding

- 116 • Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations

117 • Standards for Pharmacy Compounding of Hazardous Sterile Preparations
118 • Standards for Pharmacy Compounding of Non-Sterile Preparations
119 Standards of Practice
120 • Standards of Practice for Pharmacists
121 • Standards of Practice for Pharmacy Technicians
122 Policy – Time Delayed Safes
123 Guideline – Administering a Substance by Injection
124 Guideline – Administering a Substance by Inhalation
125 Guidance – Accreditation and Operation of a Pharmacy
126 • Checklist – Opening a New Pharmacy
127 • Required Reference Guide for Ontario Pharmacies (Pharmacy Library)
128 Guidance – Operation of a Remote Dispensing Location (RDL)
129 • Checklist – Opening a RDL Dispensary staffed by a Pharmacy Technician
130 • Checklist – Opening a RDL with an Automated Pharmacy System (APS)

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DELIVERING SERVICES

Policies and Procedures are developed and implemented to support service delivery in accordance with accepted policies, guidelines and standards of professional practice.

STANDARDS

The dispensary is secure and safeguarded from unauthorized access and drugs are located in the area of the pharmacy consistent with the appropriate drug schedule classification. ~~to support optimal practice.~~

Procedures are in place to maintain safe and effective procurement and inventory management. Medicines and medical devices are:

- Obtained from a reputable source
- Safe and fit for purpose
- Stored securely
- Safeguarded from unauthorized access
- Supplied to the patient safely
- Disposed of safely and securely

Equipment and facilities are used in a way that protects the privacy and dignity of the patients and the public who receive pharmacy services.

Option to replace 151-153:

~~Pharmacy staff members receive the appropriate training to deliver specialized services, such as sterile compounding for example, and the pharmacy is constructed to address any risks to staff or the public associated with pharmacy practice.~~

Pharmacy staff are trained on operational processes and procedures commensurate with their role and the pharmacy services provided.

Option to shift lines 156-158 away from practice focus to operations focus:

~~All services are~~ The pharmacy workflow enables pharmacy professionals to deliver pharmacy services to patients based on a review and assessment of patients' unique circumstances and provided in a patient-centred way to respect dignity and therapeutic outcomes.

Patients are provided the information needed to make decisions about their health and health care.

~~Documentation and record keeping requirements are established and all of the required records are kept and maintained.~~

Option to replace above standard (lines 160-161):

Procedures are in place that enable pharmacy professionals to document the care and services provided in a timely and consistent manner, and include:

- Training requirements for how to use the pharmacy's records management system
- Protocols regarding who must document, the information that must be documented, and options for managing delays in documenting information

169 The pharmacy has the clinical decision support tools, reference databases, and patient health
170 information sufficient to allow pharmacy professionals to exercise independent authority within their
171 scope of practice to provide patient care.

174 **Additional Resources (Continued on next page)**

175 Code of Ethics

176 Standards for Pharmacy Compounding

- 177 • Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations
- 178 • Standards for Pharmacy Compounding of Hazardous Sterile Preparations
- 179 • Standards for Pharmacy Compounding of Non-Sterile Preparations

180 Standards of Practice

- 181 • Standards of Practice for Pharmacists
- 182 • Standards of Practice for Pharmacy Technicians

183 Policy – Faxed Transmission of Prescriptions

184 Policy – Opioid Policy

185 Policy – Operating Internet Sites

186 Guideline – Administering a Substance by Injection

187 Guideline – Administering a Substance by Inhalation

188 Guideline – Documentation

189 Guideline – Record Retention, Disclosure and Disposal

190 Guidance – Accreditation and Operation of a Pharmacy

- 191 • Checklist – Opening a New Pharmacy
- 192 • Required Reference Guide for Ontario Pharmacies (Pharmacy Library)

193 Guidance – Operation of a Remote Dispensing Location

- 194 • Checklist – Opening a RDL Dispensary staffed by a Pharmacy Technician
- 195 • Checklist – Opening a RDL with an Automated Pharmacy System (APS)

EQUIPMENT AND TECHNOLOGY

The equipment, supplies, and technology used in the provision of pharmacy services safeguard the health, safety and wellbeing of patients, the public and staff.

STANDARDS

The pharmacy has the appropriate layout, equipment, supplies, and technology to support the delivery of pharmacy services.

The pharmacy has the facilities, systems and equipment needed to meet the requirements established in legislation, and to safeguard the health, safety and wellbeing of patients and the public, including:

- Facilities for washing utensils and sterilizing equipment;
- Specialized equipment for the practice of pharmacy; The necessary equipment for the pharmacy services provided;
- Adequate work space; Workspaces that are adequate and appropriate for the services provided;
- Hand-washing facilities for employees;
- Secure and temperature appropriate storage facilities.

~~Equipment is calibrated and certified as required supported documentation.~~

Option to expand and clarify line 214:

Procedures are in place to facilitate the safe and effective use of equipment and supplies, in accordance with their intended purpose, and include:

- Maintenance, calibration, and certification of equipment as per manufacturer instructions or other supporting documentation
- Documentation of equipment maintenance, calibration, and certification that is available and readily retrievable

Additional Resources

Standards for Pharmacy Compounding

- Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations
- Standards for Pharmacy Compounding of Hazardous Sterile Preparations
- Standards for Pharmacy Compounding of Non-Sterile Preparations

Policy – Medication Procurement and Inventory Management

Policy – Protecting the Cold Chain

Guidance – Accreditation and Operation of a Pharmacy

- Checklist – Opening a New Pharmacy

Guidance – Operation of a Remote Dispensing Location

- Checklist – Opening a RDL Dispensary staffed by a Pharmacy Technician
- Checklist – Opening a RDL with an Automated Pharmacy System (APS)

237 INFORMATION MANAGEMENT

238 Pharmacy professionals have access to the information systems and technological
239 support that enables them to meet the standards of practice of the profession.

240 STANDARDS 241

242 The information technology deployed at the pharmacy meets the minimum standards for national
243 technical, functional and administrative requirements outlined in national standards for pharmacy
244 practice management systems.

245 Pharmacy professionals are able to access references and resources as required to support the
246 delivery of patient care.

247 The personal health information of patients and those who receive pharmacy services is protected
248 through the implementation of both administrative and technical safeguards.

249 Option to clarify lines 250-253:

250 Procedures are in place for the management of patient records, including an established schedule for the retention, retrieval and destruction of information. The pharmacy has an
251

252 The pharmacy has technology necessary for the storage and retrieval of all documents associated
253 with the practice of pharmacy at that location.
254

255 Additional Resources 256

- 257 Code of Ethics
- 258 Policy – Centralized Prescription Processing (Central Fill)
- 259 Policy – Operating Internet Sites
- 260 Guideline – Record Retention, Disclosure and Disposal
- 261 Guidance – Accreditation and Operation of a Pharmacy
 - 262 • Checklist – Opening a New Pharmacy
 - 263 • Required Reference Guide for Ontario Pharmacies (Pharmacy Library)
- 264 Guidance – Operation of a Remote Dispensing Location
 - 265 • Checklist – Opening a RDL Dispensary staffed by a Pharmacy Technician
 - 266 • Checklist – Opening a RDL with an Automated Pharmacy System (APS)
- 267 Pharmacy Practice Management System Requirements
 - 268 • Pharmacy Practice Management Systems Supplemental Requirements

SAFE MEDICATION MANAGEMENT SYSTEM AND QUALITY IMPROVEMENT:

The Pharmacy has implemented a safe medication management system and quality improvement program to support patient safety.

STANDARDS

Pharmacy services are effectively managed and delivered to support patient safety, according to requirements established by the College. Quality improvement practices include a process for detecting, recording, analysing, correcting and sharing lessons learned from medication incidents.

The community pharmacy has implemented the Medication Safety Program in a manner that supports pharmacy professionals in meeting the requirements under the supplemental Standard of Practice.

In hospitals, the organization supports pharmacy professionals in meeting the requirements under the Supplemental Standard of Practice by reporting incidents involving medications to the safety incident management system.

Pharmacy professionals are aware of obligations to report adverse reactions involving medications, including prescription and non-prescription medications, natural health products, and vaccines, and are supported to do so.

Additional Resources

Code of Ethics

Standards of Practice

- Standards of Practice for Pharmacists
- Standards of Practice for Pharmacy Technicians
- Supplemental Standard of Practice

Policy – Medication Procurement and Inventory Management

Guidance – Accreditation and Operation of a Pharmacy

- Checklist – Opening a New Pharmacy
- Pharmacy Safety Self-Assessment (PSSA).
- Pharmacy Safety Self-Assessment User Guide

IMPLEMENTATION

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Revision History

Version #	Date	Action
1.00	September 2018	Standards of Operation for Pharmacies initial release.
2.00	Date TBD	Several standards revised, and new standards added to support the implementation of expanded scope of practice.