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Ontario College of Pharmacists

Putting patients first since 1871

STANDARDS OF OPERATION FOR PHARMACIES

STANDARDS OF OPERATION

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. A remote dispensing location is under the supervision of a pharmacist who may not be physically present, but is available to staff and the public by audio-visual link.

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.

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.

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.

STANDARDS

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

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

Option for new standards:

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

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

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

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

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

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

Additional Resources

Code of Ethics
Policy – Medication Procurement and Inventory Management
Policy – Supervision of Pharmacy Personnel
Guidance – Accreditation and Operation of a Pharmacy

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.

STANDARDS

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

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

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

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

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

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

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

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

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

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

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

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

Additional Resources

Code of Ethics

Standards of Practice

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

Policy – Medical Directives and the Delegation of Controlled Acts

Policy – Opioid Policy

Policy – Supervision of Pharmacy Personnel

PHARMACY PREMISES

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

STANDARDS

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

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

Option to replace lines 99-100 below:

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

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

Option to expand lines 92-93 above:

The pharmacy has a separate and distinct area for patient consultation where the provision of pharmacy services may take place without being overheard by others and which respects the privacy needs of each patient. This includes both acoustical and visual privacy, as appropriate for the pharmacy service provided and determined to be acceptable by the patient. Such an area must also be provided in RDLs, where a private direct audio-visual link with the remote supervising pharmacist is available.

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

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

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

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

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

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

Additional Resources

Code of Ethics

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

Standards of Practice

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

Policy – Time Delayed Safes

Guideline – Administering a Substance by Injection

Guideline – Administering a Substance by Inhalation

Guidance – Accreditation and Operation of a Pharmacy

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

Guidance – Operation of a Remote Dispensing Location (RDL)

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

These checklists need to be reviewed.
It is suggested that the point of care symbol for an RDL be of a different colour and amended to include the following statements "This is a remote dispensing location. A pharmacist may not be on-site, but one is available for remote consultation." These statements could alternatively be required within a Notice to Patients sign.
Furthermore, the checklist must include:
- that clear identification of the pharmacy professional manning the site, i.e., their degree and title, and that they are listed in the OCP Register
- verification that there is a private consultation area of the RDL and assurance that an audio-visual link to the supervising/remotely located pharmacist is available and is not within hearing of other patients nor of the Pharmacy professional manning the site.

DELIVERING SERVICES

Policies and Procedures are developed, documented, 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 associated ~~commensurate~~ with their role and scope of practice 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 a patient's ~~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 ~~s~~ management system
- Protocols regarding who must document, the information that must be documented, and options for managing delays in documenting information

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

Additional Resources (Continued on next page)

Code of Ethics

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

Standards of Practice

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

Policy – Faxed Transmission of Prescriptions

Policy – Opioid Policy

Policy – Operating Internet Sites

Guideline – Administering a Substance by Injection

Guideline – Administering a Substance by Inhalation

Guideline – Documentation

Guideline – Record Retention, Disclosure and Disposal

Guidance – Accreditation and Operation of a Pharmacy

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

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)

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.
If an RDL loses its audio-visual link with the remote supervising pharmacist, operation must cease.
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)

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.

STANDARDS

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

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

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

Option to clarify lines 250-253:

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

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

Additional Resources

Code of Ethics
Policy – Centralized Prescription Processing (Central Fill)
Policy – Operating Internet Sites
Guideline – Record Retention, Disclosure and Disposal
Guidance – Accreditation and Operation of a Pharmacy
- Checklist – Opening a New Pharmacy
- Required Reference Guide for Ontario Pharmacies (Pharmacy Library)

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)

Pharmacy Practice Management System Requirements
- 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.