



COUNCIL BRIEFING NOTE

MEETING DATE: SEPTEMBER 2018

FOR DECISION

X

FOR INFORMATION

INITIATED BY: Susan James, Director of Quality

TOPIC: Standards of Operation

ISSUE: Approval of Standards of Operation for pharmacies in Ontario.

BACKGROUND:

- The Ontario College of Pharmacists (“the College”) has developed draft [Standards of Operation](#) that clarify the expectations regarding the operation of pharmacies in Ontario.
- Following the changes to the *Drug and Pharmacies Regulation Act* (DPRA) in 2016, the Standards of Operation are required to clarify the expectations of the College for accredited community and hospital pharmacies.
- Specific details outlining expectations for the operation of pharmacies were removed from the general regulations of the DPRA in favour of an outcome-based model which would allow the College to regulate in a more responsible and flexible manner. The College committed to formalizing these expectations as Standards of Operation for pharmacies.
- The purpose of the Standards of Operation 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 DPRA.
- Within the Standards of Operation, the following changes to existing requirements were made:
 - Revisions to the Required Reference Guide for Ontario Pharmacies are being proposed, including revised Minimum Library Requirements. Rather than specifying that all pharmacies have a subscription to a Drug Information Service, the new requirements are outcome focused and allow pharmacy professionals to assess their practice and determine what references and resources are required to best meet their need. At a minimum, every pharmacy must continue to have at least one reference in each of the following areas: Canadian Drug Reference / Compendium; Drug Interaction Publication; Drug Therapy Publication; and Patient Counselling Guide.
 - Clear expectations regarding the implementation of the medication safety program, including a requirement that the environment allows for the [supplemental Standard of Practice](#) (sSOP) to be met. The sSOP, posted for consultation at the same time as the Standards of Operation, outlines the expectations for Ontario pharmacy professionals regarding medication safety based on the existing NAPRA Model Standards of Practice.

- No other changes were introduced through the Standards of Operation.
- The College posted the draft Standards of Operation for public consultation from June 22nd to August 6th, 2018.

ANALYSIS:

- The [consultation](#) resulted in nine responses; seven from pharmacists and two from associations (Ontario Pharmacists Association (OPA) and Canadian Society of Hospital Pharmacists (CSHP)).
- The comments fell into two themes: Lack of clarity on expectations, and concerns over changes to the required reference guide.

1. Lack of clarity on expectations:

Consultation Feedback:

- Two pharmacists, and both associations identified a need for further clarity on the expectations outlined in the standards.

College Response:

- Moving to an outcome-based model allows the College to regulate in a more responsible and flexible manner and necessitates less operational detail. However, the concerns around lack of clarity are important to consider throughout the implementation process. Access to existing guidelines, fact sheets, policies and related legislation will continue to be available through direct hyperlinks in the Standards. The College will ensure additional communication materials are made available if necessary

2. Feedback related to changes to the reference guide:

Consultation Feedback:

- Three pharmacists and one association (OPA) voiced concern over the revised Minimum Library Requirements.
- Respondents noted that removal of the requirement to have an annual subscription to a drug information service could prevent access to information in situations where pharmacists are not given open access to the internet, thus limiting pharmacist access to drug information as needed. However, one respondent voiced support of the revised reference materials.

College Response:

- The removal of the requirement for a specific subscription service is intended to allow pharmacy professionals the flexibility to select references and resources required to support the delivery of patient care.
- Through routine pharmacy assessments and communication with pharmacy owners, designated managers and organizations, the College will stress the expectation that pharmacy professionals must continue to be able to access the references and resources required to support the delivery of patient care.

- Concerns that fell outside the scope of this consultation included:
 - Recommending that the College require that the Hospital Pharmacy Administrator be a registered member of the College.
 - One pharmacist and one association identified this as an issue.
 - Concerns over the fees the College charges.
 - One pharmacist identified this as an issue.
 - Eliminating Preferred Pharmacy Networks
 - One pharmacist identified this as an issue.
- One consultation, from the Neighbourhood Pharmacy Association of Canada (NPAC), was submitted after the consultation deadline. NPAC stated support of the Standards of Operation, and agreed that the minor changes made are in the best interest of patients and the public.

Based on the analysis of the feedback and the absence of any opposition to the proposed Standards of Operation, no revisions to the proposed Standards are suggested.

NEXT STEPS:

- Pending Council approval, the Standards of Operation will be posted on the College's website, and communicated broadly with clarifying information.
- With the exception of the minor changes described above, the requirements in the Standards of Operation were unchanged and are already in effect. The minor changes will come into effect upon Council approval.
- Updated pharmacy assessment tools that reflect the Standards of Operation, for both community and hospital pharmacy, will be implemented in Winter 2019.

FOR DECISION FOR COUNCIL:

Recommend that Council approve the Standards of Operation to clarify the expectations of the College for accredited community and hospital pharmacies.

ONTARIO COLLEGE OF PHARMACISTS

STANDARDS OF OPERATION FOR PHARMACIES

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STANDARDS OF OPERATION

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TERMS

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).

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.

Member: A regulated health professional registered with the College.

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 Services: A framework of a services that augment drug therapy, including enhanced medication related services, expanded patient care services and core dispensing services.

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.

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.

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 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 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:

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

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

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 understands his / her 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 — Professional Supervision and Pharmacy Personnel](#)

[Policy — Required Signage in a Pharmacy](#)

[Guidance - Accreditation and Operation of a Pharmacy](#)

MANAGEMENT AND EMPLOYEE RELATIONS

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.

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 -- Administering a Substance by Injection or Inhalation](#)

[Policy - Medical Policy Directives and the Delegation of Controlled Acts](#)

[Policy - Methadone Maintenance Treatment \(MMT\) and Dispensing](#)

[Policy — Professional Supervision and Pharmacy Personnel](#)

[Guidance - Operation of a Remote Dispensing Location](#)

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.

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

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.

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 -- Administering a Substance by Injection or Inhalation

Guidance - Accreditation and Operation of a Pharmacy

- [Checklist – Opening a New Pharmacy](#)
- [Checklist – Opening a Remote Dispensing Location](#)
- [Required Reference Guide for Ontario Pharmacies \(Pharmacy Library\)](#)

Guidance - Operation of a Remote Dispensing Location

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.

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.

All services are based on a review and assessment of patients' circumstances and provided in order to optimize 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.

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 -- Administering a Substance by Injection or Inhalation](#)

[Policy – Faxed Transmission of Prescriptions](#)

[Policy - Methadone Maintenance Treatment \(MMT\) and Dispensing](#)

[Policy -- Operating Internet Sites](#)

[Guideline — Documentation](#)

[Guideline — Record Retention, Disclosure and Disposal](#)

Guidance - Accreditation and Operation of a Pharmacy

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

Guidance - Operation of a Remote Dispensing Location

Methadone Maintenance Treatment (MMT) and Dispensing Policy

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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.

STANDARDS

The pharmacy has the appropriate layout, equipment and technology to support practice.

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;
- Adequate work space;
- Hand-washing facilities for employees;
- Secure and temperature appropriate storage facilities.

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

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](#)
- [Checklist – Opening a Remote Dispensing Location](#)

Guidance - Operation of a Remote Dispensing Location

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.

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](#)
- [Checklist – Opening a Remote Dispensing Location](#)
- [Required Reference Guide for Ontario Pharmacies \(Pharmacy Library\)](#)

[Guidance - Operation of a Remote Dispensing Location](#)

[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 -- Centralized Prescription Processing \(Central Fill\)](#)

[Policy — Medication Procurement and Inventory Management](#)

[Policy – Protecting the Cold Chain](#)

[Guideline -- Multi-Medication Compliance Aids](#)

[Guidance - Accreditation and Operation of a Pharmacy](#)

- [Checklist – Opening a New Pharmacy](#)
- [Checklist – Opening a Remote Dispensing Location](#)

[Guidance - Operation of a Remote Dispensing Location](#)