

## **Hospital Pharmacy Assessment Criteria**

The following chart outlines the hospital pharmacy operations criteria that are used by Hospital Operations Advisors (HOAs) when conducting a hospital pharmacy assessment. The document is divided into categories and for each category specific standards are identified with a link to the appropriate reference (legislation, standards, policies, guidelines, etc.). The guidance section illustrates specific activities required to ensure adherence to the standard and is provided to assist pharmacy professionals in understanding expectations and preparing for an assessment. Educational resources may also be listed in the Guidance column to provide additional information.

Any location where drugs are stored, compounded, dispensed, supplied from or supplied for hospital patients (by a hospital, in premises located in a hospital, whether inpatient or outpatient) is deemed to be a pharmacy<sup>1</sup>. For the purposes of an assessment, the standards will be evaluated both in the primary pharmacy location itself (where applicable) and in other locations throughout the hospital (e.g., wards, patient care units, pharmacy satellites, etc.) referred to as “patient care areas” hereafter.

Hospital pharmacy administrators and Chief Executive Officers (CEO)/owners are responsible for implementing and maintaining the standards of [accreditation](#) and [operation](#) of the pharmacy<sup>2</sup>. Failure to maintain the standards could result in referral to the Accreditation Committee and may constitute proprietary misconduct and/or professional misconduct.

### **CATEGORIES**

#### **Hospital Pharmacy, Patient Care Areas**

- [Standards of Operation](#)
  - [MEDICATION STORAGE & SECURITY IN PATIENT CARE AREAS](#)
  - [SAFE MEDICATION MANAGEMENT SYSTEMS IN PATIENT CARE AREAS](#)
  - [CONTROLLED SUBSTANCES IN PATIENT CARE AREAS](#)
  - [RECORD RETENTION, AUDITABILITY AND TRACEABILITY](#)

#### **Hospital Pharmacy, Primary Location(s)**

- [Standards of Operation](#)
  - [MEDICATION STORAGE & SECURITY IN PHARMACY](#)
  - [SYSTEMS TO PROVIDE SAFE AND EFFECTIVE PHARMACY SERVICES](#)
  - [TECHNOLOGY IN PHARMACY](#)
  - [PACKAGING AND REPACKAGING](#)
  - [CONTROLLED SUBSTANCES IN PHARMACY](#)
- [Automated Dispensing Cabinets](#)
- [Delegation](#)
- [Telepharmacy](#)

<sup>1</sup> [Drug and Pharmacies Regulation Act](#), s119

<sup>2</sup> [Drug and Pharmacies Regulation Act](#), s166

## Hospital Pharmacy, Patient Care Areas

### Category: Standards Of Operation

STANDARD	GUIDANCE
<b>MEDICATION STORAGE &amp; SECURITY IN PATIENT CARE AREAS</b>	
<p>The hospital has the facilities and equipment needed to ensure medications are stored securely and safeguarded from unauthorized access.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; Accreditation Canada, Medication Management</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Medications stored in patient care areas must be secure and safeguarded from unauthorized access (e.g. workstations with medications must be locked when not in use; protected by locked doors, swipe access, key, or similar secure barriers).</li> </ul>
<p>The hospital has policies and operational processes to ensure medications are stored securely and safeguarded from unauthorized access.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; Accreditation Canada, Medication Management</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Personnel authorized to obtain medications stored in patient care areas must be documented.</li> <li><input type="checkbox"/> Access to medication storage areas must be removed when individual personnel leave the hospital, including for an extended leave.</li> </ul>
<p>Medication storage areas are designed, located, constructed and maintained to be fit for their purpose to preserve the integrity of the medication supply.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; <a href="#">Protecting the Cold Chain Guideline</a>; Accreditation Canada, Medication Management; Accreditation Canada, Required Organizational Practices; ISMP Targeted Medication Safety Best Practices for Hospital; High-Alert Medications Need Multiple Safeguards (ISMP); ISMP MSSA; <a href="#">O. Reg. 67/93: HEALTH CARE AND RESIDENTIAL FACILITIES (under the Occupational Health and Safety Act)</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Medication storage areas must have the appropriate conditions of temperature, light and humidity necessary to ensure a safe medication management system.</li> <li><input type="checkbox"/> Refrigerator temperatures must be monitored regularly. For manual recording, the minimum and maximum temperature should be recorded twice per day.</li> <li><input type="checkbox"/> All personnel involved in handling cold chain products must be trained on cold chain maintenance policies and procedures.</li> <li><input type="checkbox"/> Risk identification and mitigation strategies must be in place for high-alert medications (e.g., segregation, labelling, etc.) in storage and preparation areas. High-alert medications that are available as ward stock require additional safeguards to ensure a safe medication management system.</li> <li><input type="checkbox"/> All large-volume bags and bottles of irrigation solutions, organ storage solution, and sterile water (e.g., for inhalation, irrigation) must be stored and labeled in a way that clearly differentiates them from solutions that may be administered parenterally.</li> <li><input type="checkbox"/> Medication storage areas must have the sanitary conditions necessary to ensure a safe medication distribution system. The medication storage areas must not be used to store food and drinks and only used to store only medication and medication-related supplies.</li> </ul>

<p>Specialized equipment is appropriate to safeguard the health, safety and wellbeing of patients.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a></p>	<p><input type="checkbox"/> Oral syringes which cannot be connected to parenteral tubing should be available in the patient care areas for medication administration.</p> <p><input type="checkbox"/> Medications should be dispensed/available in single-unit (unit dose) packages, in a ready-to-administer form wherever possible to minimize the potential for an incident to occur.</p>
<p>The hospital has policies and operational processes for the handling of hazardous medications to mitigate risk while providing healthcare to patients.</p> <p><b>Reference:</b> NIOSH list of antineoplastic and other hazardous drugs in healthcare settings</p>	<p><input type="checkbox"/> Hazardous medications must be clearly identified and have safe-handling processes in place. It is recommended that the hospital review occupational health and safety resources (e.g., NIOSH, CCO, ISMP, etc.)</p> <p><input type="checkbox"/> Solid dosage forms of hazardous drugs should not be manipulated (e.g., crushing tablets, opening capsules) in patient care areas to avoid cross-contamination and unintentional exposure.</p>
<p>The hospital has policies and procedures to regularly audit medication storage areas and ensure inventory is managed in a manner that maintains the quality and timeliness of the medication supply.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; <a href="#">OCP Guideline – Protecting the Cold Chain</a></p>	<p><input type="checkbox"/> There must be a procedure to evaluate and determine which medications can be stocked in specific patient care areas. The review should be done in collaboration with a pharmacist.</p> <p><input type="checkbox"/> There must be a process to remove and dispose of expired, outdated, unusable or recalled medications from patient care areas in a timely manner.</p> <p><input type="checkbox"/> The process of auditing medication storage in patient care areas should be documented and shared within the organization.</p>
<h3>SAFE MEDICATION MANAGEMENT SYSTEMS IN THE PATIENT CARE AREAS</h3>	
<p>The hospital has processes to ensure medication administration records (MARs) serve as a complete documentation record of the medications administered to a patient.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management</p>	<p><input type="checkbox"/> Medication administration records (MARs) must be current and kept up to date.</p> <p><input type="checkbox"/> Policies and procedures for medication administration records (MARs) should be consistent hospital-wide and not unique to specific patient care areas.</p> <p><input type="checkbox"/> All orders transcribed onto the medication administration record (MAR) must be verified against the original order before the first dose is administered.</p>
<p>The hospital has a collaborative process for performing medication reconciliation at each transition of care.</p> <p><b>Reference:</b> Accreditation Canada, Required Organizational Practices; <a href="#">ISMP Ontario Primary Care Medication Reconciliation Guide</a>; <a href="#">Strengthening Medication Reconciliation (MedRec) at Discharge (ISMP)</a></p>	<p><input type="checkbox"/> There must be a process to ensure relevant information obtained during Best Possible Medication History (BPMH) and the Medication Reconciliation is documented in the patient health care record.</p> <p><input type="checkbox"/> There must be a process to ensure the health care professional’s responsibility in the Best Possible Medication History (BPMH) and/or Medication Reconciliation is clearly documented and reflects accountability.</p>

<p>The hospital has policies and procedures to address the identification, storage, security and use of patient’s own medication(s) when brought into the hospital by/for patients.</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be a policy outlining requirements to be in place for a patient to use their own medications.</li> <li><input type="checkbox"/> There must be strategies in place to prevent diversion of patient's own medication supply during storage (especially narcotics, controlled drugs, benzodiazepines and targeted substances).</li> <li><input type="checkbox"/> Patient’s own medications must not be stored in pharmacy to safeguard the medication supply.</li> </ul>
<p>The hospital has policies and procedures for medications dispensed to patients leaving the hospital.</p> <p><b>Reference:</b> <a href="#">Drug and Pharmacies Regulation Act</a>, s156</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Criteria for the provision of Leave of Absence (LOAs) medications must meet legislative and regulatory body requirements and be consistent across the organization.</li> <li><input type="checkbox"/> Criteria for dispensing of “to go” doses must meet legislative and regulatory body requirements and should only occur if it has been determined that the patient does not have reasonable or timely access to a community pharmacy.</li> <li><input type="checkbox"/> Criteria for medications dispensed to ambulatory patients for home use must meet legislative and regulatory body requirements.</li> <li><input type="checkbox"/> There must be a process to track medications dispensed to patients going home.</li> </ul>
<p>The hospital has a policy on self-administration of medication by patients.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Criteria for determining which patients can self-administer medications, and which medications can be self-administered, must be established.</li> <li><input type="checkbox"/> A prescriber's order is required for self-administration such as "May self-administer", specifying drug, dose, frequency, route, etc.</li> <li><input type="checkbox"/> A prescriber's order is required for medications to be kept at bedside and should include “May be kept at the bedside”. Medications should be kept secure (i.e. locked).</li> </ul>
<p>The hospital has policies and procedures to monitor, report, and review adverse drug reactions (ADRs).</p> <p><b>Reference:</b> <a href="#">R.R.O. 1990, Reg. 965: HOSPITAL MANAGEMENT</a>; Accreditation Canada: Medication Management; <a href="#">Food and Drug Regulations</a>; <a href="#">Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)</a>; <a href="#">ISMP: Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be an interdisciplinary review process for each reported adverse drug reaction, to identify trends and plan for system improvements to mitigate risk. The review should be done in collaboration with a pharmacist.</li> <li><input type="checkbox"/> Adverse drug reactions should be reported to Health Canada and the manufacturer: (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>)</li> <li><input type="checkbox"/> Serious adverse drug reactions (defined in C.01.001(1.1) of the <i>Food and Drug Regulations</i>) must be reported to Health Canada as outlined in the <a href="#">Guidance document - Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals</a></li> </ul>

<p>The hospital has continuous quality improvement program to detect, record, analyze and manage medication incidents.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies; OCP AIMS (Assurance And Improvement In Medication Safety) Program Standards &amp; Expectations</a>; Accreditation Canada: Required Organizational Practices; Accreditation Canada: Medication Management; CSHP Medication Incidents: Guidelines on Reporting and Prevention (2012); <a href="#">ISMP Canada Medication Safety Self-Assessment® (MSSA)</a></p>	<p><input type="checkbox"/> There must be a process to identify when patients are not receiving medications as ordered by the prescriber or “missed” receiving a dose of medication.</p> <p><input type="checkbox"/> There must be procedures for recording medication incidents and near-misses in the safety incident management system.</p> <p><input type="checkbox"/> There must be a collaborative interdisciplinary process to review and analyze individual medication related incidents and near misses in a timely manner for contributing and/or causal factors, including follow-up with individuals involved, and to identify possible trends.</p> <p><input type="checkbox"/> There must be a process to plan for system improvements and/or implementation of risk mitigation strategies to reduce the likelihood of incident reoccurrence.</p> <p><input type="checkbox"/> Changes must be monitored after implementation for evidence of effectiveness and improvement towards safer systems/processes and patient outcomes.</p> <p><input type="checkbox"/> There must be a process to complete a medication safety self-assessment (MSSA) at least every 2-3 years.</p>
<p>The hospital has a process to communicate safe medication practices and share lessons learned within the organization.</p> <p><b>Reference:</b> <a href="#">OCP Supplemental Standard of Practice</a>; Accreditation Canada, Required Organizational Practices; CSHP Medication Incidents: Guidelines on Reporting and Prevention (2012)</p>	<p><input type="checkbox"/> There must be a process to educate staff on patterns or trends of medication incidents, contributing factors, and how to avoid a recurrence.</p> <p><input type="checkbox"/> There must be a process to communicate unsafe medication practices to the hospital’s risk management department.</p> <p><input type="checkbox"/> There must be a process to communicate continuous quality improvement plans and outcomes with staff.</p>
<p>In consultation with Infection Prevention and Control (IPAC), the hospital has policies and procedures to ensure medications do not contribute to cross contamination.</p> <p><b>Reference:</b> O. Reg 264/16; Infection Prevention and Control (IPAC) Program Standard</p>	<p><input type="checkbox"/> Procedures must ensure the medication supply is kept free of potential contamination.</p> <p><input type="checkbox"/> Contaminated medications should not be returned to the pharmacy from patient care areas.</p> <p><input type="checkbox"/> There must be procedures to ensure medication storage areas are not sources for potential contamination (e.g. returns bin in Automated Dispensing Cabinets, patient bins/drawers, medication cassettes, medication carts, medication rooms, Workstation On Wheels, barcode scanners, etc.).</p>
<p>Sterile preparations compounded in the patient care areas are only for immediate use.</p> <p><b>Reference:</b> NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and Hazardous Sterile Preparations; USP &lt;797&gt;; Accreditation Canada, Medication Management</p>	<p><input type="checkbox"/> Hazardous sterile preparations do not qualify as immediate-use preparations.</p> <p><input type="checkbox"/> Compounded sterile preparations prepared for immediate use in patient care areas must comply with the following conditions:</p> <ul style="list-style-type: none"> <li>• Compounding is performed only when the situation is critical, with a requirement for immediate administration to the patient</li> </ul>

	<ul style="list-style-type: none"> <li>• The preparation does not exceed 3 “sterile units” and for each sterile unit used, there are no more than two entries into any one container/device</li> <li>• Aseptic technique is rigorously applied and does not require more than 1 hour of continuous preparation</li> </ul> <p><input type="checkbox"/> The Beyond-Use Date (BUD) at controlled room temperature or stored in the refrigerator is one hour. Products cannot be stored for later use (i.e. in freezer). Administration of the preparation must begin within 1 hour after the start of compounding; otherwise, the preparation must be discarded.</p> <p><input type="checkbox"/> Compounding in worse than ISO Class 5 conditions increases the likelihood of microbial contamination, and administration durations exceeding a few hours increase the potential for clinically significant microbial colonization and patient harm, especially in critically ill or immunocompromised patients.</p>
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## CONTROLLED SUBSTANCES IN PATIENT CARE AREAS

<p>A random audit performed in the patient care area during the OCP assessment did not reveal a discrepancy and demonstrates accurate documentation of controlled substance administration.</p> <p><b>Reference:</b> NCR s63; FDR G05.004; BOTSR s 72(1)</p>	<p><input type="checkbox"/> There must be a process to regularly perform random audits for controlled substances, including tracers, to reconcile the prescriber's order, transcription, the withdrawal record, the medication administration record (MAR), count/waste sheets, etc. to ensure accurate completion and reconciliation.</p> <p><input type="checkbox"/> The hospital must review the <a href="#">CSHP Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines in Secure Management and Diversion Prevention</a> and the regulations governing controlled substances to ensure appropriate practices are in place to protect controlled substances in the hospital against loss or theft.</p>
<p>The hospital CEO ensures that the requirements of the relevant controlled substances legislation are met.</p> <p><b>Reference:</b> NCR s63; FDR G05.004; BOTSR s 72(1); <i>Safeguarding our Communities Act</i> (Patch for Patch Return Policy); <a href="#">OCP Opioid Policy</a>; CSHP – Controlled Drugs and Substances in Hospitals and Health Care Facilities: Guidelines on Secure Management and Diversion Prevention (February 2019); <a href="#">Framework for Improving the Safety and Security of Controlled Substances in Hospital High Risk Areas (December 2019)</a></p>	<p><input type="checkbox"/> There must be a documented policy for fentanyl patches used in the hospital that safeguards the patches from misuse, abuse and diversion, including an auditing process to ensure fentanyl patches are accounted for.</p> <p><input type="checkbox"/> There must be policies and procedures for the prescribing and handling of methadone and buprenorphine/naloxone in maintenance treatment of opioid use disorder to facilitate staff training and awareness.</p> <p><input type="checkbox"/> There must be a process for completing controlled substances counts hospital-wide at scheduled intervals (including Automated Dispensing Cabinets, etc.).</p> <p><input type="checkbox"/> There must be a process for completing controlled substances counts with a sudden change in staffing and after an incident (e.g., loss or theft).</p> <p><input type="checkbox"/> The hospital must have policies and procedures to identify and resolve discrepancies in controlled substances counts.</p> <p><input type="checkbox"/> The hospital must evaluate and limit the availability of controlled substances in patient care areas and that formats with the potential to cause harmful medication incidents are not stocked.</p>

	<input type="checkbox"/> The hospital is responsible for ensuring that controlled substances in the patient care areas are secure at all times. Safeguards must be in place to prevent unauthorized access.
	<input type="checkbox"/> The hospital must ensure that all the documentation is complete on the controlled substances administration and withdrawal records.
	<input type="checkbox"/> Unexpected loss of controlled substances must be reported to the Office of Controlled Substances within 10 days of discovery, as per the Health Canada <a href="#">Guidance Document: Reporting of loss or theft of controlled substances, precursors (CS-GD-005)</a> .
	<input type="checkbox"/> Destruction of controlled substances must follow the Health Canada <a href="#">Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances</a> .

## RECORD RETENTION, AUDITABILITY AND TRACEABILITY

<p>Provision of medications delivered to patients includes a process that ensures medications are auditable and traceable to the patient level.</p> <p><b>Reference:</b> NAPRA Pharmacy Practice Management Systems Supplemental Requirements; NAPRA Compounding Standards</p>	<input type="checkbox"/> As an organization continue to strive for auditability and traceability of all medications doses to the patient level.
	<input type="checkbox"/> There is auditability and traceability for patient specific oral solids.
	<input type="checkbox"/> There is auditability and traceability for patient specific oral liquids.
	<input type="checkbox"/> There is auditability and traceability for patient specific non-sterile compounding.
	<input type="checkbox"/> There is auditability and traceability for patient specific methadone (MMT).
	<input type="checkbox"/> There is auditability and traceability for patient specific non-hazardous sterile compounding.
	<input type="checkbox"/> There is auditability and traceability for patient specific TPN.
<p>Records are retained in accordance with legislation.</p> <p><b>Reference:</b> R.R.O. 1990, Reg. 965: HOSPITAL MANAGEMENT; OCP Guideline - Record Retention, Disclosure and Disposal</p>	<input type="checkbox"/> Documents relating to the care of a patient, including medication records, must be maintained for a period of at least 10 years from the last visit/date of discharge, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.
	<input type="checkbox"/> Medication-related quality assurance/quality improvement documentation must be retained for 10 years.
<p>In consultation with the privacy officer, patient confidentiality and personal health information is protected.</p> <p><b>Reference:</b> Personal Health Information Protection Act</p>	<input type="checkbox"/> There must be policies and procedures to maintain confidential medication records and maintain privacy for all patients, and these must records be readily retrievable.
	<input type="checkbox"/> The hospital must ensure that when disposing of personal health information that it be performed in a manner that ensures confidentiality.

## Hospital Pharmacy, Primary Location

### Category: Standards of Operation

#### STANDARD

#### GUIDANCE

### MEDICATION SECURITY AND STORAGE IN THE PHARMACY

The pharmacy has the facilities and equipment needed to ensure medications are stored securely and safeguarded from unauthorized access

**Reference:** [OCP Standards of Operation for Pharmacies](#); Accreditation Canada, Medication Management

Medications stored in the pharmacy must be secure and safeguarded using physical security measures (e.g. protected by locked doors, swipe access, key, or similar secure barriers).

If medications being received are not delivered immediately and directly to the pharmacy, they must be stored in a secure environment (i.e. locked area) until received by authorized pharmacy staff.

The pharmacy has policies and operational processes to ensure medications are stored securely and safeguarded from unauthorized access

**Reference:** [OCP Standards of Operation for Pharmacies](#); Accreditation Canada, Medication Management

There must be appropriate measures in place to restrict access to the pharmacy to authorized pharmacy personnel only. Authorized personnel must be documented and access removed when staff leave the hospital, including for an extended leave.

There must be swipe card/access code/key assignment records and a process to audit entry/attempted entry/detect unauthorized entry to the pharmacy areas to ensure personnel compliance with policies and procedures.

Medication storage areas and equipment are designed, constructed and maintained to be fit for their purpose to preserve the integrity of the medication supply.

**Reference:** [OCP Standards of Operation for Pharmacies](#); [OCP Protecting the Cold Chain Guideline](#); Accreditation Canada, Medication Management; Accreditation Canada, Required Organizational Practices; ISMP Targeted Medication Safety Best Practices for Hospital; [O. Reg. 67/93: HEALTH CARE AND RESIDENTIAL FACILITIES](#)

The pharmacy must have adequate storage and work space, supplies, the appropriate layout, facilities, and equipment to store medications in a safe, secure and appropriate manner and location. Medications and supplies must be kept off the floor.

Medication storage areas must have risk identification and mitigation strategies in place for high-alert medications (e.g., segregation, labelling, etc.) to ensure a safe medication distribution system.

Products for irrigation must be clearly differentiated, labelled and stored separately from parenteral solutions for injection (e.g. manufacturer or pharmacy-prepared-irrigation solutions, organ storage solution, and sterile water).

Medication storage areas must have evidence of the appropriate conditions of temperature, light and humidity necessary to ensure a safe medication management system.



	<input type="checkbox"/> The pharmacy must ensure medication integrity and security is maintained throughout the preparation, delivery and transport process. This includes the medication drop off and returns bins/boxes.
<p>The pharmacy has policies and procedures to regularly audit medication storage areas and ensure inventory is managed in a manner that maintains the quality and timeliness of the medication supply.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; <a href="#">OCP Guideline – Protecting the Cold Chain</a>; <a href="#">O. Reg. 67/93: HEALTH CARE AND RESIDENTIAL FACILITIES</a></p>	<input type="checkbox"/> Storage of poisons and flammable products must follow the relevant occupational health and safety legislation, guidelines and standards.
<p>The pharmacy has operational processes to ensure the cold chain is maintained.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; <a href="#">OCP Standards of Operation for Pharmacies</a>; <a href="#">OCP Guideline – Protecting the Cold Chain</a></p>	<input type="checkbox"/> There must be a process to remove and dispose of expired, outdated, unusable or recalled medications and active pharmaceutical ingredients (used for compounding) from the dispensing process (including automated packaging machines) in a timely manner.
	<input type="checkbox"/> All cold storage equipment for medication must be fit for its purpose and maintained at the required storage temperature range, calibrated and certified as required and supported by documentation.
	<input type="checkbox"/> Refrigerator temperatures must be monitored regularly. For manual recording, the minimum and maximum temperature should be recorded twice per day.
	<input type="checkbox"/> Standard operating policies and procedures must be in place within the pharmacy to ensure that the cold chain is maintained throughout the time a product is received, stored, dispensed and delivered and/or administered to the patient.
	<input type="checkbox"/> There should be emergency preparedness processes to address any temperature excursions or breaks in cold chain (e.g. due to equipment failure, power outages, etc.).
	<input type="checkbox"/> The Pharmacy administrator is responsible for ensuring all medications found in the refrigerator/freezer during a temperature variance are appropriate to dispense. The integrity of medications must be assessed and verified such that patients do not receive a potentially sub-potent product.
	<input type="checkbox"/> All pharmacy and support staff involved in handling cold chain products must be trained on cold chain maintenance policies and procedures.
	<input type="checkbox"/> Pharmacy staff must be familiar with the Protecting the Cold Chain Guideline and the associated references located on the OCP website.
	<input type="checkbox"/> Pharmacy staff should review the standards specified in the Ontario Ministry of Health Vaccine Storage and Handling Guideline.

<p>The pharmacy has policies and operational processes for the handling of hazardous medications to mitigate risk to staff and patients.</p> <p><b>Reference:</b> NIOSH list of antineoplastic and other hazardous drugs in healthcare settings; Accreditation Canada, Medication Management; NAPRA Model Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations and Hazardous Sterile Preparations; NAPRA Model Standards for Pharmacy Compounding of Non-sterile Preparations</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be separate storage areas for hazardous medications (e.g., segregation by location, by shelf, by drawers or another means) which are clearly labelled to alert all personnel. Storage areas should prevent spillage or breakage if the container falls.</li> <li><input type="checkbox"/> Hazardous medications must be clearly identified and pharmacy personnel are educated on safe handling and storage requirements. It is recommended that the pharmacy administrator review occupational health and safety resources (e.g., NIOSH, CCO, ISMP, etc.)</li> <li><input type="checkbox"/> There must be an inventory list of hazardous medications in the pharmacy that is accessible to all staff.</li> <li><input type="checkbox"/> Hazardous waste must be sealed and packaged in the appropriated container, kept segregated and clearly labelled.</li> <li><input type="checkbox"/> There must be processes that guides the proper packaging and delivery of liquid dosage forms, including parenteral formats, of hazardous drugs (including antineoplastics) to prevent leakage/spillage.</li> </ul>
<p>Medication storage areas must have the sanitary conditions necessary to ensure a safe medication management system.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; R.R.O. 1990, Reg. 965: HOSPITAL MANAGEMENT; <a href="#">O. Reg. 67/93: HEALTH CARE AND RESIDENTIAL FACILITIES</a>; Public Health Ontario: Routine Practices and Additional Precautions In All Health Care Settings, 3rd edition; Best Practices for Environmental Cleaning for Prevention and Control of Infections in All Health Care Settings, 3rd Edition</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be a policy to assess compliance with infection prevention and control (IPAC) procedures in the pharmacy.</li> <li><input type="checkbox"/> The medication and prescription storage areas must not be used to store food and drinks and used to store only medications and medication-related supplies</li> <li><input type="checkbox"/> The pharmacy must have policies and procedures for the routine cleaning of the department.</li> <li><input type="checkbox"/> Patient’s own medications must not be stored in pharmacy to safeguard the medication supply.</li> <li><input type="checkbox"/> Patient’s own medications must not be sent to pharmacy for destruction, with the exception of narcotics, controlled drugs, benzodiazepines and targeted substances</li> <li><input type="checkbox"/> The pharmacy staff should be aware of Infection Prevention and Control (IPAC) resources on the Public Health website.</li> <li><input type="checkbox"/> The pharmacy staff should understand how and when to contact an Infection Prevention &amp; Control (IPAC) Professional or Public Health.</li> </ul>

## SYSTEMS TO PROVIDE SAFE AND EFFECTIVE PHARMACY SERVICES

<p>There are systems in place to safely dispense medications when the pharmacy is closed.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Medications obtained after-hours or in emergency situations must be verified and reconciled with the order by the pharmacist or pharmacy technician to ensure accurate medication selection when the pharmacy re-opens.</li> <li><input type="checkbox"/> There must be a process for a pharmacist to review prescriptions obtained after-hours to ensure therapeutic appropriateness.</li> <li><input type="checkbox"/> The pharmacy must have policies and procedures to regulate, limit, dispense and ensure safe after hour access to medications with necessary safeguards in place (e.g. access to an on-call pharmacist, authorized personnel only, controlled access, a limited selection of urgently required medication, etc.).</li> <li><input type="checkbox"/> Additional safeguards must be in place for high-alert medication. (e.g. requires a call to a pharmacist to review order prior to release of medication).</li> </ul>
<p>The pharmacy provides oversight for distribution and control of all medications used by the hospital.</p> <p><b>Reference:</b> Regulated Health Professions Act; O. Reg. 202/94; DPRA; <a href="#">Canadian Pharmacists Association – Drug Shortages: A Guide for Assessment and Patient Management</a> ; ISMP: Drug Shortages and Medication Safety Concerns.</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> A pharmacist must approve all policies and procedures related to product specifications, drug distribution and control of medications throughout the hospital’s medication management system</li> <li><input type="checkbox"/> There must be policies and procedures for medication supply issues such as shortages, back orders, and distribution allocations.</li> <li><input type="checkbox"/> There must be a process in place to address medication recalls.</li> <li><input type="checkbox"/> There should be a process in place to communicate and educate staff about drug shortages.</li> <li><input type="checkbox"/> There should be a process in place to alert stakeholders to impending shortages and potential alternatives.</li> <li><input type="checkbox"/> Emergency kits/trays/boxes prepared by the pharmacy must have a seal which visually indicates when they have been opened.</li> <li><input type="checkbox"/> There must be a process to audit medication management systems, and to track and trend reports for ongoing system and service improvement (e.g. unit dose cart fill, ADC processes, IV admixture preparation, controlled substance record audits, etc.).</li> <li><input type="checkbox"/> The pharmacy must ensure medication integrity and security is maintained throughout the delivery and transport process. This includes the medication drop off and returns bins/boxes.</li> <li><input type="checkbox"/> The pharmacy has a policy and procedure to notify pharmacists of all returned doses that cannot be explained by orders changes (e.g. changes to a drug, dose or frequency).</li> </ul>

<p>All medication orders received by pharmacy must be reviewed by a pharmacist for appropriateness.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; <a href="#">Ministry of Health and Long-Term Care Professional Pharmacy Services Guidebook 3.0</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be a policy and process to ensure that during pharmacy hours of operation all medication orders are reviewed by a pharmacist prior to release to the patient care area.</li> <li><input type="checkbox"/> There must be a policy and process to ensure that a pharmacist reviews new medication orders as well as ongoing medication orders against the patient’s medication profile to ensure the medication is therapeutically appropriate for the specific patient.</li> <li><input type="checkbox"/> For patients with lengths of stay 90 days or greater, there must be a policy and process to ensure a pharmacist conducts a medication review at least every 3 months (quarterly).</li> </ul>
<p>The pharmacy has a process to document patient care and professional activities.</p> <p><b>Reference:</b> CSHP – Documentation of Pharmacists’ Activities in the Health Record: Guidelines (2013); <a href="#">OCP Documentation Guidelines</a>; <a href="#">OCP Record Retention, Disclosure and Disposal Guideline</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be a process to ensure that pharmacy professionals document their decisions/actions, supporting patient and related medication-related information in the patient health care record, as per hospital policy and as required by current legislation, standards, policies and guidelines applicable to pharmacy practice. Records must be clear, accurate and legible.</li> <li><input type="checkbox"/> There must be a process to enable pharmacy professionals to document pertinent information in the patient record in a way that is timely, readily retrievable, saved in a standardized fashion and done consistently to ensure continuity of care and that patient outcomes are optimized.</li> </ul>
<p>The pharmacy has policies and procedures to ensure accurate dispensing of medications.</p> <p><b>Reference:</b> Accreditation Canada: Medication Management</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The pharmacy must ensure dispensing policies and procedures are effective and safe. Policies and procedures must be sufficiently detailed for the labelling and verification of dispensed products.</li> <li><input type="checkbox"/> There must be a process to ensure pharmacy professionals document their activities and the information necessary to support the rationale and quality of these activities, in a timely manner, when preparing, dispensing and distributing medication.</li> <li><input type="checkbox"/> Authorization of the individuals responsible for each step in the dispensing process must be clearly documented and reflect accountability.</li> <li><input type="checkbox"/> Policies and procedures for accurate stock replenishment of medications in patient care areas must be sufficiently detailed.</li> <li><input type="checkbox"/> Policies and procedures for high risk medication therapies and high risk patient populations (e.g. pediatrics, neonates, etc.), must have additional safeguards to ensure patient safety prior to dispensing.</li> </ul>
<p>The pharmacy has organized workflow to enable pharmacists and pharmacy technicians to meet their standards of practice and to optimize patient care.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> There must be processes to permit optimal work flow management which do not impede pharmacy professionals from practicing to their full scope</li> <li><input type="checkbox"/> There must be processes to support patient care and permit pharmacy professionals to provide healthcare and services that meet the standards of practice of the profession.</li> <li><input type="checkbox"/> There must be a process to gather relevant information to enable Pharmacy Technicians to verify the technical accuracy of the medication against the order prior to dispensing the first dose, during Pharmacy hours of operation.</li> </ul>

	<input type="checkbox"/> There must be a process for pharmacy technicians to refer drug utilization alerts and patients which require assessment, clinical analysis or application of therapeutic knowledge to a pharmacist for review prior to releasing the medication order.
	<input type="checkbox"/> There must be a process for pharmacy technicians to identify and refer to the pharmacists discrepancies between a patient’s current drug therapy and the intended therapy.
	<input type="checkbox"/> There should be a process to prioritize patient monitoring based by identifying high risk populations and/or patients on high-alert medications.
	<input type="checkbox"/> There must be a process to ensure pharmacists are responsible for monitoring medication therapy to detect, resolve and prevent drug therapy problems, at a frequency appropriate for the medical condition being treated, in accordance with NAPRA Standards.
	<input type="checkbox"/> There must be a process for pharmacy professionals to prepare and provide handoff communication to appropriate personnel.
	<input type="checkbox"/> Pharmacy personnel must receive appropriate orientation and training to premises-specific procedures and equipment, relevant to the services provided.
	<input type="checkbox"/> Pharmacy personnel must be able to access references and resources as necessary to support the delivery of patient care.
	<input type="checkbox"/> The Pharmacy Administrator must have a system to assess and update policies and procedures as required to ensure consistency with legislation, OCP by-laws, standards, policies and guidelines.
	<input type="checkbox"/> The Pharmacy Administrator must be responsible for ensuring all pharmacists and pharmacy technicians maintain current licensure with the Ontario College of Pharmacists.
	<input type="checkbox"/> The Pharmacy Administrator should review the <a href="#">NAPRA Model Standards of Practice for Pharmacists</a> .
	<input type="checkbox"/> The Pharmacy Administrator should review the <a href="#">NAPRA Model Standards of Practice for Pharmacy Technicians</a> .
<p>The pharmacy has a collaborative process for performing medication reconciliation at each transition of care.</p> <p><b>Reference:</b> Accreditation Canada, Required Organizational Practices; <a href="#">ISMP Ontario Primary Care Medication Reconciliation Guide</a></p>	<input type="checkbox"/> There must be a process for pharmacy professionals conducting a Best Possible Medication History (BPMH) to document the BPMH in the patient health care record.
	<input type="checkbox"/> There must be a process for pharmacists conducting Medication Reconciliation to document in the patient health care record.
	<input type="checkbox"/> There should be a process for pharmacists to work collaboratively with other healthcare professionals to design, implement and deliver medication reconciliation at transitions of care.
<p>The pharmacy has a continuous quality improvement program to detect, record, analyze and manage medication incidents.</p>	<input type="checkbox"/> There must be a process to review and analyze individual medication incidents and near misses in a timely manner for contributing and/or causal factors, including follow-up with individuals involved, and to identify possible trends.

<p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; <a href="#">OCP Supplemental Standard of Practice</a>; Accreditation Canada, Medication Management; CSHP Medication Incidents: Guidelines on Reporting and Prevention (2012); <a href="#">NAPRA Model Standards for Continuous Quality Improvement and Medication Incident Reporting</a></p>	<input type="checkbox"/> The pharmacy must have a process to plan for system improvements and/or implementation of risk mitigation strategies to reduce the likelihood of recurrence.
	<input type="checkbox"/> Changes must be monitored after implementation for evidence of effectiveness and improvement towards safer systems/processes and patient outcomes.
	<input type="checkbox"/> There must be procedures for recording medication incidents and near-misses in the hospital's safety incident management system.
	<input type="checkbox"/> Medication incident reporting processes should cultivate and foster a safety culture for promoting open and honest discussions and support shared accountability.
	<input type="checkbox"/> Pharmacy professionals should be supported to meet their Standards of Practice. The Supplemental Standard of Practice outlines requirements for pharmacy professionals in the College's Assurance and Improvement in Medication Safety (AIMS) program.
<p>The pharmacy has a process to communicate safe medication practices and share lessons learned with pharmacy staff.</p> <p><b>Reference:</b> <a href="#">OCP Supplemental Standard of Practice</a>; CSHP Medication Incidents: Guidelines on Reporting and Prevention (2012)</p>	<input type="checkbox"/> The pharmacy must have a process to communicate continuous quality improvement plans and outcomes with staff.
	<input type="checkbox"/> There must be a process to educate staff on patterns or trends of medication incidents/near misses, contributing factors, and how to avoid a recurrence.
	<input type="checkbox"/> There must be a process to communicate unsafe medication practices to the hospital's risk management department.

## TECHNOLOGY IN PHARMACY

<p>The pharmacy has policies and procedures to ensure the safe operation of all pharmacy equipment and appropriate use of technology.</p> <p><b>Reference:</b> <a href="#">OCP Standards of Operation for Pharmacies</a>; NAPRA PPMS</p>	<input type="checkbox"/> There must be documentation that tracks the dispensing process from entry of an order into the system to final verification and includes the authorization (signature or some other unique identifier) of the individuals responsible for each step. Policies and procedures need to outline the checks embedded into the process in order to minimize the risk of error and detect unauthorized access.
	<input type="checkbox"/> The pharmacy must ensure technology used is safe to use and fit for its purpose within the medication management system, including, as applicable, for the preparation, dispensing, distribution, storage and compounding of drugs and other medications.
	<input type="checkbox"/> The pharmacy must have a log for initial certification, preventative maintenance, repairs, cleaning, and maintenance routines for all medication-related equipment.
	<input type="checkbox"/> There must be policies and procedures related to medication-related equipment down time or failure to avoid delays or interruptions in a patient's therapy. Contingency procedures should be tested, documented and reviewed for system improvements.
	<input type="checkbox"/> There must be a process to identify malfunction within the technology used (scanning, barcoding, dispensing automation, etc.) to determine the root cause. These deficiencies must be reviewed by the Pharmacy Administrator to track and trend improvements.

<p>The pharmacy has a policy and procedure to ensure appropriate barcoding of the medication throughout the medication management system.</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; ISMP/CPSI Medication Bar Code System Implementation Planning; NAPRA PPMS - Supplemental Requirements on Traceability and Bulk Preparation Labelling</p>	<input type="checkbox"/> There must be systems in place to ensure barcodes are applied accurately before product release.
	<input type="checkbox"/> Documentation (in a log or in an electronic database) must track the barcoding process from barcode generation to final verification and includes the signatures of the individuals involved in each step of the process.
	<input type="checkbox"/> The policies and procedures must outline the checks embedded into the process to minimize the risk of error.
	<input type="checkbox"/> There must be a process to identify deficiencies with scanning technology and determine and address the root cause.
	<input type="checkbox"/> Records of barcode scanning failures should be retained and reviewed to track and trend for system improvements.
	<input type="checkbox"/> There is barcoding for restocking of Automated Dispensing Cabinets.
	<input type="checkbox"/> There is barcoding for inventory only.
	<input type="checkbox"/> There is barcoding for removal of medications in patient care area.
<input type="checkbox"/> There is bedside barcode verification.	

**PACKAGING AND REPACKAGING**

<p>The Pharmacy has policies and procedures for repackaging according to standards.</p> <p><b>Reference:</b> O.Reg. 264/16: GENERAL; Accreditation Canada, Medication Management; CSHP - Repackaging: Guidelines for Healthcare Facilities; USP General Chapter &lt;1178&gt;, &lt;1146&gt;</p>	<input type="checkbox"/> The Pharmacy must have a policy and procedure for repackaging including the use personal protective equipment (PPE).
	<input type="checkbox"/> There must be a process for pharmacy staff to be trained on repackaging including the use personal protective equipment (PPE) prior to engaging in this task.
	<input type="checkbox"/> Repackaging records must be complete, auditable and traceable, and available for reference (methods, equipment, labelling, beyond use date (BUD), storage conditions, personnel responsible for packaging and checking (verification), etc.)
	<input type="checkbox"/> There must be a policy and procedure to ensure unused medication is only returned to inventory if it is in a sealed dosage unit or container as originally dispensed, the labelling is intact includes a legible drug lot number and expiry date or beyond use date (BUD), and the integrity of the drug can be verified prior to re-distribution.
	<input type="checkbox"/> Pharmacy policies and procedures must outline which drugs can be prepared/packaged using specific packaging and equipment/machines.
	<input type="checkbox"/> Pharmacy must use the appropriate packaging to maintain the physical integrity, sterility and stability of the medication during handling, transportation and storage and until it is administered to the patient.

	<ul style="list-style-type: none"> <li><input type="checkbox"/> Pharmacy staff should review USP for packaging and repackaging standards.</li> <li><input type="checkbox"/> Pharmacy staff should review CSHP - Repackaging: Guidelines for Healthcare Facilities</li> <li><input type="checkbox"/> Repackaging and storage of repackaged drugs should occur in an environment that is consistent with the conditions described in the original drug product’s labeling. If temperature and humidity are not specified in the original labeling, the product should be maintained at “controlled room temperature” and in a “dry place”</li> </ul>
<p>The pharmacy has a policy and procedure for the assignment of beyond use dates (BUDs) for repackaged medications.</p> <p><b>Reference:</b> CSHP - Repackaging: Guidelines for Healthcare Facilities; USP General Chapter &lt;1178&gt;, &lt;1146&gt;</p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> The pharmacy must have a policy and procedure for assignment of beyond use dates (BUDs) for repackaged medications including documentation of approval, date of review, and reference used.</li> <li><input type="checkbox"/> A pharmacist must be responsible for determining the BUDs for all medications in the pharmacy.</li> <li><input type="checkbox"/> The pharmacy must use the appropriate packaging containers and materials to maintain the physical integrity, sterility and stability of the medication during handling, storage and transportation.</li> <li><input type="checkbox"/> The pharmacy must have policies and procedures on criteria that guide the appropriate selection of packaging materials for each type of drug/package/product/machine (e.g. ATC, PacMed, dry and wet Cadets).</li> </ul>
<p>The pharmacy has policies and procedures for repackaging of hazardous drugs according to established standards.</p> <p><b>Reference:</b> NIOSH list of antineoplastic and other hazardous drugs in healthcare settings; USP &lt;800&gt; Hazardous Drugs—Handling in Healthcare Settings );Model Standards for Pharmacy Compounding of Non-Sterile Preparations; <a href="#">O. Reg. 67/93: HEALTH CARE AND RESIDENTIAL FACILITIES</a></p>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Dedicated equipment must be segregated and properly labelled for hazardous drug use. (I.e. chemotherapy counting tray in addition to a non-antineoplastic drug counting tray). Equipment must be deactivated, decontaminated and cleaned after each use, or if disposable equipment is used, disposed of appropriately.</li> <li><input type="checkbox"/> The pharmacy must determine and identify medications requiring dedicated equipment and personal protective equipment (PPE).</li> <li><input type="checkbox"/> There must be a process to ensure personnel comply with the personal protective equipment (PPE) policies and procedures for hazardous product repackaging. Training must be completed and documented prior to engaging in this activity.</li> <li><input type="checkbox"/> Solid dosage forms of hazardous drugs should not be placed in automated packaging machines or counting machines which subject them to stress and may introduce powdered contaminants into the machine and/or environment.</li> <li><input type="checkbox"/> Hazardous drugs supplied by the manufacturer in unit dose packaging which do not require further manipulation must be dispensed in the original package, unless otherwise specified by the manufacturer or there are indicators of exposure hazards present (e.g. visible dust, leakage, etc.)</li> <li><input type="checkbox"/> Non-antineoplastic hazardous drugs that only require transfer from the manufacturer’s package to the prescription container must be dispensed without any further requirements for containment unless required by the manufacturer.</li> </ul>



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|  | <input type="checkbox"/> Non-sterile hazardous drug manipulation (such as crushing/splitting tablets or opening capsules) must be performed in accordance with occupational health and safety guidelines and recognized standards (i.e. in a BSC/CACI using appropriate PPE as outlined in NIOSH, OSHA, etc.). |
|  | <input type="checkbox"/> For occasional non-sterile hazardous drug manipulation, a C-PEC used for hazardous sterile compounding (e.g., Class II BSC or CACI) may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.                               |

## CONTROLLED SUBSTANCES WITHIN THE PHARMACY

A random controlled substances count performed during the OCP assessment did not reveal a discrepancy and demonstrated matching documentation between the expected and actual count.

- There must be a process to regularly perform random audits and verifications of purchase orders and receipts, dispensing, perpetual inventory records, etc. for controlled substances.

The Pharmacy Administrator ensures that the requirements of the controlled substances legislation for hospitals are met, as delegated by the hospital's CEO.

**Reference:** NCR s63; FDR G05.004; BOTSr s 72(1); *Safeguarding our Communities Act* (Patch for Patch Return Policy); Opioid Policy; CSHP – Controlled Drugs and Substances in Hospitals and Health Care Facilities: Guidelines on Secure Management and Diversion Prevention (February 2019); Framework for Improving the Safety and Security of Controlled Substances in Hospital High Risk Areas (December 2019)); [Health Canada Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances](#)

- The Pharmacy Administrator should review relevant legislation as it pertains to accountability with respect to controlled substances.
- The pharmacist is responsible for ensuring that all controlled substances in the pharmacy are secure. Safeguards must be in place, to prevent unauthorized access.
- Unexpected loss of controlled substances must be reported to the Office of Controlled Substances within 10 days of discovery, as per the Health Canada [Guidance Document: Reporting of loss or theft of controlled substances, precursors \(CS-GD-005\)](#).
- Destruction of controlled substances must follow the Health Canada [Guidance Document for Pharmacists, Practitioners and Persons in Charge of Hospitals: Handling and Destruction of Unserviceable Stock Containing Narcotics, Controlled Drugs or Targeted Substances](#).
- Pharmacy staff should review the [Fact Sheet - Controlled Substances: Security and Reconciliation](#) located on the OCP website.
- Pharmacy staff should review the Fact Sheet - [Controlled Substances: Destruction of Unserviceable Stock and Post-Consumer Returns](#) located on the OCP website.
- A reconciliation of controlled substances in the pharmacy must be completed at scheduled intervals, in addition to when there is change in staffing and/or after a theft /loss.
- There must be policies and procedures to identify and resolve discrepancies for controlled substances.
- A pharmacist with controlled substance signing authority must review controlled substances records and compare to actual inventory on hand to protect against diversion.
- The pharmacy must ensure transportation and delivery of controlled substances (within the hospital and between sites) is secure, auditable and traceable.
- If controlled substances being received are not delivered immediately and directly to the pharmacy, they must be stored in a secure environment (i.e. locked area) until received by authorized pharmacy staff.

	<input type="checkbox"/> The pharmacy must have a system to reconcile controlled substances from emergency kits upon use. (e.g. code blue trays)
	<input type="checkbox"/> Controlled substances should be double locked and access restricted to designated staff to protect against loss, theft or diversion.
	<input type="checkbox"/> The pharmacy must have a copy of, or access to, the hospital’s documented policy to account for fentanyl patches used in the hospital.
	<input type="checkbox"/> The pharmacy must review the <a href="#">CSHP Controlled Drugs and Substances in Hospitals and Healthcare Facilities: Guidelines in Secure Management and Diversion Prevention</a> and the regulations governing controlled substances to ensure safe and appropriate practices are in place.
<p>The pharmacy has policies and procedures to prepare and dispense methadone (MMT) and buprenorphine/naloxone in maintenance treatment of opioid use disorder, in accordance with federal legislation and OCP policy.</p> <p><b>Reference:</b> <a href="#">OCP Opioid Policy</a>; CAMH – Opioid Agonist Maintenance Treatment: A Pharmacist's Guide To Methadone And Buprenorphine For Opioid Use Disorder (2015); Narcotic Control Regulations</p>	<input type="checkbox"/> Methadone (MMT) doses must be prepared using a commercially available product as per the Health Canada <a href="#">Policy on Manufacturing and Compounding Drug Products in Canada (POL-0051)</a> .
	<input type="checkbox"/> There must be policies and procedures for dispensing of methadone (MMT) and buprenorphine/naloxone to facilitate staff training and awareness.
	<input type="checkbox"/> The pharmacy must have access to current copies of the Required References outlined in the Opioid Policy.
	<input type="checkbox"/> Prior to dispensing MMT to any patient admitted to hospital, the patient's pharmacy (or clinic/facility where the patient is receiving methadone) must be contacted to notify them of the patient’s admission and to determine details of the last dose.
	<input type="checkbox"/> Prior to the discharge of any patient on MMT, the patient’s pharmacy (or clinic/facility where the patient is receiving MMT) must be contacted to notify them of the discharge date, time and amount of last dose to ensure uninterrupted treatment and a safe transition of care.

## AUTOMATED DISPENSING CABINETS

STANDARD	GUIDANCE
<p>There are policies and procedures for the use of Automated Dispensing Cabinets (ADCs) within the medication management system</p> <p><b>Reference:</b> Accreditation Canada, Medication Management; ISMP Guidelines for the Safe Use of Automated Dispensing Cabinets; ISMP Canada Automated Dispensing Cabinets in the Canadian Environment; NAPRA Pharmacy Practice Management Systems Requirements</p>	<p><input type="checkbox"/> There must be policies and procedures to determine the location, access, which medications are stored in which patient care areas and in what quantity, type of medication information available, and verification for restocking.</p>
	<p><input type="checkbox"/> There must be a process to ensure medications are loaded accurately, and the ADC is stored safely and appropriately (e.g. temperature, humidity, low traffic areas, etc.) to maintain the integrity of the medications.</p>
	<p><input type="checkbox"/> There should be a process for a pharmacist to determine the appropriateness of medications in each ADC.</p>
	<p><input type="checkbox"/> There must be a process to identify and address security breaches within the ADCs.</p>
	<p><input type="checkbox"/> All ADCs should have an interface with the pharmacy practice management system (PPMS) for order entry and verification.</p>
	<p><input type="checkbox"/> Medications should be withdrawn from an active patient profile during pharmacy business hours. Limit overrides for ADC medications to after pharmacy hours.</p>
	<p><input type="checkbox"/> There must be a process for pharmacist review of all orders prior to administration when the pharmacy is open.</p>
	<p><input type="checkbox"/> An independent double check should be required for selected items removed through the override function (e.g., high-alert drugs, controlled substances, etc.)</p>
	<p><input type="checkbox"/> Access via override must be reconciled against the order by a pharmacist or pharmacy technician for each dose obtained; overrides for new orders must be reviewed by a pharmacist to ensure clinical appropriateness.</p>
<p><input type="checkbox"/> The hospital should establish indicators and targets for use of the override function, and audit these indicators and targets regularly (e.g., monthly).</p>	

DELEGATION	
STANDARD	GUIDANCE
<p>There is a delegation process for authorizing an individual to perform a controlled act.</p> <p><b>Reference:</b> <i>Regulated Health Professions Act (RHPA)</i>; O. Reg. 202/94; <a href="#">OCP Policy - Medical Directives and the Delegation of Controlled Acts</a>; HPRO - An Interprofessional Guide on the Use of Orders, Directives and Delegation for Regulated Health Professionals in Ontario</p>	<input type="checkbox"/> There must be a delegation policy and process for all controlled acts undertaken by regulated and unregulated staff in the pharmacy who do not have the independent authority to perform those acts.
	<input type="checkbox"/> There must be documented procedures outlining the controlled act(s) being delegated and the assessment of the knowledge, skill and judgement to competently perform the acts.
	<input type="checkbox"/> The Pharmacy Administrator must ensure there are documented procedures for the training of volunteers and confirmation that all volunteers have received training prior to performing assigned duties, even if not performing controlled acts, in the pharmacy.
	<input type="checkbox"/> The Pharmacy Administrator should review the OCP policy on <a href="#">Medical Directives and the Delegation of Controlled Acts</a> .
TELEPHARMACY	
STANDARD	GUIDANCE
<p>There are operational policies to ensure telepharmacy services meet all professional standards.</p> <p><b>Reference:</b> CSHP Telepharmacy: Guidelines 2018; <a href="#">OCP Virtual Care Policy</a></p>	<input type="checkbox"/> The Pharmacy Administrator must have policies and procedures to ensure the safe, effective and consistent provision of pharmacy services and delivery of patient care via telepharmacy services.
	<input type="checkbox"/> Pharmacy professionals providing telepharmacy services must have access to the same patient care and medication related information as the hospital pharmacy.
	<input type="checkbox"/> The Pharmacy Administrator must ensure there are processes for auditing and evaluating the telepharmacy service provider on a regular basis.
	<input type="checkbox"/> Telepharmacy viewers must only access electronic pharmacy records using a secure method of transmission that does not store unencrypted personal health information on the user's remote computer.
<p>There are processes to facilitate documentation by the pharmacy professionals at the telepharmacy service.</p> <p><b>Reference:</b> CSHP Telepharmacy: Guidelines 2018; <a href="#">OCP Virtual Care Policy</a>; <a href="#">OCP Documentation Guidelines</a></p>	<input type="checkbox"/> The hospital must have a process to ensure that pharmacy professionals document their decisions/actions, supporting patient and related medication-related information in the patient record, as per hospital policy and as required by current legislation, standards, policies and guidelines applicable to pharmacy practice.
	<input type="checkbox"/> The hospital must have a process to enable pharmacy professionals to document their decisions/actions, supporting patient and related medication-related information in the patient record in a way that is timely, readily retrievable, saved in a standardized fashion and done consistently to ensure continuity of care and that patient outcomes are optimized.