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HOSPITAL PHARMACY ASSESSMENT CRITERIA

The following chart outlines the Hospital Pharmacy Criteria that is used by Hospital Operations Advisors (HOAs) when conducting a Hospital Pharmacy Assessment. The document is divided into categories and for each category there are specific standards which have been taken from relevant legislation, policies, guidelines or standards of practice. The guidance section illustrates specific insights or activities required to ensure adherence to the standard and is provided to assist in understanding expectations and preparing for an assessment.

CATEGORIES

- ☐ General
- ☐ Pharmacy Standards Of Operations
- ☐ Pharmacy Standards Of Practice
- ☐ Automated Dispensing Cabinets
- ☐ Delegation
- ☐ Telepharmacy

GENERAL

STANDARD	GUIDANCE
MEDICATION SECURITY	
The Hospital ensures processes are in place to maintain medication security.	☐ Appropriate security of all medications must be secure and safeguarded from unauthorized access including in patient care areas and throughout the Hospital. (i.e. protected by locked doors or similar secure barriers)
	☐ The Pharmacy must ensure medications are appropriately stored in a locked area with controlled, restricted access (swipe card, key, access code, locked door and access is restricted to authorized nursing staff, Pharmacists or Pharmacy Technicians and documented). This includes removing access when staff leave the Hospital including on extended leave.
	☐ Medications stored in patient care areas must be secure (e.g. workstations with medications must be locked when not in use).
MEDICATION STORAGE	
The Hospital has operational processes in place for the safe handling, storage, and monitoring of medications to ensure patient safety.	☐ Medication storage in patient care areas (inpatient and outpatient) must have processes in place to ensure medication are stored in a safe, secure and appropriate manner and location.
	☐ Ensure conditions of sanitation, temperature, light, humidity, ventilation are appropriate for medication storage and preparation areas.
	☐ Products for irrigation must be clearly differentiated (labelling) and stored separately from parenteral solutions in both the Pharmacy and patient care areas. (e.g. manufacturer or pharmacy-prepared-irrigation solutions, organ storage solution, and sterile water).
	☐ The medication storage areas must not be used to store food and drinks.

	☐ Refrigerator(s) must be clean and in good working condition, and temperature must be monitored continuously to maintain a temperature between 2°C to 8°C.
	☐ It is recommended that the Hospital review the OHSA and NIOSH bulletin to ensure the crushing of hazardous medication tablets or opening of hazardous medications capsules in patient care areas does not occur.
Medication storage areas in the patient care areas (inpatient and outpatient) are regularly audited by the most responsible personnel to ensure safe handling, storage and monitoring of medications for patient safety.	☐ The process of auditing medication storage in patient care areas should be documented and shared within the organization.
	☐ Medication storage in patient care areas (inpatient and outpatient) must have a process to remove expired/outdated medications in a timely manner.
MEDICATION SAFETY	
The Hospital has continuous quality improvement processes in place to manage and review medication incidents.	☐ The Hospital must have policies and procedures in place that minimize errors, incidents and unsafe practices, including supporting staff in their obligation to report incidents and near misses.
	☐ All medication incident reports and/or documentation must be reviewed by a Pharmacist.
	☐ A process must be in place for review of individual medication incidents, including follow-up with individuals involved and an action plan for system improvements and/or risk mitigation strategies.
	☐ Education on patterns and trends of medication incidents should be communicated to staff and documented.
	☐ The Hospital should have a process to identify when patients are not receiving medications as ordered by the prescriber or “missed” receiving a dose of medication.
There is a process in place to communicate and manage safe medication practices within the Hospital.	☐ Risk identification and mitigation strategies must be in place for the use of high risk medications. High risk drugs that are available as ward stock, require additional safeguards.
	☐ The organization must have a process in place to communicate unsafe medication practices to the Hospital’s risk management.
	☐ The organization must have a process in place to analyze individual medication related incidents and near misses in a timely manner for causal factors to reduce the likelihood of reoccurrence.
	☐ The organization must have a process in place to implement appropriate steps to minimize the likelihood of recurrence.
	☐ The organization must have a process in place to communicate CQI plans and outcomes with staff.
	☐ The organization must have a process in place to complete a medication safety self-assessment at least every 2-3 years.
	☐ The organization should review the content of the AIMS (Assurance and Improvement in Medication Safety) program on the OCP website.
The Hospital has processes in place to ensure medication administration records (MARs) serve as a complete documentation record of the medications administered to a patient.	☐ Medication administration records (MARs) must be current and kept up to date.
	☐ Policies and procedures for MARs should be consistent Hospital wide and not unique to specific patient care areas.
	☐ All orders transcribed onto the MAR must be verified against the original order by a nurse before the first dose is administered.

In consultation with Infection Prevention and Control (IPAC), there are policies and procedures in place to ensure medications do not contribute to cross contamination.	☐ The Hospital must ensure the medication supply is kept free of potential contamination.
	☐ Contaminated medications should not be returned to the Pharmacy from patient care areas.
	☐ The Hospital must ensure medication storage units are not sources for potential contamination (e.g. may include but is not limited to returns bin in ADC, patient bins/drawers, medication cassettes, medication carts, medication rooms, COWs/WOWs, barcode scanner, etc.).
The pharmacy has operational processes in place to ensure that infection prevention and control practices are adhered to.	☐ The Pharmacy should have a policy in place to address infection prevention and control (IPAC) procedures that are in place at the pharmacy.
	☐ The pharmacist shall review Infection Control for Regulated Healthcare Professionals: Pharmacists Edition on the OCP website.
	☐ The pharmacy staff are aware of Infection Prevention and Control (IPAC) resources on the Public Health website.
	☐ The pharmacy staff understand how and when to contact the Infection Control Professional or Public Health.
Sterile medication preparation occurring in the patient care areas are only for immediate use.	☐ Hazardous sterile preparations do not qualify as immediate-use preparations.
	☐ Compounded sterile preparations prepared for immediate use in the patient's room or on patient care units must comply with the following conditions: Compounding is performed only when the situation is critical, with a requirement for immediate administration to the patient, the preparation does not exceed 3 "sterile units", for each sterile unit used, there are no more than two entries into any one container, package or administration container/device. Aseptic technique does not require more than 1 hour of continuous preparation, aseptic technique is rigorously applied.
	☐ The BUD at room temperature or stored in the refrigerator is one hour. Products cannot be stored for later use (i.e. in freezer).
	☐ Compounding in worse than ISO Class 5 conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.
CONTROLLED SUBSTANCES IN THE PATIENT CARE AREAS	
A random narcotic audit performed in the patient care area during the OCP assessment demonstrates matching documentation from the prescriber's orders, to the narcotic withdrawal record and medication administration record.	☐ The Hospital must review the Controlled Drugs and Substances in Hospitals and Healthcare Facilities Guidelines in Secure Management and Diversion Prevention and/or Narcotic Control Legislation and/or the Controlled Drug and Substances Act to ensure safe practices are in place.
In patient care areas, Controlled Substances administration records are complete. Inventory is counted and reconciled at shift change; discrepancies are identified and resolved.	☐ The Hospital must have policies and procedures to identify and resolve discrepancies.
	☐ The Hospital must ensure that all the documentation is complete on the Controlled Substances withdrawal record.
	☐ There must be a system in place for completing Controlled Substances counts in the patient care areas at scheduled intervals. This includes automated dispensing cabinets (ADC's).

	☐ The Hospital must evaluate and limit the availability of Controlled Substances to ensure that formats with the potential to cause harmful medication incidents are not stocked in patient care areas.
	☐ The Hospital should perform random audits, including tracers, to reconcile the prescriber's order, the MAR, counting sheets and orders to ensure accurate completion and reconciliation for Controlled Substances.
	☐ The Hospital should review the Controlled Drugs and Substances in Hospitals and Healthcare Facilities Guidelines in Secure Management and Diversion and Prevention.
RECORD RETENTION, AUDITABILITY AND TRACEABILITY	
Provision of patient specific medications includes a process that ensures medications are auditable and traceable to the patient level.	☐ As an organization continue to strive for auditability and traceability of all medications doses to the patient level.
	☐ There is auditability and traceability for patient specific oral solids.
	☐ There is auditability and traceability for patient specific oral liquids.
	☐ There is auditability and traceability for patient specific non-sterile compounding.
	☐ There is auditability and traceability for methadone.
	☐ There is auditability and traceability for patient specific non-hazardous sterile compounding.
	☐ There is auditability and traceability for patient specific TPN.
	☐ There is auditability and traceability for patient specific hazardous sterile compounding.
	☐ There is auditability and traceability for chemotherapy.

PHARMACY STANDARDS OF OPERATIONS

STANDARD	GUIDANCE
Appropriate security measures are in place in the Pharmacy and Pharmacy satellites.	☐ All medication storage areas must be secured and protected by locked doors or similar secure barriers within the Pharmacy and Pharmacy satellites.
	☐ When the Pharmacy or Pharmacy satellite is closed, the premises must be equipped with a monitored security system that will detect unauthorized entry.
	☐ The alarm code or keys to the Pharmacy or satellites should be restricted to Pharmacists and Pharmacy Technicians to safeguard from unauthorized access.
	☐ The Pharmacy must keep access code/key assignment records and should audit entry or attempted entry to Pharmacy areas to ensure compliance with policies and procedures.
The Pharmacy has a system to safely dispense medications when the Pharmacy is closed.	☐ Medications obtained afterhours must be reconciled with the order by the Pharmacist or Pharmacy Technician to ensure accurate medication selection when the Pharmacy re-opens.
	☐ Pharmacy must have a process for a Pharmacist to review prescriptions obtained afterhours to ensure therapeutic appropriateness.

	☐ To ensure patient safety, the Pharmacy must have policies and procedures to regulate, limit, dispense and ensure safe after hour access to medications with necessary safe guards in place (e.g. access to an on-call pharmacist, emergency box/kits/trays, night cupboard or ADC to provide a limited selection of urgently required medication).
	☐ There must be a system in place to document and monitor access to the Pharmacy or Pharmacy satellite after closing.
	☐ Additional safeguards must be in place for high risk medication. (e.g. requires a call to a pharmacist to review order prior to release of medication).
The Pharmacy has adequate storage space and work space for staff to provide safe medication practice.	☐ The Pharmacy should have adequate work space for staff to provide safe medication practice.
	☐ There must be an established work flow to ensure safe medication practice.
	☐ Adequate storage space for medications, supplies and equipment is needed to support safe medication practice. Medications and supplies must be kept off the floor. There should be clear segregation and differentiation for high risk medication.
The Pharmacy has operational processes in place for the safe handling, storage, and monitoring of medications to ensure patient safety.	☐ The Pharmacy must have processes in place to ensure medications are stored in a safe, secure and appropriate manner and location. Proper conditions of sanitation, temperature, light, humidity, ventilation, segregation and security are ensured for medication storage and preparation areas and provide supporting documentation (manual or electronic).
	☐ Pharmacy needs to meet DPRA and OHSA requirements related to no beverages or food permitted in areas where medications, supplies or original copies of the prescriptions are handled or stored in the Pharmacy.
	☐ Storage of poisons and flammable products and preparations must follow appropriate WHMIS, legislative guidelines/requirements and standards.
	☐ The Pharmacy must have a process to remove expired/outdated medications and chemicals (used for compounding) from the dispensing process (including automated packaging machines) in a timely manner.
	☐ The Pharmacy administrator/designate must ensure that Pharmacy has policies and procedures for the cleaning requirements of the department.
The Pharmacy has operational processes in place to ensure the safe handling, storage, and monitoring of hazardous medications to ensure staff and patient safety.	☐ Antineoplastic hazardous drugs (HDs) requiring manipulation other than counting or repackaging of final dosage forms and any hazardous Active Pharmaceutical ingredients (API) must be stored separately from non-hazardous drugs in a manner that prevents contamination and personnel exposure and must be stored separately in an externally vented negative pressure room.
	☐ Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator(s) in a negative pressure area.
	☐ The Pharmacy must have an inventory list of hazardous medications in the Pharmacy and personnel are educated on specific handling and storage requirements.
	☐ Hazardous waste must be sealed and packaged in the appropriated container, kept segregated and clearly labelled.
	☐ The Pharmacy must have policies and procedures that guide the proper packaging and delivery of liquid dosage forms, including parenteral formats, of hazardous drugs (including chemotherapeutic agents) to prevent leakage/spillage.

	☐ Hazardous storage area must be clearly segregated physically by location, by shelf, by drawers or another means. Storage areas should prevent spillage or breakage if the container falls. Labelling of these separate areas is clearly visible to alert all personnel.
The Pharmacy provides oversight for distribution and control of all medication products used by the Hospital.	☐ The organization must ensure a pharmacist approves all policies and procedures related to drug distribution and control of medication products throughout the Hospital.
	☐ The organization must ensure a pharmacist is responsible for product specifications, distribution and control of all medication products used by the Hospital.
	☐ The organization must ensure there is pharmacist oversight whenever the Pharmacy is open including evenings and weekend, and coverage for sole-charge pharmacists during leaves of absence vacations, etc.
The Pharmacy ensures a safe and effective drug distribution system is in place.	☐ Limit ward stock items. Ward stock items should be within approved, limited min/max levels.
	☐ The Pharmacy must have policies and procedures and is responsible for ensuring a safe and effective drug distribution system.
	☐ The Pharmacy should be working towards safe systems (e.g. unit dose & IV admixtures) or have a plan to meet these standards.
	☐ Medications should be dispensed in single-unit packages, in a ready-to-administer form where possible to minimize the potential for errors.
	☐ The Pharmacy must minimize the supply of multi-dose vials to patient care areas; single use vials or ampoules are preferred.
	☐ The Pharmacy must ensure there is a procedure to evaluate and determine which medications can be stocked in specific patient care areas.
	☐ Emergency kits/trays/boxes prepared by the Pharmacy must have a seal which visually indicates when they have been opened.
	☐ The Pharmacy must have a pharmacy information system that supports safe medication practice and is compliant with PPMS standards.
	☐ The organization must have activated the automated checking features in the pharmacy information system.
	☐ 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, narcotic record audits, etc.)
	☐ 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.
	☐ 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).
	☐ The organization should review the Pharmacy Practice Management Systems (PPMS) Requirements and Supplemental Requirements.
All medication orders received by Pharmacy must be reviewed by a Pharmacist for appropriateness.	☐ During Pharmacy hours of operation all medication orders must be reviewed by a Pharmacist prior to release to the patient care area.

	☐ A Pharmacist must review medication orders that a patient is taking for the first time as well as ongoing medication orders to ensure the medication is the most appropriate for the specific patient.
	☐ Pharmacists must review the medication orders against the patient's medication profile.
	☐ In emergency situations or after hours, the Hospital must have an established procedure to ensure a review of medication orders occurs as soon as a pharmacist is available when the Pharmacy re-opens.
	☐ The Hospital must have a policy and procedure for healthcare providers to follow if there is a disagreement regarding the medication order as prescribed.
	☐ For patients with lengths of stay 90 days or greater, a Pharmacist conducts a medication review at least every 3 months (quarterly).
The Pharmacy has policies and procedures for verification of dispensed products.	☐ Policies and procedures must be sufficiently detailed for the verification of dispensed products. (e.g. Labelling)
	☐ Policies and procedures for accurate stock replenishment of medications should be sufficiently detailed including but not limited to OR kits, ADCs, pharmacy technology.
	☐ High risk medication therapies and high risk patient populations (e.g. pediatrics, neonates), must have additional safeguards to ensure patient safety prior to dispensing as outlined in the Pharmacy policy and procedure.
The Pharmacy has organized staffing and workflow to enable Pharmacists and Pharmacy Technicians to practice to their standards of practice and to optimize patient care.	☐ The Pharmacy must have workflow processes in place to ensure accuracy in dispensing for patient safety.
	☐ The Pharmacy must have an environment and workflow process in place, including the provision of equipment, systems and staffing, which are necessary for the members to practice to their full scope and meet the standards of practice of the profession.
	☐ The Pharmacy must develop a process for Pharmacy staff to gather relevant information to enable Pharmacy Technicians to check the medication to be dispensed against the order prior to dispensing the first dose, during Pharmacy hours of operation
	☐ The Pharmacy manger should review the Policy Supervision of Pharmacy Personnel located on the OCP website.
	☐ Pharmacists and Pharmacy Technicians should review the Code of Ethics located on the OCP website.
The pharmacy has implemented an incident management system in a manner that supports pharmacy professionals in meeting the requirements under the supplemental Standard of Practice.	☐ The Pharmacy must have a process in place to analyze individual pharmacy incidents and near misses in a timely manner for causal factors to reduce the likelihood of recurrence.
	☐ The Pharmacy must have a process in place to implement appropriate steps to minimize the likelihood of incident recurrence.
	☐ The Pharmacy must have a process in place to communicate CQI plans and outcomes with staff.
	☐ The Pharmacy must have a process in place to complete a safety self-assessment at least every 2-3 years.
	☐ Pharmacy Staff should review the content of the AIMS program located on the OCP website.

PATIENT MEDICATION POLICY	
The Hospital has a written process to address the identification, storage, security and use of patient's own medications when brought into the Hospital setting by patients and/or family.	☐ The organization must have a process outlining requirements to be in place for a patient to use their own medications.
	☐ The organization must have strategies in place to prevent diversion of patient's own medication supply during storage (especially narcotics, controlled drugs, benzodiazepines and targeted substances).
	☐ Patient's own medications may not be stored in Pharmacy in order to maintain a safe Pharmacy medication supply.
	☐ Patient's own medications must not be sent to Pharmacy for destruction. Exception, narcotics, controlled substances and benzodiazepines.
The Pharmacy has polices and/or procedures to ensure that when medications are dispensed to patients leaving the Hospital, legislative and regulatory body requirements are met.	☐ The organization must ensure criteria for the provision of the Leave of Absence (LOAs) medications, meets legislative and regulatory body requirements.
	☐ The organization must ensure criteria for "to go doses", meets legislative and regulatory body requirements. Dispensing of "to go "doses should only occur if it has been determined that the patient does not have reasonable or timely access to a community Pharmacy.
	☐ The organization must ensure criteria for medications dispensed to ambulatory patients for home use meets legislative and regulatory body requirements.
	☐ The Hospital must ensure there is an effective process in place to track medications dispensed to patients going home.
There is a policy and procedure on self-administration of medication by patients.	☐ The Hospital should outline criteria for determining which patients can self-administer medications.
	☐ A prescriber's order is required for self-administration such as "May self-administer", specifying drug, dose, frequency, route, etc.
	☐ A prescriber's order is required for medications to be kept at the beside and should include "May be kept at the bedside". Medications should be kept secure (i.e. locked).
RECORD RETENTION, AUDITABILITY AND TRACEABILITY	
Pharmacy records are retained for ten years and patient confidentiality is protected.	☐ The Hospital is working towards 10 year record retention as stated by a Hospital policy
	☐ The Hospital must ensure that confidential information is protected. The Pharmacy must ensure that when disposing of confidential information that it be performed in a manner that ensures confidentiality.
	☐ Documents relating to the care of a patient must be maintained for a period of at least 10 years from the last recorded pharmacy service provided to the patient, or until 10 years after the day on which the patient reached or would have reached the age of 18 years, whichever is longer.
	☐ The Pharmacy must maintain confidential medication records for all patients, and these must records be readily retrievable and maintained appropriately for a time period not less than 10 years from the last professional pharmacy service
	☐ Quality assurance and quality improvement records and documentation including audits, medication discrepancies, adverse drug reaction (ADR), BUD validation, inspections, etc. need to be retained for 10 years.
	☐ Pharmacy staff should review the Guideline Record Retention, Disclosure and Disposal located on the OCP website.

	☐ Dispensing records must be maintained for all medications dispensed and issued from the Pharmacy for 10 years. Pharmacy staff should review OCP's Record Keeping and Scanning Requirements Fact Sheets.
TECHNOLOGY IN PHARMACY	
The Pharmacy ensures the safe operation of all Pharmacy technology and equipment as per standards.	☐ There should be documentation (in a log or in an electronic database) that tracks the process from entry of medication into the system to final verification and includes the signatures of the individuals involved in each step of the process. Policies and procedures need to outline the checks embedded into the process in order to minimize the risk of error and detect unauthorized access
	☐ 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.
	☐ The Pharmacy should have a log for initial certification, preventative maintenance, repairs, cleaning, and maintenance routines for all medication related equipment.
	☐ The Pharmacy must have established policies and procedures related to medication related equipment down time or machine failure. Contingency or down time procedures should be tested, documented and reviewed for system improvements.
	☐ The Pharmacy should have a process to identify deficiencies within the technology used (scanning, barcoding, dispensing automation, etc.) to determine the root cause. These deficiencies must be reviewed by a pharmacist in a management role to track and trend improvements.
The Pharmacy has a policy and procedure to ensure appropriate barcoding of the medication throughout the medication use process.	☐ There must be systems in place to ensure barcodes are applied accurately before product release.
	☐ 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.
	☐ The policies and procedures must outline the checks embedded into the process to minimize the risk of error.
	☐ The Hospital must have a process to identify deficiencies with scanning technology (i.e. to determine if the root cause is the barcode or the barcode reader/scanner or scanning technique).
	☐ The Hospital should retain records of barcode scanning failures and they are reviewed by a pharmacist in a management role to track and trend for system improvements.
	☐ There is barcoding for restocking of ADC's.
	☐ There is barcoding for inventory only.
	☐ There is barcoding for removal of medications in patient care area.
	☐ There is bedside barcode verification.
PACKAGING AND REPACKAGING	
	☐ The Pharmacy must have a policy and procedure for repackaging.

The Pharmacy has policies and procedures for repackaging according to standards.	☐ Personnel must comply with the departmental PPE policies and procedures for non-hazardous product repackaging including completing required training. Documentation of training is required prior to personnel commencing repackaging activities.
	☐ The Pharmacy must ensure that repackaging records are complete and available for reference (methods, equipment, labelling, BUD, storage conditions, personnel responsible for packaging and checking, etc.).
	☐ There should be a policy and procedure in place for unused, returned to Pharmacy, prepacked medications to ensure proper handling and medication integrity.
	☐ Pharmacy policies and procedures must outline which drugs can be prepared/packaged using specific packaging and equipment/machines.
	☐ Pharmacy staff should review USP for packaging and repackaging standards.
	☐ Ensure specially designed oral syringes, are available for dispensing/administering oral/enteral liquid medications that are not available in commercially prepared unit dose cups.
	☐ Oral syringes which cannot be connected to parenteral tubing should be available in the patient care areas for medication administration.
	☐ Repackaging and storage 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" during the repackaging process, including storage.
The Pharmacy has a policy and procedure for assignment of beyond use dates (BUD) for repackaged and compounded medications by Pharmacy personnel.	☐ The Pharmacy must have a policy and procedure for assignment of beyond use dates (BUDs) for repackaged medications by Pharmacy personnel including documentation of approval, date of review, and reference used.
	☐ A pharmacist must be responsible for determining the BUDs for all medications in the Pharmacy.
The Pharmacy has policies and procedures on the appropriate selection of packaging material.	☐ 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.
	☐ 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).
The Pharmacy has policies and procedures for repackaging of hazardous drugs according to established standards.	☐ Dedicated equipment must be segregated and properly labelled for hazardous drug use. (I.e. chemo 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.
	☐ The Pharmacy must determine medications requiring dedicated equipment and PPE.
	☐ Personnel must comply with the departmental PPE policies and procedures for hazardous product repackaging. Training must be completed and documented prior to repackaging activities.
	☐ Tablet and capsule forms of hazardous drugs should not be placed in automated counting machines, which subject them to stress and may introduce powdered contaminants into the work area.

	☐ Hazardous drugs in unit dose packaging that do not require further manipulation must be dispensed in the original package unless otherwise specified by the manufacturer or if visual indicators of HD exposure hazards are present (e.g. HD dust or leakage)
	☐ 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.
	☐ Hazardous drug manipulation (such as crushing/splitting tablets or opening capsules) must be performed in a BSC/CACI with a plastic-backed preparation mat on the work surface, using appropriate PPE and clean equipment.
	☐ For occasional non-sterile hazardous drug manipulation, a C-PEC used for 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	
The Pharmacy administrator/designate ensures that the requirements of the Controlled Substances legislation in Hospitals are met as delegated by the Hospital's CEO.	☐ The Pharmacy administrator/designate should review relevant legislation as it pertains to accountability with respect to Controlled Substances.
	☐ The Pharmacy must have policies and procedures for the prescribing, dispensing and handling of buprenorphine/naloxone (Suboxone) in maintenance treatment of opioid dependence.
	☐ The Hospital must have policies and procedures to ensure fentanyl patches are accounted for including an auditing process to meet Patch 4 Patch legislation.
The Pharmacy has systems and procedures in place to ensure the security of narcotic and controlled substances.	☐ The Pharmacist is responsible for ensuring that narcotics in the Pharmacy are secure. Safeguards must be in place, to prevent unauthorized access.
	☐ A narcotic reconciliation should be completed on a regular basis, in addition to when there is change in staffing and/or after a theft or robbery.
	☐ All Controlled Substances must be counted Hospital wide.
	☐ The Pharmacist is responsible for ensuring that all Controlled Substances in the Pharmacy are secure. Safeguards must be in place, to prevent unauthorized access. In addition to performing a reconciliation on a regular basis, with a sudden change in staffing and after a theft or robbery.
	☐ A pharmacist with narcotic signing authority must review the Narcotic Sales Report Purchase orders and compare to inventory to protect organization against narcotic diversion.
	☐ The Pharmacy must have a system to reconcile Controlled Substances from emergency kits upon use. (e.g. code blue trays)
	☐ Destruction of Controlled Substances must follow the current regulations and policy established by the Office of Controlled Substances at Health Canada. Records of destruction, containing the name, strength per unit and quantity of the Controlled Substance destroyed are kept.
	☐ Pharmacy delivery of narcotic and controlled substances must be secure, auditable and traceable. This also applies to transport between Hospitals/sites.
	☐ The Pharmacy must keep Controlled Substances double locked and have a policy on the restriction of the access to designated staff.
	☐ Pharmacy staff should review; the Fact Sheet Narcotic Reconciliation and Security, and Video – Narcotic Reconciliation located on the OCP website.

A random narcotic count performed during the OCP assessment of Pharmacy inventory reveals no errors.	
The Pharmacy has processes in place to protect Controlled Substances on premises against loss or theft.	☐ The Pharmacy must have policies and procedures to identify and resolve discrepancies for Controlled Substances.
	☐ Each incident of unexpected loss of Controlled Substances must be reported to Health Canada Office of Controlled Drugs in Ottawa within 10 days of discovery. Please refer to the Narcotic Reporting of Forgeries and Losses Fact Sheet located on the OCP website.
	☐ The Pharmacy must have policies and procedures to identify and resolve discrepancies for benzodiazepine and other targeted substances.
	☐ The Pharmacy should have a policy and procedure to perform random audits and verifications of purchase orders, receipts, dispensing as well as perpetual inventory record of Controlled Substances.
	☐ The Pharmacy must ensure that all parts of the transportation/ delivery system protect medication from diversion.
	☐ If medications, including narcotic controlled drugs and benzodiazepines being received, are not delivered directly to the Pharmacy, they must be stored in a secure environment (i.e. locked area) until received by authorized Pharmacy staff.
	☐ The Hospital must review the Controlled Drugs and Substances in Hospitals and Healthcare Facilities Guidelines in Secure Management and Diversion Prevention and/or Narcotic Control Legislation and/or the Controlled Drug and Substances Act to ensure safe practices are in place.
The Pharmacy has policies and procedures in place to prepare and dispense methadone in accordance with current federal and provincial legislation, Standards of Practice, Code of Ethics and OCP policies and guidelines.	☐ Methadone doses must be prepared using a commercially available product as per the Health Canada Policy on Manufacturing and Compounding Drug Products in Canada.
	☐ The Pharmacy must develop policies and procedures to facilitate staff training and awareness.
	☐ The Pharmacy must have access to current copies of the Required References outlined in the MMT policy.
	☐ Prior to dispensing methadone for MMT to any patient admitted to Hospital, a Pharmacist must contact the patient's Pharmacy to notify them of the patient's admission and to determine details of the last dose dispensed.
	☐ Prior to the patient's discharge on the MMT program, the Pharmacist must contact the patient's Pharmacy or facility where the patient is receiving his/her methadone to notify them of the discharge date, time and amount of last dose of methadone to ensure continuity of outpatient care

PHARMACY STANDARDS OF PRACTICE

STANDARD	GUIDANCE
The Pharmacy administrator/designate ensures that Pharmacists and Pharmacy Technicians work within their scope, knowledge, skills and abilities and are held accountable for their actions.	☐ The Pharmacy administrator/designate must be responsible for ensuring all Pharmacists and Pharmacy Technicians maintain current licensure with the Ontario College of Pharmacists.
	☐ The Pharmacy administrator/designate must have a system to assess and update policies and procedures to ensure consistency with legislation, OCP bylaws, OCP standards, practice policies and guidelines.

	☐ The Pharmacy must have policies and procedures that do not impede the Pharmacist or Pharmacy Technician scope of practice.
	☐ Pharmacy personnel must receive appropriate orientation and training to premises-specific procedures and equipment, relevant to the services provided.
	☐ The Pharmacy must ensure dispensing policies and procedures are effective and safe.
	☐ The Pharmacy administrator/designate should review the NAPRA Model Standards of Practice for Pharmacists.
	☐ The Pharmacy administrator/designate should review the NAPRA Model Standards of Practice for Pharmacy Technicians.
The Pharmacy has written policies and/or procedures for the review and investigation of adverse drug reactions.	☐ All adverse drug reactions must be reviewed by a pharmacist.
	☐ Adverse drug reactions should be reported to Health Canada and the manufacturer.
	☐ Serious adverse drug reactions must be reported to Health Canada.
	☐ There must be a review process for each reported adverse drug events, including follow-up with individuals involved, a plan for system improvements to mitigate risk and to identify trends.
	☐ Changes should be monitored for evidence of safer systems/processes subsequent to changes/system improvements.
	☐ Pharmacists should review NAPRA MSOP's regarding reporting of suspected Adverse Drug Reactions (ADR's) and actual ADR's.
	☐ Pharmacy Technicians should review NAPRA MSOP's regarding reporting suspected adverse drug events, medication incidents and close calls.
The Pharmacy has a process in place to document patient care and operational activities.	☐ The Pharmacy must have a process to ensure that Pharmacists 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, regulations and policies applicable to pharmacy practice.
	☐ The Pharmacy must have a process in place to enable pharmacists 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.
	☐ Pharmacy Technicians must maintain clear, accurate and legible records that are consistent with applicable legislation, regulations, policies and standards.
	☐ Pharmacy Technicians must document their activities and the information necessary to support the rationale and quality of these activities, in a timely manner, when distributing drugs (unit dose, ADC fill, IV compounding, Narcotics) and compounding of drug products including documenting calculations and procedures.
The Pharmacy has a process to work collaboratively with other healthcare professionals in performing medication reconciliation at each transition of care.	☐ The Pharmacy must have a process to ensure relevant information obtained during a Pharmacist's medication review and medication reconciliation is entered in the patient health care record.
	☐ If conducting a Best Possible Medication History, the Pharmacy Technicians must document the BPMH in the patient heath care record.
	☐ Pharmacists should work collaboratively with other healthcare professionals to design, implement and deliver medication reconciliation at transitions of care.

	☐ Pharmacists should review the NAPRA Standards (1.28) for providing Best Possible Medication Histories (BPMH).
	☐ Pharmacists should review NAPRA Standards (1.29) regarding completing Medication Reconciliation and documenting in the patient record.
	☐ Responsibility of the Health Care Professional in the medication reconciliation process must be clearly documented, transparent and reflect accountability.
The Pharmacy has a process in place for pharmacists to monitor medication therapy to detect, resolve and prevent drug therapy problems at a frequency appropriate for the medical condition being treated.	☐ Pharmacists must be responsible for monitoring medication therapy to detect, resolve and prevent drug therapy problems at a frequency appropriate for the medical condition being treated and should review the legislation and NAPRA Standards.
	☐ Pharmacists must maintain current and accurate medication profiles on all patients.
	☐ Pharmacists should prioritize patient monitoring based on a review of the medication profile and identifying high risk populations and/or medications.
	☐ Pharmacists should ensure patient continuity of care throughout course in Hospital stay and at time of discharge.
	☐ High-risk medications should be identified and monitored by the Pharmacist for drug therapy problems.
The Pharmacy has a process in place for Pharmacy Technicians to apply their expertise in drug distribution while performing their daily activities.	☐ The Pharmacy Technician(s) should review legislation and the NAPRA Model Standards of Practice for Pharmacy Technicians.
	☐ Pharmacy Technicians must refer all alerts and flags to a Pharmacist to review prior to releasing the prescription or medication order.
	☐ Pharmacy Technicians must identify and refer patients to the Pharmacist who have discrepancies between their current drug therapy and their recent or intended drug therapy.
	☐ Pharmacy Technicians must refer patients to the pharmacist who require assessment, clinical analysis or application of therapeutic knowledge.
	☐ Pharmacy Technicians should review the NAPRA MSOP's for Pharmacy Technicians as it pertains to best possible medication histories.
	☐ Pharmacy Technicians must provide handoff communication to appropriate personnel.

AUTOMATED DISPENSING CABINETS

STANDARD	GUIDANCE
The organization has policies and procedures in place for the use of Automated Dispensing Cabinets (ADC's).	☐ The organization must have written policies and procedures to address access, location, determination of which medications are stored in which patient care areas, determination of quantities including seasonal variation, type of medication information available, and verification for restocking of medications.
	☐ The organization must have a system in place to ensure medications are loaded accurately, stored safely and appropriately (e.g. temperature, humidity, low traffic areas) and in a manner that maintains the integrity of the medications.

	☐ The Pharmacy has established procedures for a pharmacist to determine the appropriateness of medications to be utilized in each machine.
	☐ The Hospital must have the means to identify and address security breaches within the Automated Dispensing Cabinet system within the medication management system.
	☐ All automated dispensing cabinets should have an interface with the Pharmacy information system for order entry and verification.
The use of the override function, on the Automated Dispensing Cabinet (ADC), has additional safeguards to ensure patient safety.	☐ Medications should be withdrawn from an active patient profile during pharmacy business hours.
	☐ For safe practice, limit overrides for from ADC medications to after pharmacy hours to ensure Pharmacist review of all orders prior to administration when the pharmacy is open.
	☐ For safe practice, establish a requirement for an independent double check of selected items removed through the override function (e.g., high-alert drugs, high potency narcotics).
	☐ Access via override must be reconciled against the order by a Pharmacist or Pharmacy Technician for each dose obtained. All overrides for new orders must be reviewed by a Pharmacist to ensure clinical appropriateness.
	☐ The organization should establish indicators and targets for use of the override function, and audit these indicators and targets regularly (e.g., monthly).

DELEGATION

STANDARD	GUIDANCE
There is a delegation process in place authorizing an individual to perform a controlled act in the Pharmacy.	☐ The Pharmacy administrator/designate must ensure a delegation process is in place for all Controlled Acts undertaken by regulated and unregulated staff in the pharmacy who are not authorized to perform these Acts.
	☐ The Pharmacy must have written policies and procedures outlining; duties, appropriate knowledge, skill and judgement required to competently perform the acts assigned to unregulated personnel. This includes documentation of the delegation.
	☐ The Pharmacy must have written procedures for the training of volunteers and all volunteers receive training prior to performing assigned duties, even if not performing Controlled Acts.
	☐ The Pharmacy administrator/designate should review the OCP policy on Medical Directives and the Delegation of Controlled Acts.

TELEPHARMACY

STANDARD	GUIDANCE
The Pharmacy has operational standards in place to ensure telepharmacy services meet all professional standards.	☐ The Pharmacy administrator/designate must have policies and procedures in place to ensure the safe, effective and consistent distribution of pharmacy services and delivery of patient care by personnel providing telepharmacy services.

	☐ Personnel providing telepharmacy services must have access to the same patient-care and medication related information as the Hospital pharmacy.
	☐ The Pharmacy administrator/designate for pharmacy must ensures there are audits in place for the evaluation of the telepharmacy service
	☐ Telepharmacy viewers must only access electronic pharmacy records if access uses a secure transmission and does not store unencrypted personal health information on the user's remote computer.