COLLEGE OF PHARMACY
OF NEWFOUNDLAND AND LABRADOR

STANDARDS OF PHARMACY OPERATION

Hospital Pharmacy

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TABLE OF CONTENTS

INTRODUCTION 2
1. GENERAL STANDARDS OF PHARMACY OPERATION 4
2. SUPPLEMENTAL STANDARDS OF PHARMACY OPERATION 21
3. PHARMACY PRACTICE 25
APPENDIX A A-1
Protecting the Cold Chain A-1
APPENDIX B B-1
Required Reference Materials B-1

INTRODUCTION

The Standards of Pharmacy Operation are made under the authority of section 6.(2)(d) of the *Pharmacy Act, 2024* (Act) and are just one component of the legislative framework that governs the practice of pharmacy and the operation of pharmacies in Newfoundland and Labrador. They must be read in conjunction with other pieces of this framework, including:

- the *Pharmacy Act, 2024*;
- the *Pharmacy Regulations, 2024*;
- the College of Pharmacy of Newfoundland and Labrador (CPNL) Bylaws;
- the CPNL Code of Ethics; and
- all CPNL Standards of Practice and Guidelines.

Pharmacy professionals, in particular pharmacists-in-charge, as well as individuals on the pharmacy management team, must know, understand, and comply with this overall legislative framework.

These standards describe the minimum acceptable standards for operating a licenced hospital pharmacy in Newfoundland and Labrador, unless otherwise specifically exempted by CPNL, and are intended to promote consistency in the provision of pharmacy services in the province.

In this document,

- "controlled substance" means a drug defined in the *Controlled Substances Regulations (Canada)* as a narcotic, controlled drug, targeted substance (including benzodiazepines), or restricted drug.
- "direct supervision" means supervision provided by a regulated pharmacy professional who is physically present when the activity requiring supervision is being performed, and in a manner that allows for observation and prompt intervention on the actions of the individual being supervised.
- "dispensary" means the portion of the pharmacy where scheduled drugs are, or were, prepared, compounded, or dispensed.
- "dispensary staff" means employees of the pharmacy who specifically work in the dispensary.
- "drug establishment licence (DEL)" is a license issued by Health Canada and is required to fabricate, package/label, distribute, import, wholesale or test a drug in accordance with Part C, Division 1A of the *Food and Drug Regulations (FDR)*.
- "electronic health record (EHR)" means a secure and private record of an individual's health care information, available electronically to their authorized health care professionals. An

EHR is designed to facilitate better sharing and interpretation of health information among the health professionals involved in a person's care anywhere within the jurisdiction.

- "health information system (HIS)" refers to a system designed to manage healthcare data. Components of health information systems include the EHR as well as practice management software that enable healthcare professionals to manage daily operations. Within hospital pharmacies, a HIS contributes to drug distribution functions, inventory management, and reporting, and can be integrated with systems like Computerized Physician Order Entry (CPOE).
- "HEALTH*e* NL Viewer" refers to the component of the NL electronic health record, HEALTH*e* NL, a portal that provides authorized health care professionals with one point of access into HEALTH*e* NL to view important patient information such as patient medications, laboratory results, and other available clinical reports.
- "medication order" has the same meaning as "prescription" as defined in the Act.
- "outpatient" refers to a patient who receives medical treatment and/or is prescribed medications when not being admitted to hospital, including residents of long-term care facilities.
- "pharmacist-in-charge" means a person designated by CPNL in accordance with section 8. of the *Pharmacy Regulations, 2024*, who is responsible for the operation of the pharmacy in accordance with section 9. of the same regulations.
- "pharmacy" means the portion of a hospital licenced under Section 31 of the Act.
- "pharmacy management team" refers to regional and provincial pharmacy managers and directors within the health authority.
- "Pharmacy Network" means the component of the provincial electronic health record, HEALTH*e* NL, that includes prescription and other medication-related information for individuals who have had prescriptions or services provided by an NL community pharmacy or hospital outpatient pharmacy.
- "pharmacy staff" means all the employees of the pharmacy, including those who work in the dispensary.
- "practice of pharmacy", as defined in the Act, means:
  - promoting health and the prevention and treatment of diseases, disorders, and conditions,
  - collaborating with patients to meet their health and drug-related needs through patient assessment, drug therapy monitoring and management of drug therapy,
  - providing patients with information about prescription and non-prescription drug and non-drug therapy and assisting with prescription and non-prescription drug and non-drug therapy selection and use,

- compounding, preparing, dispensing, administering, and selling drugs,
- supervising and managing drug distribution systems to maintain public safety and drug system security,
- conducting or collaborating in health-related research, and
- engaging in administration, education, management, policy, or regulation relevant to an activity referred to above.

- "supervision", if not preceded by the word direct, means supervision provided by a regulated pharmacy professional in a manner whereby, while they may not directly observe all activities being performed by the person being supervised, they provide direction and general oversight, and are readily available for consultation or assistance when needed.

1. GENERAL STANDARDS OF PHARMACY OPERATION

The following standards of pharmacy operation apply to **all** licensed hospital pharmacies in Newfoundland and Labrador, unless otherwise specifically exempted by CPNL.

1.1 Operational Policies and Procedures

a) *Oversight.*

i) Each licenced hospital pharmacy must be under the oversight and supervision of an approved pharmacist-in-charge who has the appropriate knowledge and skills to be responsible and accountable for the practice of pharmacy at that pharmacy.

ii) The hospital pharmacy management team and other individuals with decision-making authority on behalf of the Provincial Health Authority, must ensure that the pharmacist-in-charge is provided with the support and resources necessary to comply with the federal and provincial legislation pertaining to the practice of pharmacy, including the duties of a pharmacist-in-charge as listed in section 9 of the *Pharmacy Regulations 2024* and all applicable CPNL standards, and guidelines. Should any individual impede, through action or inaction, the ability of the pharmacist-in-charge to meet their obligations, the pharmacist-in-charge must inform CPNL and CPNL will assess whether an inspection of the pharmacy's operation is required in accordance with Part VI of the Act.

b) *Hours of Operation.*

i) Hours of pharmacy service shall be adequate to meet the scope and programs of the service and the needs of the patient. They shall depend on the size, location, and the functions of the institution and the availability of staff.

ii) If 24-hour pharmacy services are not available on-site, the pharmacist-in-charge must ensure that urgently needed medications and patient-oriented pharmacy services are always available by:

- allowing automated dispensing cabinet (ADC) overrides for access to medication by nursing staff when the dispensary is closed, prior to pharmacist review, when a delay in medication administration may result in patient harm, or
- providing a locked, secure area such as a night cupboard outside of the hospital pharmacy which must:
  - be accessible only by authorized persons;
  - be stocked with a minimum supply of medications most commonly required for urgent use;
  - only contain controlled substances if they are provided by an automated dispensing system, wherever possible, or alternatively, a double-locked cabinet;
  - contain medications that are packaged to ensure integrity of the drug and labeled with the medication name, strength, quantity (if not unit dose), expiry date and lot number; and
  - include a log, in physical or electronic form, in which medication withdrawals are documented;
- arranging for on-call pharmacy services for pharmacist consultation and provision of medications that are urgently needed and not available within unit stock or in the night cupboard.

PLEASE NOTE:

- Medications that are obtained by nursing staff after hours or in emergency situations must be verified and reconciled with the medication order when the pharmacy re-opens, or at the earliest opportunity, to ensure accurate medication selection and clinical appropriateness.
- Pharmacy technicians may participate in on-call services to retrieve medications from the pharmacy, including performing technical duties and final product checks, if a pharmacist is also available to perform clinical assessments of all new medication orders and provide consultation when required, and appropriate policies and procedures are in place.

c) *Policies and Procedures*. The pharmacy must have well-organized and easily accessible policies and procedures that all pharmacy staff are familiar with and understand. The pharmacist-in-charge is expected to ensure that there is a process in place for these documents to be regularly reviewed and updated as required.

Policies and procedures shall include information relating to the administrative and procedural aspects of pharmacy services, including roles and responsibilities of pharmacy staff, as well as copies of guidelines for medication-related activities in the hospital that have been approved by hospital administration, pharmacy administration, the Pharmaceuticals and Therapeutics Committee, or other established committees. They should also include information specific to any special services provided by the hospital pharmacy.

d) *Committees and Programs*. Committees responsible for establishing or monitoring medication- or pharmacy-related policies and procedures, for example, the Pharmaceuticals and Therapeutics Committee, must have pharmacists as members and active participants.

e) *Continuous Quality Improvement*. The pharmacist-in-charge must participate in the development, documentation, and implementation of an ongoing quality improvement program appropriate for the level of pharmacy services provided. This program should include, but not be limited to, the following:

i) maintaining and enforcing policies and procedures to comply with all legislation applicable to the operation of a hospital pharmacy;

ii) monitoring staff performance, facilities, equipment, and adherence to these Standards;

iii) a process for reporting, documenting, and following up on known, alleged, and suspected errors, incidents, discrepancies, and near-misses;

- Individual medication incidents and near-misses must be reviewed and analysed in a timely manner to identify contributing or causal factors and to identify possible trends.
- Processes must be in place to implement system improvements and risk mitigation strategies to reduce the likelihood of medication incident recurrences and to monitor the effectiveness of these changes.

iv) documenting periodic audits of the medication distribution process to ensure auditability and traceability of medication doses to the patient level;

v) a process that audits pharmacist and pharmacy technician documentation notes in the patient health record for format, content, and appropriateness;

vi) following up on identified missed doses and when patients are not receiving medication as ordered by the prescriber;

vii) policies and procedures to monitor, review, and report adverse drug reactions:

- An interdisciplinary review process must be established, in cooperation with medical and nursing staff, to ensure that reported adverse drug reactions are investigated and follow-up information is collected.
- In general, all adverse drug reactions should be reported to Health Canada and the manufacturer. Serious adverse drug reactions (as defined in C.01.001(1.1) of the *Food and Drug Regulations (Canada)*) **must** be reported to Health Canada as outlined in Health Canada's Guidance Document - Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals.

viii) a process to evaluate medication use; and

- This evaluation can be done in collaboration with other health care professionals, and the Pharmaceuticals and Therapeutics Committee, or other established committees, and may involve:
  - establishment of criteria or a formulary for medication use;
  - an assessment of actual usage against established criteria;
  - the identification of problematic areas (including when medications should be removed from the formulary); and/or
  - the provision of education to rectify patterns of improper medication use.

ix) regular updates to policies and procedures for medication use control and patient-oriented pharmacy services in collaboration with the medical and nursing staff and appropriate committees.

1.2 Staffing and Supervision

a) *Staffing Complement*. The pharmacist-in-charge must ensure that the professional, technical, and supportive staffing levels of the pharmacy are sufficient to safely provide quality patient care through both medication distribution and clinical services. Consideration should be given to:

i) past and anticipated workload volumes;

ii) the patient care needs;

iii) the total number of staff and various staff roles needed to ensure continuous operation of the pharmacy (including accounting for coverage for emergency situations, staff illness, vacation, etc.); and

iv) the number of staff and various staff roles that must be present in the pharmacy at any given time to provide consistent, safe, and quality services to patients, (including accounting for breaks, overlap, number of consecutive hours worked, etc.).

b) *Name Tags*. All pharmacy personnel, whether registered with CPNL or not, must wear a suitable name tag that identifies to the public and other hospital staff that person's name and position. Registered pharmacy staff (including students and interns) must be identified by their full name.

c) *Position Descriptions*. There shall be written position descriptions for all pharmacy personnel containing detailed information on the knowledge, skills, experience, and abilities that should be maintained by pharmacists, pharmacy technicians, pharmacy assistants, and other pharmacy support personnel. Position descriptions must be provided to and reviewed with all new staff and when existing staff change roles. These descriptions should be regularly reviewed and revised, as necessary.

d) *Education, Training and Orientation*. The pharmacist-in-charge must ensure that all pharmacy personnel have the necessary education, training, knowledge, and skills to carry out their assigned duties.

Specifically, pharmacists-in-charge are expected to have processes in place to confirm that regulated pharmacy personnel are actively registered with CPNL and have continuous professional liability insurance coverage in accordance with CPNL's *Professional Liability Insurance Requirements for Registration*.

e) *Supervision and Oversight*. The pharmacist-in-charge must ensure that:

i) the staffing complement of the pharmacy is appropriately balanced to allow adequate levels of supervision and/or oversight to be provided to all pharmacy staff including pharmacists, pharmacy technicians, pharmacy assistants, interns, and students; and

ii) registered pharmacy professionals do not assign tasks to any person unless that person is qualified and has received appropriate training to engage in the specific task.

1.3 Physical Layout and Security

a) *Physical Space*. The pharmacy must have sufficient physical space and be designed in such a way to facilitate a safe, healthy, and effective working environment for all staff.

i) The pharmacy should be well-ventilated, appropriately lighted, and clean and tidy at all times. Policies and procedures must be in place regarding:

- cleaning requirements for each area of the department; and

- documentation of maintenance routines and maintenance logs for pharmacy and medication-related equipment.

ii) The pharmacy must have adequate working space to support safe medication practice.

iii) The pharmacy must have adequate storage space for medications and supplies that allows for proper conditions of sanitation, temperature, light, humidity, ventilation, regulation, and security.

iv) Temperature and humidity levels must be monitored in medication storage areas to ensure appropriate environmental conditions for maintaining safe medication management.

v) The pharmacy must provide a safe working environment for pharmacy staff with consideration given to the handling of cytotoxic, biological, and hazardous products. It is recommended the pharmacist-in-charge regularly review occupational health and safety resources (e.g., NIOSH, ISMP, WorkplaceNL) to ensure that safe storage and handling processes are in place within the pharmacy.

b) *Security*. Pharmacists-in-charge must ensure that reasonable steps are taken to protect drugs and other health care products on the premises from loss, theft, diversion, and tampering, as well as to provide a safe working environment for staff. The pharmacy must be self-contained and secured against entry by the public or non-authorized staff when a pharmacist or a pharmacy technician is not present in the pharmacy. To meet these expectations, the pharmacy must have a combination of security measures as described below:

i) Physical measures. For example, deadbolt locks, metal or metal-clad doors, window protection via shatterproof glass, and panic buttons (if appropriate and deemed necessary).

ii) High-resolution video surveillance equipment. Cameras must be visible and appropriately positioned on both the exterior and interior of the pharmacy (e.g., at the entrances to the main premises, the pharmacy, and the dispensary; within the dispensary; and where controlled substances are stored). Recording equipment must be kept in a locked area out of public view with recordings kept for at least 30 days.

iii) A monitored alarm system. This must include the use of motion detectors and door alarms. The alarm system must be periodically tested to ensure that it is functioning correctly.

iv) All security equipment must be kept up to date and in good working order and readily accessible to relevant pharmacy staff members when needed or in response to an incident.

c) *Access*. Keys, access cards, and/or codes must be limited to a minimum number of appropriately authorized pharmacists and pharmacy technicians. Access may be provided to other pharmacy personnel as long as such access is limited to when a pharmacist or pharmacy technician is present in the pharmacy. Access codes must be individualized and kept private by authorized staff members. Other requirements regarding access include:

i) The pharmacy must have a policy on how key/access assignments are made, removed, and documented. Access to the pharmacy by authorized personnel must be removed when staff leave their positions within the hospital pharmacy, including for extended leaves.

ii) Pharmacy maintenance and cleaning should be completed during regular pharmacy hours when regulated pharmacy staff is present. Specific cleaning activities that cannot be completed during regular hours can occur after hours only if a pharmacist or pharmacy technician is present during the activity.

iii) The pharmacist-in-charge may permit appropriate non-pharmacy personnel (e.g., security personnel) to access the pharmacy after-hours in emergency situations such as fire, flood, and security breach. Keys to enter the pharmacy shall be stored in a secure area, and a system must be in place to alert the pharmacist-in-charge of access.

1.4 Equipment and Supplies

a) *Equipment- and Supply-Related Policies and Procedures.*

i) Decisions related to the selection, evaluation, use and monitoring of drug distribution systems (e.g., medication carts, automated dispensing units, infusion pumps) must involve pharmacists.

ii) There must be policies and procedures in place to ensure equipment used in the preparation, distribution, and administration of medications is certified, cared for, and appropriately maintained, serviced, and cleaned.

iii) There must be policies and procedures in place in the event of equipment failure or down time.

b) *Required Equipment and Supplies.* The pharmacist-in-charge is responsible for ensuring that the pharmacy and the equipment contained within is kept clean, in good condition, and in proper working order, so that pharmacy personnel can perform their intended

tasks in a safe, secure, and appropriate manner. At a minimum, the pharmacy must be equipped with:

i) a secure computer system with:
   - a health information system;
   - the ability to view information within the electronic health record;
   - suitable internet connection and access to allow staff access to CPNL email and website as well as other electronic resources appropriate to pharmacy practice, as indicated in section 1.4 b) xi); and
   - adequate backup and recovery systems in place to allow for information retrieval in the event of system failure or destruction.

ii) a printer or printers capable of printing any relevant labels, and required reports;

iii) suitable equipment that allows the staff to send, receive, and/or copy electronic or non-electronic documents (e.g., a fax machine). Such equipment must be located in an area that preserves patient confidentiality;

iv) suitable equipment that allows staff to scan documents (including medication orders and other patient records) and store them electronically (e.g., a scanner);

v) a storage system, either physical or electronic, for patient records that is readily accessible to appropriate pharmacy staff, but secured against unauthorized access;

vi) a telephone;

vii) a sanitary sink with a supply of hot and cold water;

viii) a shredder or service for the safe disposal of confidential information;

ix) appropriate waste disposal equipment and methods to meet applicable federal and provincial legislation (including a method to dispose of drug and other hazardous or biomedical waste);

x) appropriate drugs and drug storage space, equipment, and supplies, including:
   - a sufficient supply of drugs to meet patient needs;
   - refrigerator(s) for the exclusive storage of drugs requiring refrigeration that meets the cold chain requirements described in Appendix A;
   - an appropriately anchored secure safe, or a storage area for the secure and storage of narcotics and controlled drugs;
   - adequate shelf and storage space, including suitable storage area and equipment to ensure compliance with legislation and guidelines regarding the handling of hazardous drugs; and

- dispensing equipment and consumable materials related to dispensing and compounding activities, such as, graduated cylinders, mortars and pestles, spatulas, counting trays, prescription and auxiliary labels, safety and non-safety vials, liquid medication bottles, ointment jars, and distilled water.

xi) required reference material as described in Appendix B, along with current references relevant to any specialized services provided (e.g., oncology, pediatrics, psychiatry).

PLEASE NOTE:

- Reference materials may be hardcopy, electronic or online, or may be provided through an electronic comprehensive pharmacy information system database, provided they mirror the hard copy, provide the same or greater information, and meet the same requirements for currency.
- When electronic or online references are utilized, the pharmacist-in-charge ensure that pharmacy staff are familiar with the resources that are available and that they are accessible and available to all pharmacy staff, including casual and on-call staff, where and when they need them.

c) *Optional Equipment and Supplies*. The dispensary may also be equipped with additional equipment as is appropriate to the needs and workflow of the practice.

i) If automated equipment, such as pre-packaging machines, are used during the dispensing process, the pharmacy must have appropriate policies and procedures in place including, but not limited to, those related to:

- determining the appropriateness of medications to be utilized in these machines;
- how medications are added to the machines, including initial setup, replenishment, and related documentation processes (e.g., the identity of pharmacy personnel involved in each process);
- calibration and recalibration, and maintenance of the machine (including cleaning) as per manufacturer recommendations, and appropriate documentation of such;
- the assignment of beyond-use-dates based on established standards;
- maintaining records of dispensing and packaging for each machine; and
- the responsibility of the pharmacist-in-charge to review any reports related to the machines to ensure patient safety.

ii) Suitable equipment to ensure compliance with compounding standards (sterile and/or non-sterile) and/or guidelines regarding the handling of hazardous drugs.

1.5 Inventory Management

a) *Procurement*. All drug inventory must be sourced from a regulated supply chain that assures the quality, safety, and integrity of drug products. Drug inventory must be procured in a manner that complies with applicable federal and provincial legislation and regulatory requirements, and may include purchase from:

i) licensed wholesalers/distributors, manufacturers, and other suppliers with a valid drug establishment license issued by Health Canada;

ii) a Special Access Program approved by Health Canada;

iii) sources approved by Health Canada's regulatory framework for authorized clinical trails; or

iv) another pharmacy when:

- a limited supply is required to meet urgent patient needs, and it cannot be sourced in a timely manner through the sources noted above, and a written order signed by a person authorized to order for the hospital is provided to the pharmacy; or
- a drug product is not available commercially, and compounding or repackaging is required to meet patient needs, and the hospital pharmacy does not have the capacity to compound or repackage themselves.

PLEASE NOTE:

Requirements of CPNL's *Central Fill Policy* must be met if a hospital pharmacy engages another pharmacy to compound preparations or repackage drugs (e.g. compliance or unit dose packaging) on their behalf, including establishment of a central fill agreement and patient-specific medication orders.

b) *Deliveries*. All drug supply orders must be delivered unopened to the pharmacy department. If deliveries for pharmacy are first accepted by the receiving department of the hospital, the receiving department should maintain a log for pharmacy deliveries. This log should contain essential details such as the date and time the delivery was received, the number of packages received, and the names of the individuals who participated in the delivery and receipt of the order.

c) *Non-Useable or Expired Medications*. Non-usable and expired medications must be stored in an area separate from other pharmacy inventory or drug products until final disposal.

d) *Return to Stock*. Unused dispensed medications must be returned to the hospital pharmacy. Previously dispensed medications must not be re-dispensed unless:

i) they are returned to the hospital pharmacy in a sealed dosage unit or container as originally dispensed;

ii) the labeling is intact and includes a legible drug lot number and expiry date; and

iii) the integrity of the drug, including the storage conditions of the medication on the nursing unit, can be verified.

1.6 Medication Distribution Systems

a) *Systems*. There must be pharmacist involvement in the establishment of information and medication distribution systems (e.g., medication carts, automated dispensing units, infusion pumps) that:

i) provides medications in identified dosage units ready for administration whenever possible and practical;

ii) protects medications from contamination;

iii) allows for a method of recording medications at the time of administration; and

iv) eliminates or reduces the need to maintain ward stock.

PLEASE NOTE:

- A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing medications.
- Ward stock medication systems are associated with the greatest potential for error, and therefore should be limited to those medications which:
  - are commonly prescribed on an "as needed" basis;
  - are of low potential for toxicity;
  - are required on an urgent basis; or
  - are bulky in size.

b) *Policies and Procedures*. Regardless of which drug distribution systems are utilized, the pharmacy must have appropriate policies and procedures in place including those related to:

i) the care, cleaning, and maintenance of the system;

ii) the security of any system located in a patient care area including how security breaches are detected and handled;

iii) levels of access and training for pharmacists and pharmacy technicians who use the system;

iv) maintenance of accountability records related to stock replenishment that include date and identification of the pharmacist or pharmacy technician checking and replenishing the stock;

v) ensuring nursing has adequate training on the appropriate use of medication distribution systems;

vi) review of all appropriate reports, or visual medication inspections for expiry dates, at least monthly to ensure inventory is within the "use by" date;

vii) monitoring of refrigerator and freezer temperatures, including ensuring that those located in patient care areas are consistently monitored, especially in areas lacking 24-hour staff coverage;

viii) contingency procedures for system down-time or machine failure; and

ix) processes that enable the tracking and traceability of medications dispensed to individual patients, including those currently hospitalized and from a historical viewpoint.

1.7 Record Keeping and Information Management

a) *Documentation*.

i) The pharmacist-in-charge must ensure that all records required by legislation, these Standards of Pharmacy Operation, and the standards of practice are documented appropriately and retained in a secure, but readily accessible format (either physical or electronic) for the appropriate time period.

ii) All records maintained by the pharmacy must be current and accurate with respect to the pharmacist's, pharmacy technician's, or pharmacy's activities.

b) *Electronic Records*.

i) The pharmacy's computer equipment, system, and software must have the capability to:

- store and report all required patient health information;

- identify each user who is granted access, control the access granted to the users, and create an accurate audit trail of access;
- electronically view medication orders and other relevant patient records; and
- generate reports of medication order information chronologically and by drug name and strength, patient name, and prescriber name.

ii) A daily backup of electronic records is required, and it must be regularly tested for recovery. The backup should be securely stored to ensure it can be retrieved in case of system failure or destruction. Storage options include:

- storage in an on-site fire- and theft-resistant safe;
- storage at an approved off-site location; or
- utilizing a secure cloud-based service provider where the data is retained within Canada.

c) *Record Storage and Security*.

i) Patient records, including:

- medication orders, and
- any other records related to patient care that are required by legislation, these Standards of Pharmacy Operation, or standards of practice (e.g., patient assessment records, clinical documentation forms, compounding records, consultation records, or packaging records),

must be retained in a secure, but readily accessible format (either physical or electronic) for a minimum of ten years.

ii) All patient records (including backups) must be adequately secured to protect them from unauthorized access, use, disclosure, modification, theft, and destruction.

iii) Security measures should include appropriate physical, administrative, and technical safeguards.

d) *Destruction of Records*

i) Physical records must be destroyed using an in-pharmacy shredder, a contracted secure service for the safe disposal of confidential information, or by complete incineration. To ensure that the requirement for record retention outlined in section 1.7 c) is met, the presence of an electronic version of the record should be confirmed before the record is destroyed.

ii) Electronic records must be erased or destroyed in such a manner that the information cannot be reconstructed.

1.8 Security and Accountability of Controlled Substances (Narcotics, Controlled Drugs, and Targeted Substances, including Benzodiazepines)

a) *General Requirements*. Section 172. of the *Controlled Substances Regulations (Canada)* states that "a hospital must take all reasonable measures to ensure the security of any controlled substance in its possession".. Practically speaking, specific responsibilities can be delegated at an operational level, and should be defined in organizational policy.

CPNL expects that pharmacists-in-charge implement appropriate policies, procedures and physical measures to protect controlled substances on the pharmacy premises against loss or theft. This includes protection from external theft such as burglary or robbery but also includes protection from internal drug diversion. To meet this requirement, pharmacies must employ a variety of security, inventory reconciliation, and record-keeping measures, as described below.

b) *Storage and Security*.

i) Within the pharmacy department, all narcotics and controlled drugs must be stored in a secure safe that can be appropriately anchored to the floor or wall, or in a separate secure room used for the exclusive storage of these drugs in accordance with section 1.4. b).

ii) In patient care areas, narcotics and controlled drugs should be stored in automated dispensing cabinets within a locked room or another area which is not accessible to the public, or by employing another double or triple lock procedure (e.g., a locked cabinet within a locked room, or a locked cupboard within a locked storage area in a locked room).

c) *Perpetual Inventory*. Pharmacies must maintain a perpetual inventory – a continuous rolling count – of all controlled substances. Pharmacy staff must be able to generate a report for each individual drug that shows the sequential inventory changes by date, including dispenses/sales, purchases, cancelled prescriptions, and any manual inventory changes (including who made them and the reason for such). If it is not possible to have a computerized perpetual inventory record, a manual record must be maintained with separate documentation for each controlled substance.

i) A physical inventory count of all controlled substances must be performed and documented at least every three months in accordance with the following:

- All controlled substances should be counted, including active inventory, expired or damaged stock, products awaiting destruction, and any compounded mixtures containing a controlled substance.

- Drugs returned to the pharmacy for destruction should not be included in the inventory count as these products are not part of the pharmacy's inventory.
- The inventory count should be documented in a separate and dedicated record that includes:
  - the name, strength, form, and quantity of the drug counted;
  - the signature of the counter(s); and
  - the date the count was performed.
- The physical inventory count must be reconciled with the perpetual inventory, and any discrepancy must be investigated by reviewing the perpetual inventory record, dispensing/sales records, and purchase invoices. Identified discrepancies and their resolution must be documented, filed with the inventory record, and retained for two years.

PLEASE NOTE:

When investigating discrepancies, all possible explanations should be considered, including dropped or broken tablets, manufacturer errors, a compounded product not yet removed from the inventory, emergency supplies received from other pharmacies, or internal diversion.

ii) Additional physical inventory counts of controlled substances must also be performed and documented as follows:

- when the pharmacist-in-charge changes, whenever possible, with the departing pharmacist-in-charge and the new pharmacist-in-charge jointly conducting the inventory count and documentation;
- when a pharmacy closes;
- to document losses after a break-in, robbery, fire, etc.;
- to account for discrepancies caused by internal diversion or process losses (e.g., compounding);
- to reconcile purchase/invoice discrepancies;
- to validate or monitor the pharmacy's storage and security.

d) *Handling of Post-Consumer Returns and Unserviceable Stock*. Pharmacists-in-charge should ensure that unserviceable stock containing controlled substances are handled in

accordance with the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada.

PLEASE NOTE:

Examples of unserviceable stock include:

- expired or recalled drugs;
- overfill in vials;
- partial doses (e.g., partial tablet);
- drug remaining in infusion bags or syringes;
- drugs that were specifically compounded for an individual and cannot be used by another patient;
- drugs remaining in transdermal delivery systems;
- patient's own medications for which disposal has been requested; or
- other unusable drugs (e.g. drugs that were spit out by the patient).

e) *Maintenance and Retention of Controlled Substances Records.* All documentation related to controlled substances should be recorded, maintained, and retained in accordance with sections 122-126 of the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada.

f) *Preventing Loss or Theft*. Pharmacists-in-charge must ensure that reasonable steps are taken to protect drugs and other health care products on the premises from loss, theft, diversion, and tampering.

i) *Preventing Robberies and Burglaries*. While not possible to completely prevent robberies and burglaries, pharmacists-in-charge are expected to take reasonable steps to decrease their likelihood and to protect pharmacy staff, medications, and property. This may include:

- ensuring physical security measures and appropriate surveillance are implemented in accordance with section 1.3 b), as well as any additional security measures that are deemed necessary based on pharmacy-specific risks;
- developing and implementing policies and/or procedures related to pharmacy security that include information about preventing and responding to robberies and burglaries;
- regular staff training on the use of security equipment, how to monitor for security risks, and how to respond to incidents when they occur; and/or

- consultation with police and/or other security experts to identify and implement strategies to deter potential perpetrators and enable successful investigations should an incident occur.

ii) *Monitoring for Internal Diversion*. There must be policies and procedures in place related to processes aimed to prevent and detect diversion by hospital personnel. These processes may include:

- random audits of purchase invoices against the perpetual inventory record to ensure that purchases have been accurately received into the pharmacy's inventory;
- random audits of dispenses to ensure that there is a corresponding valid medication order and that it has been dispensed accurately;
- random audits to reconcile the prescriber's order, the controlled substances ledger, and the medication administration record (MAR) to ensure appropriate usage;
- designating a **limited** number of individuals who can order controlled substances from licensed dealers. For electronic ordering, each designated individual must have an individual access code which is not shared or used by others;
- technology safeguards such as automated ordering and receiving, restricted ability to make manual inventory changes, and requirement for the rationale for a manual inventory change to be documented; and/or
- regularly generating or reviewing a report that details all manual inventory changes made within a period of time (e.g., weekly, or monthly).

PLEASE NOTE:

Physical inventory counts and audits of controlled substances should be performed randomly on different days of the week and throughout the month by various individuals whenever feasible to increase the likelihood of the detecting discrepancies.

g) *Reporting Losses or Thefts*. Any unexplained inventory discrepancies identified through reconciling routine physical inventory counts with the perpetual inventory, inventory monitoring, or losses due to robberies or break-ins must be reported to Health Canada's Office of Controlled Substances within 10 days in accordance with section 173. of the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada.

2. SUPPLEMENTAL STANDARDS OF PHARMACY OPERATION

These standards of pharmacy operation apply only to those hospital pharmacies that choose to offer the particular service. As noted in section 1.1 c), if these services are provided, the pharmacy's policies and procedures should contain information pertaining to each of the services provided.

2.1 Investigational and Special Access Program Drugs

Pharmacy professionals must comply with the policies and directives of Health Canada with respect to storage and dispensing of investigational or special access drugs.

2.2 Service to Clinics or Other Hospitals

a) Service to clinics, or other hospitals that do not have a pharmacy on site, must be provided in accordance with established policies and procedures that are consistent with these Standards.

b) A pharmacist or pharmacy technician must conduct an audit on medication rooms or storage areas of any clinics or hospitals serviced by the pharmacy at least every six months to identify any potential medication safety issues. These audits should be conducted in-person whenever possible.

PLEASE NOTE:

Virtual audits may be appropriate when performing an in-person audit is impractical due to geographical limitations or when there is an issue that necessitates prompt evaluation.

c) Provision of controlled substances to community healthcare facilities must be performed in accordance with Health Canada's Subsection 56(1) Class Exemption for the Person in Charge of a Hospital and/or a Pharmacist who Supplies Controlled Substances to a Community Health Facility.

2.3 Other Specialized Services

Specialized services offered by the pharmacy must be offered in accordance with established policies and procedures and these standards of pharmacy operation, as well as any associated CPNL standard of practice, policy, or guideline. This includes, but is not limited to:

- Administration of Inhalations or Injections;
- Central Fill Services;
- Medical Assistance in Dying;

- Non-Sterile Compounding;
- Opioid Agonist Therapy Medications;
- Pharmacist-Ordered Laboratory Tests;
- Point of Care Testing;
- Prescribing;
- Service to Long-Term Care Facilities;
- Service to Personal Care Homes;
- Sterile Compounding; or
- Any other service or practice area with specific regulatory requirements.

2.4 Outpatient Services

Service to outpatients, must be provided in accordance with CPNL's *Standards of Pharmacy Operation – Community Pharmacy* as well as established policies and procedures.

PLEASE NOTE:

- **All** outpatient dispensing services, including dispensing to long term care facilities and provision of home IV therapy, must be performed using a practice management system that is connected to the Pharmacy Network to ensure that patient profiles on the electronic health record are accurate, complete, and visible to all members of the patient's health care team.
- Prescription pick-up information must be transmitted to the electronic health record via the Pharmacy Network as close to the actual pick-up time as possible to help ensure the data integrity of the patient's personal health information and to enable drug utilization reviews to be performed accurately.

2.5 Medication Delivery

a) *Intended Use*. These standards must be met in any situation where a medication is delivered to any site outside of hospital premises, including a clinic or another facility, and they are applicable irrespective of whether the delivery is conducted by pharmacy personnel, a courier, or through mail.

PLEASE NOTE:

Home delivery to a patient is regarded as a component of outpatient dispensing and must be conducted in compliance with CPNL's *Standards of Pharmacy Operation – Community Pharmacy*, along with the established policies and procedures.

b) Decisions about whether medications are to be delivered, and by what method, should be made on a case-by-case basis. If the decision is made to deliver a medication, it must be done so in accordance with the following:

i) Prescriptions for controlled substances must be delivered in accordance with sections 170-171 and 182 of the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada.

ii) Medications must be packaged and delivered in a manner that maintains the stability and integrity of the drug, and does not expose the drug to temperatures that fall outside manufacturer specifications.

iii) Patient confidentiality must be protected at all times by ensuring that the outer package contains only the name and address of the facility or clinic to which the medication is being delivered.

iv) For each medication delivery, there must be a record that includes the details necessary to confirm that the medication was received by the intended recipient, such as the name of the recipient, the name of the delivery person, and/or a tracking number with documentation that pharmacy staff used to confirm successful delivery to the recipient.

2.6 Inpatient Leave of Absence (Pass) Medications and "Tide-Over" Medications

a) All inpatient leave of absence medications must be documented in the patient record.

b) Labels for leave of absence medications must include:

i) the hospital's name, and telephone number;

ii) the patient's name;

iii) the practitioner's name;

iv) the drug name, strength, and directions for use;

v) the drug quantity; and

vi) the date the medication is issued.

c) All leave of absence medications must be dispensed in child-resistant containers unless:

i) the practitioner, the patient or the patient's representative directs otherwise;

ii) in the pharmacy professional's judgment it is not advisable to use a child-resistant container; or

iii) a child-resistant package is not suitable because of the physical form of the drug or the design of the manufacturer's packaging.

d) In any instance where a child-resistant container is not utilized, a notation to that effect must be documented on the patient medication profile.

e) Policies must be in place regarding the release of medications to patients being discharged from the emergency department or other outpatient departments if they are unable to obtain them from a community pharmacy within a reasonable time frame. The provision of emergency tide-over doses must be documented in the patient record.

f) There must be a process to track medications dispensed to patients going on a pass to ensure that patients on leave-of-absences are contacted, if necessary, in the event of a drug recall or medication incident.

2.7 Patients' Own Medications

The pharmacy must have policies and procedures in place with respect to the use of patients' own medications. These policies and procedures should include, but not be limited to:

a) when it is appropriate to identify and utilize a patient's own medication product for use in hospital;

b) the requirement for written orders by the prescriber for administration of the patient's own medication;

c) when examination of the product by the pharmacist is required to confirm the identity and integrity of the product and documentation of such on the product itself and in the patient record;

d) the process for handling situations when a medication cannot be positively identified;

e) the process for provision of factual, unbiased information about the medicinal product to the patient and the health care team and documenting as such;

f) processes for storage of patients' own medications outside of the pharmacy to safeguard the medication supply; and

g) strategies to prevent the diversion of patients' own medication supply during storage – especially in the case of controlledsubstances.

2.8 Self-Administration of Patient Medications

There must be policies and procedures in place regarding the self-administration of medications by patients. These policies and procedures should include, but not be limited to:

a) the criteria for determining which patients can self-administer medications, and which medications can be self-administered.

b) the requirement for a prescriber's order for self-administration such as "may self-administer," specifying the drug, dose, frequency, and route; and

c) the criteria for which medications can be kept at bedside and the requirement for a doctor's order for a medication to be kept at bedside.

2.9 Sterile Compounding

Sterile compounding must be performed in accordance with CPNL's *Standards of Practice for Pharmacy Compounding of Non-Hazardous Sterile Preparations* and *Standards of Practice for Pharmacy Compounding of Hazardous Sterile Preparations*, whichever is applicable in the circumstance, as well as established policies and procedures.

2.10 Non-Sterile Compounding

Non-sterile compounding must be performed in accordance with CPNL's *Standards of Practice for Pharmacy Compounding of Non-Sterile Preparations*, as well as established policies and procedures.

2.11 Provision of Opioid Agonist Therapy Medications

Opioid dependence treatment services must be performed in accordance with CPNL's *Standards of Practice for the Provision of Opioid Agonist Therapy Medications*, as well as established policies and procedures.

3. PHARMACY PRACTICE

These standards of pharmacy practice apply to ALL licenced hospital pharmacies in Newfoundland and Labrador, unless otherwise exempted by CPNL. Any person or corporation who operates a hospital pharmacy in Newfoundland and Labrador must meet all the following practice requirements.

3.1 Patient Record

a) A patient record must be initiated and maintained for each patient for whom medications are prepared, except patients admitted for less than 24 hours to:

i) surgical day care;

ii) ambulatory care;

iii) emergency short-stay; or

iv) other short-stay diagnostic or treatment units.

b) The patient record must be complete, accurate and current and include the following patient information:

i) full name;

ii) medical care plan (MCP) number;

iii) patient location within the hospital (e.g. room number);

iv) admission date;

v) attending physician's name;

vi) date of birth;

vii) gender, weight and height, if applicable to therapy;

viii) allergies, adverse drug reactions, intolerances, and diagnoses;

ix) a chronological list of medications prescribed for the patient since admission to hospital, or, if admission is prolonged, for a minimum period of ten years;

x) a list of all current medication orders that includes the following information:

- medication name, strength, and dosage form;
- dosage;
- route;
- directions for use;
- administration time or frequency;
- name of prescriber, or attending physician;
- start and stop date, or length of therapy, if applicable; and date the medication was dispensed, refilled, or discontinued;

xi) other therapies (e.g. parenteral nutrition, enteral nutrition); and

xii) other pertinent information (e.g., smoking status, alcohol use, renal function, etc.).

3.2 Medication Order Requirements

a) Medication orders must include the following information:

i) patient name;

ii) name and strength of the medication to be administered;

iii) route of administration;

iv) dosage instructions including frequency, interval, or maximum daily dose;

v) date the medication order was written;

vi) time the medication order was written, if appropriate;

vii) weight, if applicable; and

viii) name of prescriber.

b) If the prescription is received verbally from the prescriber, the pharmacist or pharmacy technician receiving the prescription must document the prescription in accordance with section C.01.041 of the *Food and Drug Regulations (Canada)*, or section 181 of the *Controlled Substances Regulations (Canada)*.

c) Regardless of how medication orders are received, the pharmacist or pharmacy technician is expected to ensure that prescriptions are current, authentic, complete, and appropriate before dispensing.

d) Organizational automatic stop policies should be followed for classes of drugs for which a limited duration of therapy is desirable, otherwise a medication order may not be filled beyond one year from the date on which the medication order was originally written.

e) If the medication order is ordered to be started at a later date or time, the following must be completed as soon as possible to ensure the accuracy of the patient's medication profile:

i) The pharmacist or pharmacy technician must ensure that the medication order is accurately entered into the patient's medication profile, as if it were to be dispensed immediately.

ii) The pharmacist must assess the therapeutic appropriateness of the drug therapy, considering the patient's current status and information available at the time, and address any identified drug related problems.

iii) The medication order record must include the identity of any staff members involved in entering the prescription into the patient profile.

f) When a medication order has been held indefinitely, or for an extended period of time, it must be noted as such in the patient record. If the medication is restarted, it must be handled as if it were a new medication order and entered as such, to ensure that an appropriate drug utilization review takes place to identify any potential drug related problems. Consideration should be given to any changes in the patient's medications, diagnosis, history, etc. that may have occurred since the medication was initially held.

3.3 Professional Responsibilities

a) Pharmacists and pharmacy technicians are expected to practice in accordance with the National Association of Pharmacy Regulatory Authorities' (NAPRA) *Model Standards of Practice for Pharmacists and Pharmacy Technicians in Canada*.

b) Pharmacists-in-charge are responsible for establishing policies and procedures related to functions and tasks that may be performed by unregulated staff members, such as pharmacy assistants, and the levels of supervision required for each function or task. Unregulated staff members may participate in these functions or tasks, as long as they are appropriately supervised by a pharmacist or pharmacy technician, in accordance with the established policies and procedures.

3.4 Prescription Labelling Requirements

a) All patient-specific dispensed inpatient medications must be labelled with the following:

i) patient's first and last name, and a unique patient identifier;

ii) generic name, and strength of the drug;

- For multiple-entity products, the brand name and strength (if applicable), or all active ingredients and their strengths should be used.
- For compounded preparations, all active ingredients, and relative strengths should be used.

iii) directions for use, including frequency and route of administration, which may use hospital approved abbreviations and symbols;

iv) date of dispense; and

v) appropriate auxiliary or cautionary statements, as indicated.

PLEASE NOTE:

While the identity of the pharmacy staff involved in the preparation and verification of the medication is not required to be present on the label, a record of the individuals involved must be retained within the pharmacy, in either physical or electronic form.

b) Ward stock medications, not provided in the original manufacturer's packaging, should be labelled with, but not limited to, the following:

i) pharmacy name or pharmacy identifier;

ii) drug and strength; and

iii) lot number and expiry date.

3.5 Protecting the Cold Chain

All pharmacy staff involved in handling cold chain products must be trained on cold chain maintenance policies and procedures to ensure that temperature-sensitive products are received, stored, and dispensed according to manufacturers' specifications as discussed in Appendix A.

3.6 Checking Processes

a) *Clinical / Therapeutic Check*. Prior to dispensing any medication from the pharmacy for administration to a patient, a pharmacist must review the patient's profile, and, when necessary, the provincial electronic health record, and take appropriate action, where applicable, with respect to:

i) appropriateness of drug therapy;

ii) drug interactions;

iii) allergies, intolerances, or adverse drug reactions;

iv) therapeutic duplication;

v) correct dosage, route, frequency and duration of administration, and dosage form;

vi) contraindicated drugs;

vii) intravenous administration problems such as potential incompatibilities, drug stability, dilution volume, and rate of administration; and

viii) any other potential drug-related problems.

b) *Final Check*. Before being released to be administered to a patient, a pharmacist or pharmacy technician must ensure that a final technical check is performed ensuring that each step in the dispensing process has been completed properly by verifying that:

i) the drug, strength, dosage form, route and quantity dispensed are correct according to the medication order; and

ii) the label is accurate according to the medication order and contains the information required under these Standards, as well as any relevant Federal or provincial legislation.

3.7 Documentation

a) Documentation must be timely, readily retrievable and saved in a standardized and consistent manner that facilitates sharing and ease of use.

b) Pharmacists and pharmacy technicians should document any activities or information pertaining to drug therapy directly into the patient record.

c) Activities and information to be documented should include, but not be limited to:

i) retrieval of information related to best possible medication history;

ii) decisions or actions regarding changes in drug therapy (for example – dosage, route of administration, duration of therapy);

iii) decisions or actions regarding for drug therapy monitoring;

iv) consultations provided to other healthcare providers regarding the patient's medication therapy;

v) medication-related patient education or counselling provided;

vi) clarification of medication orders; and

vii) actual or potential drug related problems that warrant surveillance.

APPENDIX A

Protecting the Cold Chain

Introduction

Pharmacy professionals have a responsibility to ensure that all pharmaceutical products (including those stored in patient care areas) are stored in a manner that ensures the integrity and security of the drug. This responsibility requires diligence and rigour when the products are temperature-sensitive such as with biologics and vaccines, where strict temperature requirements must be maintained, as they become less effective or inactive when exposed to temperatures outside the recommended range.

"Cold chain" refers to an uninterrupted series of storage and distribution activities that function to maintain a proper temperature range during the storage, transportation, and handling of a product to preserve the ultimate effectiveness of the product.

This appendix is intended to help pharmacy staff protect patient safety by ensuring that temperature-sensitive products are received, stored, and dispensed according to manufacturers' specifications.

The Role of the Pharmacist-in-Charge

The pharmacist-in-charge is responsible for ensuring that all temperature-sensitive products purchased by a pharmacy for use or sale are of an acceptable standard and quality.

The pharmacist-in-charge, with support from the pharmacy management team, is accountable for ensuring that there are appropriate policies and procedures in place to ensure that temperature-sensitive products are properly received, stored, and dispensed. Policies and procedures must be in place for addressing temperature excursions and breaks in the cold chain. These policies and procedures should be reviewed at least every three years.

The pharmacist-in-charge must ensure that all pharmacy staff members involved in handling cold chain products are properly trained regarding:

- the protocols necessary to receive, store, and dispense products at the appropriate temperature,
- how to recognize when there is a break in the chain; and
- how to handle a such a break in the cold chain.

Required Equipment

Equipment	Notes

REFRIGERATOR[1]
A "Purpose-Built" Refrigerator (pharmacy or vaccine refrigerators) – a specialized refrigerator that responds to fluctuations in temperature.
	• Refrigerators must be:
	  • unaffected by outside temperatures and able to maintain temperature within the recommended storage range without deviation (between 2°C and 8°C for most temperature-sensitive products) even when surrounding temperatures change or after opening the door to remove a product; AND
	  • dedicated to the storage of temperature-sensitive products.

[1] Depending on the types of medications being stored, pharmacies may also require a separate, designated, frost-free freezer.

THERMOMETER Refrigerators must be equipped with either: • a Thermometer that provides continuous monitoring (i.e., a digital data logger); or • a "Min/Max" Thermometer that shows the current temperature as well as the minimum and maximum temperatures that have been reached since the last time the thermometer was reset.	• Separate thermometers must be used to monitor the refrigerator and freezer compartments, if applicable • Thermometers should be calibrated to +/- 1ºC. • Ideally, select a thermometer that allows the temperature to be monitored without opening the door to reduce the risk of temperature fluctuations.
General Practice Requirements	
EQUIPMENT USAGE	• Ensure the refrigerator is properly installed with appropriate clearance around the unit, as per manufacturer recommendations. • The refrigerator should be plugged into an electrical outlet that is labelled and on a dedicated circuit that is not required for other appliances. The power breaker switch should also be labelled to alert others that it belongs to the refrigerator. • Ensure that new refrigerators are reliably maintaining a steady temperature before stocking the unit. Refer to manufacturer's instruction manuals as they may specify the time it takes to reach steady state. • Do not overstock the refrigerator. Filling the unit too full prevents proper air circulation around the product thus affecting the product temperature. • The refrigerator must be well-maintained and free from excessive frost build up. • Frequent opening of the door can lead to temperature instability, so the door should be opened only when necessary and closed immediately. Temperature Range • Refrigerator and freezer temperatures should be kept a value that meets the storage requirements for medications stored within. In general, refrigerator central temperatures should be kept between +2°C to +8°C. A target temperature of +5°C will provide the best safety margins for temperature fluctuations between +2°C and +8°C. Freezer compartments should be kept at -15°C or colder. • Temperature variations outside of labeled storage conditions for brief periods may be acceptable; however, where a variation has occurred, it must be documented and checked against stability data for that particular substance to demonstrate that product quality has not been affected. Recording Temperatures • The minimum and maximum temperatures should be recorded on a temperature log twice daily, at the time of pharmacy opening as well as at closing time. The min/max thermometer must be regularly reset (after properly recording temperatures) for meaningful readings.

RECEIVING	• Follow established policies and procedures for cold chain receiving, including:
	  • ensuring that temperature-sensitive products are received in packaging that maintains the cold chain during transport;
	  • examining delivery documents to ensure product was not subjected to distribution delay; and
	  • transferring the contents of a shipment promptly to the appropriate controlled storage area.

STORAGE	• Follow established policies and procedures for cold-chain storage, including:
	  • ensuring that drug storage refrigerators are dedicated for storage of drugs (e.g., no food or drink);
	  • verifying the storage conditions for cold chain products stocked by the pharmacy, including light sensitivity;
	  • regularly checking the refrigerator and other locations for inappropriately stored products;
	  • arranging products within the refrigerator so they are not stored in areas where temperature fluctuations are greatest (e.g., crispers, doors, and against walls), and so that air flow is maintained within refrigerator;
	  • checking expiration date and rotation of temperature-controlled products; and
	  • assigning and labelling a beyond-use-date for opened multi-dose vials and reconstituted products.

DISPENSING	• The dispensing workflow should take into consideration the need to maintain the cold chain for temperature-sensitive products. For example, cold chain products should not be left on the dispensary counter while awaiting labelling, final product check, and/or release to the patient. • Educate patients and other health professionals regarding the cold chain and appropriate handling, storage, and use of cold chain medications. • Ensure that packaging for home delivery meets the specifications required for the product.

REFERENCES	• Government of NL Provincial Immunization Manual
	  • Section 7 – Management of Biological Products (including vaccines)
	  • Temperature Monitoring Log
	• Public Health Agency of Canada Canadian Immunization Guide
	• Storage and Handling of Immunizing Agents

APPENDIX B

Required Reference Materials

In accordance with sections 1.4 b) xi), pharmacies must have access to the CPNL website as well as **current versions** of at least **ONE** reference, either text or electronic, from **EACH** of the following categories:

PLEASE NOTE: Additional references may be required in accordance with specific practice areas (e.g., geriatrics, pediatrics) or standards of practice (e.g., compounding, OAT).

CATEGORY	EXAMPLES
Canadian Compendium	CPS: Drug Information (text or online), Health Canada's Drug Product Database, RxVigilance
Drug Interactions	UpToDate Lexidrug, MedicinesComplete, Micromedex, RxVigilance
General Drug Information Reference	UpToDate Lexidrug, Martindale: The Complete Drug Reference (text or online), MedicinesComplete, Micromedex Pharmaceutical Knowledge
Minor Ailments	Compendium of Products for Minor Ailments **AND** Compendium of Therapeutics for Minor Ailments (text or online as part of RxTx)
Natural Health Products	RC Natural Medicines, The Review of Natural Products, AltMedDex, UpToDate Lexidrug
Parenteral Products	The Ottawa Hospital Parenteral Drug Therapy Manual, Trissel's IV Compatibility, Pediatrics Injectable Drugs (The Teddy Bear Book), King's Guide to Parenteral Admixtures
Pediatrics (*if applicable to practice site)	UpToDate Lexidrug, Micromedex Pharmaceutical Knowledge, RxVigilance, Sick Kids Drug Handbook and Formulary (text or online)
Pregnancy and Lactation	UpToDate Lexidrug, Drugs in Pregnancy and Lactation (text or online), Hale's Medications and Mother's Milk (text or online), MedicinesComplete, Micromedex
Therapeutics	Applied Therapeutics: The Clinical Use of Drugs (text), Compendium of Therapeutic Choices (text or online), Pharmacotherapy: A Pathophysiologic Approach (text), UpToDate Lexidrug, Dynamed