COLLEGE OF PHARMACY
OF NEWFOUNDLAND AND LABRADOR

STANDARDS OF PHARMACY OPERATION

Community Pharmacy

August 2022

(for implementation by September 2023)

Last Revised October 2026

TABLE OF CONTENTS

INTRODUCTION 2
1. GENERAL STANDARDS OF PHARMACY OPERATION 3
2. SUPPLEMENTAL STANDARDS OF PHARMACY OPERATION 15
3. PHARMACY PRACTICE 18
APPENDIX A A-1
Policy and Procedure Template Table of Contents A-1
APPENDIX B B-1
Protecting the Cold Chain B-1
APPENDIX C C-1
Required Reference Materials C-1

INTRODUCTION

These Standards of Pharmacy Operation are made under the authority of section 6.(2)(d) of the *Pharmacy Act, 2024* and are just one component of the legislative scheme 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 scheme 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.

Both owners and pharmacists-in-charge must know, understand, and comply with this overall legislative scheme.

These standards describe the minimum acceptable standards applicable to operating a licensed community pharmacy in Newfoundland and Labrador, unless otherwise specifically exempted by the board, 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.
- "designated representative" means an individual authorized by a corporation or partnership that owns a pharmacy to accept delivery of correspondence and other notices or documents on behalf of the pharmacy owner, to make declarations on behalf of the pharmacy owner, and to act on behalf of the pharmacy owner in all dealings with CPNL.
- "dispensary" means the portion(s) of the pharmacy where scheduled drugs are, or were, prepared, compounded, dispensed, or sold.
- "dispensary staff" means employees of the pharmacy who specifically work in the dispensary.
- "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. There are several components of the NL provincial EHR including the

Client Registry, the HEALTHe NL Viewer, the Picture Archiving and Communications Systems, the Pharmacy Network, and the Provider Registry.

- "pharmacist-in-charge" means the person designated by CPNL who is responsible for the operation of the pharmacy in accordance with section 32. of the *Pharmacy Act, 2024* and section 8. of the *Pharmacy Regulations, 2024*.
- "pharmacy" means business licensed by CPNL in accordance with section 31. of the *Pharmacy Act, 2024*.
- "pharmacy owner" means a corporation, partnership or individual that owns a pharmacy.
- "Pharmacy Network" means the component of the provincial electronic health record that allows authorized health care providers to contribute to and access patient medication profiles in real-time.
- "pharmacy staff" means all of the employees of the pharmacy, including those who work in the dispensary.
- "practice of pharmacy", as defined in the *Pharmacy Act, 2024*, 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, and
  - conducting or collaborating in health-related research, and
  - engaging in administration, education, management, policy or regulation relevant to an activity referred to above.

1. GENERAL STANDARDS OF PHARMACY OPERATION

The following standards of pharmacy operation apply to **all** licensed community pharmacies in Newfoundland and Labrador, unless otherwise specifically exempted by the board. Licensed hospital pharmacies must also comply with these standards of pharmacy operation when dispensing medications to out-patients.

1.1. Operational Policies and Procedures

a) *Policy and Procedure Manual*. The pharmacy must have a well-organized and easily accessible policy and procedure manual that all pharmacy staff are aware of and familiar

with. This manual should include information about the operations and workflow of the pharmacy including information specific to any special services that are provided (see Appendix A for a sample Policy and Procedure Manual Table of Contents). The pharmacist-in-charge is expected to ensure that the manual is regularly reviewed and updated as required.

By definition, *policies* are clear statements that guide processes, procedures, and decision-making related to pharmacy services; they are often based on standards of practice, but may also include policies related to human resources, occupational health and safety, etc. *Procedures* describe how each policy will be put into action in the pharmacy. For example, procedures should outline:

- who will do what;
- what steps they need to take;
- which forms or documents to use; and
- how documentation is retained.

b) *Hours of Operation*.

i) Except where otherwise approved by the board (for example, satellite pharmacies, telepharmacies), a pharmacy (including the dispensary) must operate a minimum of 36 hours per week.

ii) Pharmacies with an approved Lock and Leave enclosure (in accordance with section 2.1) may have pharmacy hours that vary from the dispensary hours.

iii) Hours of operation should be stable and must be posted in full view at the public entrance of the pharmacy, or at the public entrance of the pharmacy and at the dispensary, if there is an approved Lock and Leave enclosure.

1.2. Staffing and Supervision

a) *Staffing Complement*. The pharmacist-in-charge must collaborate with the pharmacy owner to ensure that the pharmacy has an adequate staffing complement to enable safe practice and quality patient care. This includes giving consideration to both past and anticipated workloads in the pharmacy and using their professional judgement to determine:

i) 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

ii) 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) *Education, Training and Orientation*. The pharmacist-in-charge must ensure that all pharmacy staff have the necessary education, training, experience, knowledge, and skills to carry out their assigned duties. Specifically, pharmacists-in-charge are expected to confirm that regulated pharmacy professionals are actively registered with CPNL and have professional liability insurance in accordance with CPNL's *Professional Liability Insurance Requirements for Registration*.

c) *Supervision*. The pharmacist-in-charge must collaborate with the pharmacy owner to ensure that:

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

ii) registrants do not delegate tasks to nonregulated staff members unless that person is reasonably qualified and has received appropriate training to engage in the specified task.

d) *Name Tags*. All pharmacy staff must wear a suitable name tag that identifies to the public that person's name and staff position. Registered pharmacy staff must be identified by their full name.

1.3. Continuous Quality Improvement

a) Pharmacists-in-charge must implement an ongoing quality management program that:

i) develops, maintains, and enforces policies and procedures to comply with all legislation and standards applicable to the operation of a community pharmacy;

ii) monitors staff performance, equipment, facilities, and adherence to these standards; and

iii) includes a process for proactive risk assessment, medication incident and near miss reporting, and continuous quality improvement in accordance with the MedSTEP NL program and CPNL's *Standards of Practice - Continuous Quality Improvement and Medication Incident Reporting in Community Pharmacies*.

1.4. Physical Layout, Security, and Signage

a) *General Requirements*.

i) The pharmacy must be well-ventilated, appropriately lighted, clean, and well-maintained.

ii) The physical layout and design of the pharmacy must support the patient care services provided by the pharmacy, and generally includes a dispensary area, professional products area, and patient consultation area, as described below.

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 for a safe working environment for staff. To meet these expectations, the pharmacy must have a combination of security measures as described below.

i) Physical measures: for example, deadbolt locks, tamper-resistant door bars, metal or metal-clad doors, window protection via shatterproof glass or bars, plexiglass and/or metal security gates or curtains.

ii) Exterior and interior lighting: for example, lighting in parking areas, all entrances and exits, areas where cash is used or stored, and access points to staff only areas.

iii) High-resolution video surveillance equipment: cameras should 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 should be kept in a locked area out of public view with recordings kept for at least 30 days.

iv) A monitored alarm system that includes the use of motion detectors and door alarms.

v) Restricted access to the pharmacy: for example, access codes, keys, and/or pass cards that are limited to a minimum number of appropriately authorized persons and enable access restrictions for the dispensary to be met. The pharmacy must have a policy on how access is granted and removed, and documentation of persons with authorized access to the dispensary, and pharmacy (if different).

> PLEASE NOTE:
>
> Per section 2.1 d), a lock and leave enclosure and alarm system is required for the dispensary if there will be times that the dispensary is closed and a pharmacist or pharmacy technician is not present, and the remainder of the pharmacy premises is open to the public or accessible to other authorized staff. If any controlled substances are accessible in the dispensary, a pharmacist must be present for other dispensary staff to enter.

vi) Pharmacies should have clear and visible signage on both the exterior and interior of the pharmacy indicating that video surveillance and other security systems are in place.

vii) All security equipment must be kept up to date and in good working order and relevant staff members should be appropriately trained in their use so that data is readily accessible when needed or in response to an incident.

c) *Signage.*

i) There must be a sign showing the trading name of the pharmacy affixed to the exterior of the premises.

ii) If the pharmacy is located inside a larger premises, there must be a sign inside the premises which clearly identifies the location of the pharmacy.

iii) The pharmacy licence issued under section 31.(2) of the *Pharmacy Act, 2024* must be displayed in a conspicuous part of the pharmacy in full public view.

iv) Other signage, including hours of operation and security-related signage, must also be posted in accordance with sections 1.1 b) and 1.4 b).

d) *Dispensary Area*. The dispensary must be self-contained and designed in such a way as to prevent entrance by anyone other than authorized persons.

i) The dispensary must be at least 9.29 square metres, including all storage areas. This does not include patient waiting area(s), the Professional Products area, or Patient Consultation area(s) (see sections 1.4 e) and f)).

ii) There must be at least 1.2 square metres of working counter space in the dispensary, excluding counter space that is used for compounding activities or occupied by equipment.

iii) The dispensary must have an appropriate area for Level A compounding in accordance with CPNL's *Standards for Pharmacy Compounding of Non-Sterile Preparations*.

iv) In accordance with the *Provincial Drug Schedules*, Schedule 2 products must be located in an appropriate "No Public Access" area within the dispensary that provides no opportunity for patient self-selection.

v) If there are times when the dispensary is closed and a pharmacist or pharmacy technician is not present, but the remainder of the pharmacy is open to the public, or accessible to other authorized pharmacy staff (such as for cleaning, inventory, or overnight stocking), the dispensary must be secured with a lock and leave enclosure and meet the requirements of section 2.1.

PLEASE NOTE:

The *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada requires that a pharmacist is present to supervise all controlled substances activities within the pharmacy. If any controlled substances (including narcotics, controlled drugs, or targeted substances, including benzodiazepines) are accessible within the dispensary (i.e. not locked in the secure safe) and a pharmacist is not present, non-pharmacist staff members may not enter the dispensary, and the dispensary must be appropriately secured.

e) *Professional Products Area*. In accordance with the *Provincial Drug Schedules*, Schedule 3 products must be located in an area immediately adjacent to the dispensary under the supervision of a pharmacist.

f) *Patient Consultation Areas*. The pharmacy must have patient consultation areas that suit the needs of the operation including at least one physically separate and private room that is dedicated to the delivery of pharmacy services. This room must:

i) be designed to be acoustically and visually private;

ii) include a sign or other appropriate indicator to specify when the room is in use, to prevent inappropriate entry;

iii) be appropriately located within the pharmacy for ease of access;

iv) be sufficiently spacious to reasonably accommodate patients who require mobility aids, a patient's support person, and the potential need to manage anaphylaxis when giving injections;

v) be appropriately furnished and equipped for the patient care activities performed within (e.g., desk/work surface, seating, storage, sink, computer terminal for accessing patient records and clinical references, health monitoring equipment, examination table, etc.); and

vi) be maintained in a clean, safe, and organized manner that is conducive to providing patient care.

1.5. Equipment and Supplies

a) 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 staff 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:

- practice management software;
- a connection to the provincial electronic health record through the Pharmacy Network;
- 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 1.5 a) xii); 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 all relevant labels, receipts, and required reports;

iii) suitable equipment that allows the staff to send, receive, and/or copy electronic or non-electronic documents (for example, 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 prescriptions and other patient records) and store them electronically (for example, a scanner);

v) a filing system 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 for cleaning equipment, hand hygiene, etc.;

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 prescription and non-prescription drugs to meet patient needs;
- refrigerator(s) for the exclusive storage of drugs requiring refrigeration that meets the cold chain requirements defined by the board in Appendix B;
- a secure safe for the storage of narcotics and controlled drugs that is appropriately anchored to the floor and out of public view;
- adequate shelf and storage space, including suitable storage area and equipment to ensure compliance with legislation and guidelines regarding the handling of hazardous drugs;
- 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) appropriate space, equipment, and materials for Level A compounding in accordance with CPNL's *Standards for Pharmacy Compounding of Non-Sterile Preparations*. This includes, but is not limited to:

- surfaces that are completely clean and that are not reactive, additive, or absorptive (glass or stainless steel preferred) so that the purity or quality of the preparation being compounded is not negatively affected;
- a prescription balance (with a minimum sensitivity of 10mg) or an electronic balance (with a minimum sensitivity of 10mg) AND a set of metric weights or a calibration weight;

- quality active pharmaceutical ingredients and inactive ingredients that are from recognized and reliable sources;
- appropriate packaging materials for compounds that maintain the integrity of the preparation and ease of use by patients; and
- equipment that is necessary to compound preparations of the highest quality (this will depend on the specific compounds prepared by the pharmacy and a pharmacy may not be able to compound certain mixtures without the appropriate equipment referenced in the given Master Formulation Record. For example, certain compounds require specialized equipment such as a triple ointment mill).

xii) required reference materials, as described in Appendix C.

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, there must be policies and procedures in place to ensure that pharmacy staff are familiar with the resources that are available and that they are accessible and available to all pharmacy staff, including relief staff, where and when they need them, when the pharmacy is open for business.

b) 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.

1.6. 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) Documentation must be made in a clear, concise, and easy to read format that facilitates sharing, ease of use, and retrieval of information.

iii) All records maintained by the pharmacy must be current and accurate with respect to the pharmacist'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;
- scan prescriptions and other relevant patient records; and
- generate reports of prescription information chronologically and by drug name and strength, patient name, and prescriber name.

ii) A backup of electronic records must be performed once daily and be tested for recovery on a regular basis. A copy of the backup should be securely stored off-site or in a fire-proof, theft-resistant safe.

c) *Record Storage and Security*

i) Patient records, including:

- prescriptions,
- written copies of verbal prescriptions, 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 service for the safe disposal of confidential information, or by complete incineration. To ensure that the requirement for record retention outlined in section 1.6 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.

1.7. Inventory Management

a) The pharmacist-in-charge must maintain an adequate inventory control system.

b) *Medication Returns*. A pharmacy must not accept back any medication previously dispensed that has been removed from the supervision of a pharmacist for any period of time except where:

i) the medication is being disposed of on behalf of the patient;

ii) the medication was packaged in a customized patient drug package, and is being repackaged for use by the same patient; or

iii) the medication was previously dispensed to a licensed long-term care facility and is being returned in accordance with CPNL's *Standards of Practice - The Provision of Pharmaceutical Care to Long-Term Care Facilities.*

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

a) *General Requirements*. Section 108. of the *Controlled Substances Regulations (Canada)* states that "a pharmacist or pharmacy technician must take all reasonable measures to ensure the security of any controlled substance in their possession".

CPNL expects pharmacists-in-charge to 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*. Narcotics and controlled drugs, including exempted codeine products, must be stored in a secure safe in accordance with section 1.5 a) x). Liquid dosage forms that require refrigeration, including prepared doses of methadone, must be stored in a locked refrigerator. In accordance with the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada, a pharmacist must be present when controlled substances are accessible.

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.

d) *Physical Inventory Counts*

i) A physical inventory count of all controlled substances must be performed and documented at least once every three months as follows:

- All controlled substances should be counted, including active inventory, expired or damaged stock, products awaiting destruction, and any compounded mixtures containing a controlled substance that have not yet been dispensed.
- Any drugs returned by patients for destruction by the pharmacy 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 inventory, "balance owings",

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 of the pharmacy changes. This count must be conducted by both the departing pharmacist-in-charge and the new pharmacist-in-charge;
- 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 address allegations from the public questioning dispensed quantities; or
- to validate or monitor the pharmacy's storage and security.

e) *Handling of Post-Consumer Returns and Unserviceable Stock*. Pharmacists-in-charge should ensure that post-consumer returns and unserviceable stock containing controlled substances are handled in accordance with guidance issued by Health Canada.

f) *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.

g) *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 1.4 b), as well as any additional security measures that are deemed necessary based on pharmacy-specific risks;
- Developing and implementing policies and 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*. Pharmacists-in-charge must have policies and procedures in place to prevent and detect diversion by pharmacy staff members. 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 prescription and that it has been dispensed accurately;
- 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).

h) *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 109. 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 pharmacies that choose to offer the particular service. As noted in section 1.1 a), if these services are provided, the pharmacy's Policy and Procedure Manual should contain information pertaining to each of the services provided.

2.1. Lock and Leave

a) *Intended Use*. If there are times when the dispensary is closed and a pharmacist or pharmacy technician is not present, but the remainder of the pharmacy is open to the public or accessible to other authorized pharmacy staff (such as for cleaning, inventory, or overnight stocking), the dispensary must be secured with a lock and leave enclosure.

PLEASE NOTE:

The *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada requires that a pharmacist is present to supervise all controlled substances activities within the pharmacy. If any controlled substances (including narcotics, controlled drugs, or targeted substances, including benzodiazepines) are accessible within the dispensary (i.e. not locked in the secure safe) and a pharmacist is not present, non-pharmacist staff members may not enter the dispensary, and the dispensary must be appropriately secured.

b) *Prior Approval*. Prior to installing a lock and leave enclosure, the pharmacist-in-charge must first apply to CPNL for approval using the designated form, indicating the anticipated hours of use, and describing the construction of the enclosure.

c) *Physical Construction*. The lock and leave enclosure must be constructed in such a way as to completely separate the dispensary physically and securely from the rest of the pharmacy during periods of closure. This is generally accomplished by the use of a folding or sliding gate or permanent wall, composed of transparent, semi-transparent, or opaque materials, or any combination thereof, that is at least five feet high.

d) *Security*. The dispensary must be physically secured and monitored by an alarm system during times that the dispensary is closed and a pharmacist or pharmacy technician is not present, but the remainder of the pharmacy remains open to the public or accessible to other authorized staff members. This alarm system could be a separate system or a separate zone within the pharmacy's monitored alarm system as described in section 1.4 b).

e) *Prescription Pick-up*. Decisions about whether previously prepared prescriptions are to be available for pick-up when the lock and leave enclosure is secured should be made on a case-by-case basis, with consideration given to the storage requirements for the particular drug, informed consent, the ability to maintain confidentiality, and whether the patient may require consultation with a pharmacist. If the decision is made to make a prescription available for pick-up, it must be done so in accordance with the following:

   i) All prescriptions are stored in an area and manner that is secure, with restricted access to the staff responsible for releasing the medication to patients.

   ii) Prescriptions for controlled substances may not be made available for pick-up.

   iii) Drugs that require refrigeration must be stored in a refrigerator that meets the cold chain requirements defined in Appendix B.

   iv) Patient confidentiality must be protected at all times by ensuring the outer package contains only the patient's name and address.

v) Prescriptions may only be released to the patient, or a person designated by the patient in accordance with section 3.8. The patient or other person must be properly identified by pharmacy staff at the time of pick-up in accordance with section 3.8.

vi) All patient consultation requirements under section 3.9 must still be met.

vii) For each prescription picked up during the period of lock and leave closure, there must be a record (either physical or electronic) that includes the name of the patient or other person who picked up the prescription as well as the name of the staff member who released the prescription. This record must be retrieved and reviewed by dispensary staff when the dispensary reopens, and confirmation of prescription pick-up must be appropriately documented in the electronic health record in accordance with section 3.8 d).

2.2. Prescription Delivery

a) *Intended Use*. These standards must be met in any situation where a prescription is delivered to a patient (or their designated agent) regardless of whether that delivery is by pharmacy staff, courier, or mail.

b) Decisions about whether prescriptions are to be delivered, and by what method, should be made on a case-by-case basis, with consideration given to the classification of the drug, storage requirements for the particular drug, informed consent, the ability to maintain patient confidentiality, and whether the patient may require consultation with a pharmacist. If the decision is made to deliver a prescription, it must be done so in accordance with the following:

i) Prescriptions for controlled substances must be delivered in accordance with sections 106-107 and 120 of the *Controlled Substances Regulations (Canada)* and related guidance issued by Health Canada.

ii) All packaging and storage considerations must be considered including security, breakage, and refrigeration.

iii) Patient confidentiality must be protected at all times by ensuring the outer package contains only the patient's name and address.

iv) Prescriptions may only be delivered to the patient, or a person designated by the patient in accordance with section 3.8. The patient or agent must be properly identified by the delivery person in accordance with section 3.8.

v) All patient consultation requirements under section 3.9 must still be met.

vi) For each prescription delivered, there must be a record (either physical or electronic) that includes the details necessary to confirm that the prescription was received by the patient, such as the name of the patient or other person to whom the prescription was delivered, the name of the delivery person, and/or a

tracking number with documentation that dispensary staff used to confirm successful delivery to the patient.

2.3. Other Specialized Services

Any 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 licensing policy, standard of practice, or guideline. This includes, but is not limited to:

- Administration of Inhalations or Injections;
- Central Fill Services;
- Compliance Packaging;
- Medical Assistance in Dying;
- Non-Sterile Compounding;
- Opioid Agonist Therapy Medications;
- Ordering Laboratory Tests;
- Point of Care Testing;
- Prescribing;
- Sale of Exempted Codeine Products;
- Service to Long-Term Care Facilities;
- Service to Personal Care Homes;
- Sterile Compounding; or
- Any other service or practice area with specific regulatory requirements.

3. PHARMACY PRACTICE

These standards of pharmacy practice apply to all licensed community pharmacies in Newfoundland and Labrador, unless otherwise specifically exempted by the board.

3.1. Roles and 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) Pharmacy assistants may participate in administrative or technical functions related to the operation of a community pharmacy where the pharmacy assistant is directly

supervised[1] by a pharmacist or pharmacy technician and appropriate procedures, checks, and controls are in place to ensure the safe and effective delivery of pharmacy services.

3.2. Patient Profile

a) A patient profile must be prepared and maintained for each patient to whom:

i) a prescription is dispensed;

ii) an inhalation or injection is administered; or

iii) another pharmacist-administered assessment or activity is performed (for example, in accordance with a request for an exempted codeine product, pharmacist prescribing, etc.).

b) At a minimum, the patient profile must include the following patient information:

i) full name;

ii) medical care plan (MCP) number;

iii) date of birth;

iv) mailing and/or street address; and

v) contact information, such as phone number(s) and/or email address.

c) The patient profile should also include other relevant information, such as:

i) clinical observations (height, weight, blood glucose, blood pressure, etc.);

ii) gender;

iii) lifestyle status (smoking status, alcohol and/or caffeine intake, etc.);

vi) documentation of any notable known clinical conditions, allergies, intolerances, or adverse drug reactions;

iv) use of non-prescription medications, clinical evaluation packages (samples), or special access medications; and

v) any other relevant clinical information.

d) The patient profile should also include a record of any person designated as a patient's agent in accordance with section 3.8.

3.3. Prescription Requirements

a) Prescriptions must include the following information:

[1] When providing "direct supervision", the pharmacist or pharmacy technician must be present when the activity is being performed and be able to observe and promptly intervene and stop or change the actions of the individual being supervised.

i) the date the prescription was written;

ii) the patient's name;

iii) the name, strength, and dosage form of the medication to be dispensed;

iv) the quantity of medication to be dispensed;

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

vi) any refill or part fill authorization, where applicable; and

vii) the prescriber's name, and, if the prescription is written, their signature.

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 117 of the *Controlled Substances Regulations (Canada)*.

c) Regardless of how prescriptions are received – on paper from the patient, or verbally, via fax or other electronic means from the prescriber – registrants are expected to ensure that prescriptions are current, authentic, complete, and appropriate before dispensing. This may include:

i) validating that a prescription was written by an appropriately registered and authorized prescriber;

ii) validating that a prescription received via fax was sent directly from the prescriber's office, prescriber's computer, a health institution, or another appropriate location; or

iii) contacting the prescriber or another person at the site of transmission who can verify the prescription.

d) Prescriptions may also be received as a transfer from another pharmacy in accordance with section 3.11.

e) Prescriptions may not be filled beyond one year from the date on which the prescription was originally written.

f) If the prescription is written for a drug that is subject to the Government of Newfoundland and Labrador's Tamper Resistant Prescription Drug Pad Program, the requirements of that program must be met.

g) In accordance with section 64. of the *Pharmacy Act, 2024*, if the prescription is written by a prescriber who is licensed to practice in a province other than Newfoundland and Labrador, the prescription may be dispensed so long as the pharmacist takes reasonable steps to ensure that:

i) the prescriber is licensed and practices in Canada, and

ii) the prescriber belongs to a class of persons who, if licensed in Newfoundland and Labrador, would be entitled to prescribe in Newfoundland and Labrador.

h) If the prescription is being logged for dispensing at a later time, the following must be completed as soon as possible to ensure the accuracy of the patient's medication profile:

i) The prescription must be accurately entered into the patient's medication profile, as if it were to be dispensed that day.

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 logged prescription record must include the identity of any staff members involved in entering the prescription into the patient profile.

i) When filling a prescription that was previously logged for the first time, it must be handled as if it were a new prescription including ensuring the accuracy and validity of the prescription and the continued appropriateness of the drug therapy. Consideration should be given to any changes in the patient's medications, diagnosis, history, etc. that may have occurred since the prescription was initially prescribed and logged.

j) When filling or logging a prescription for continuing therapy, any existing prescriptions for the same drug therapy with refills remaining must be deactivated to prevent them from being inappropriately filled in the future.

3.4. Patient Medication Profile

a) Each time a medication is dispensed, the following information must be recorded on the patient's provincial electronic health record and maintained locally:

i) date prescription was written;

ii) date of dispense;

iii) prescription number;

iv) for single-entity products,

- the Drug Identification Number;
- the strength and generic name of the drug; and
- the brand name or the manufacturer of the product;

v) for multiple-entity products,

- the Drug Identification Number;
- the brand name and strength of the drug (if applicable); or
- all active ingredients and their strengths; and
- the manufacturer of the product;

vi) for compounded preparations, all active ingredients, and relative strengths;

vii) dosage form dispensed;

viii) quantity of medication dispensed;

ix) intended duration of therapy, expressed in days;

x) date of the last fill and/or number of days since last fill (if applicable);

xi) original quantity of medication or number of refills authorized;

xii) directions to patient;

xiii) the full name and identification number of the prescriber; and

xiv) any special instructions from the prescriber to the pharmacist.

b) Each record must also contain documentation of:

i) any interactions that were detected, how they were addressed, and who addressed them; and

ii) the identity of all staff members involved in the dispensing and checking processes.

PLEASE NOTE:

The provision of exempted codeine products must also be recorded in accordance with section 3.4 a) as per CPNL's *Standards for the Sale of Exempted Codeine Products in Community Pharmacies.*

3.5. Protecting the Cold Chain

a) Pharmacy staff are expected to ensure that temperature-sensitive products are received, stored, and dispensed according to manufacturers' specifications as discussed in Appendix B.

3.6. Prescription Packaging and Labelling Requirements

a) All medications must be dispensed in child-resistant containers unless:

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

ii) in the professional judgment of the pharmacist, it is not advisable to use a child-resistant package; or

iii) a child-resistant package is not suitable because:

- of the physical form of the drug;
- the manufacturer's packaging is designed to improve patient compliance; or

- the patient has requested the use of special customized compliance packaging for their prescriptions in accordance with CPNL's *Standards for the Provision of Compliance Packages*.

b) Where a child-resistant container is not utilized, a notation to that effect must be documented on the patient medication profile.

c) All medications dispensed must be labelled with the following:

i) pharmacy name, phone number, and street address (if available, or, if not, a way of uniquely identifying the pharmacy location);

ii) patient's first and last name;

iii) prescriber's full name, or first initial and last name;

iv) for single-entity products,

- the strength and generic name of the drug and either:
  - the brand name;
  - the manufacturer; or
  - the Drug Identification Number;

v) for multiple-entity products,

- the brand name and strength (if applicable), or all active ingredients and their strengths, and either:
  - the manufacturer; or
  - the Drug Identification Number;

vi) for compounded preparations, all active ingredients, and relative strengths;

vii) quantity of medication dispensed;

viii) dosage form dispensed;

ix) directions for use;

x) prescription number;

xi) date of dispense;

xii) quantity of medication remaining or number of refills remaining;

xiii) expiry date of prescription (one year from the date the prescription was written); and

xiv) appropriate auxiliary labels, as indicated.

d) Where a drug container size is too small to accommodate a full label in accordance with section c), a trimmed label must be affixed to the small container. This label must include, at a minimum, the

i) patient's first and last name;

ii) name of the drug, in accordance with sections 3.6 c) iv), v) or vi), as appropriate;

iii) prescription number; and

iv) date of dispense;

and the complete prescription label must be affixed to a larger container and the patient counselled to keep the small container inside the large container.

PLEASE NOTE:

Exempted codeine products must also be labelled in accordance with section 3.6 c) in accordance with CPNL's *Standards for the Sale of Exempted Codeine Products in Community Pharmacies.*

3.7. Checking Processes

a) To facilitate the checking processes outlined in sections 3.7 b) and c) below,

i) the information documented under section 3.4 a) must print or be visually displayed, and

ii) the original prescription, or a scanned image of the prescription, must be referenced by the pharmacist and/or pharmacy technician during the checking processes.

b) *Clinical / Therapeutic Check*. Before any dispensed medication is released to a patient, a pharmacist must review the patient's local and provincial electronic health record profiles, 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) patient adherence issues; and

viii) any other potential drug-related problems.

c) *Technical Check*. Before any dispensed medication is released to a patient, a pharmacist or pharmacy technician must check the prepared medication and label against the original prescription to ensure that it has been filled correctly, including verification that:

i) the patient name, prescriber name, drug, dosage form, dosage, directions, and quantity dispensed are all correct according to the prescription;

ii) the prescription label is accurate according to the prescription and contains the information required under these Standards of Pharmacy Operation, as well as federal and provincial legislation or standards of practice; and

iii) any additional considerations have been accounted for including that the most appropriate packaging/container has been used and contains appropriate auxiliary labelling.

3.8. Prescription Release

a) *Informed Consent*. Pharmacy staff must obtain informed consent from a patient before releasing prescriptions or disclosing personal health information to another person. If in relation to an ongoing delegation of authority, this consent should be documented in the patient profile and the patient should be advised to inform pharmacy staff if they wish to change or revoke this consent at any time.

b) *Patient Identification.* Patients and other persons picking up prescriptions on their behalf must be positively identified prior to releasing prescriptions, in accordance with the following:

i) A minimum of two patient identifiers should be utilized. Preferred identifiers, in addition to the patient's name, include the person's address, date of birth, MCP number, or photo ID.

ii) If another person is picking up a prescription on a patient's behalf, the person must also positively identify the patient (as described above), as well as provide proof of their own identity (such as a photo ID).

c) Medications should be reviewed with the patient and/or their representative, as appropriate, to ensure that each prescription label bears the intended patient's name and matches what the patient expects to receive.

d) *Documentation*. There must be an auditable record confirming prescription release that includes the date and time the prescription was released and the name of the person to whom it was released. Prescription pick-up information must be communicated to the Pharmacy Network at the time the medication is released so that patient medication profiles within the electronic health record are accurate with respect to dispensing history.

PLEASE NOTE:

Prescription pick-up information must be transmitted to 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.

3.9. Prescription Medication Consultation

a) Pharmacists must promote the safe and effective use of medication by providing patients with information about their drug therapy on the original filling of each prescription, while also giving the patient the opportunity to ask questions.

b) Such information must include, but not necessarily be limited to:

i) confirming the identity of the patient;

ii) the identity and strength of the medication;

iii) the indication and/or intended results of the medication;

iv) directions for use of the medication including frequency, duration, and route of therapy;

v) storage requirements;

vi) common adverse effects, potential drug or food interactions, and contraindications that may be encountered including their avoidance and/or action required if they occur;

vii) monitoring parameters including expected outcomes, and when to follow up with the prescriber; and

viii) any other information relevant to the particular medication and/or patient.

c) Patient consultations should occur in person, whenever possible. If this is not possible due to the prescription being delivered to or picked up by an agent, the consultation may occur by telephone or virtually.

d) While detailed consultation may not be required each and every time a prescription is refilled, the pharmacist is expected to consider the following when making that determination:

i) how long the patient has been taking the medication;

ii) whether there has been a change to the dosage, dosage form, or appearance of the medication since the last fill;

iii) whether the prescription is for a "high-alert" medication[2] or medication that requires increased monitoring;

[2] See ISMP High-Alert Medications in Community/Ambulatory Care Settings. Available at https://home.ecri.org/blogs/ismp-resources/high-alert-medications-in-community-ambulatory-care-settings

iv) the patient's history with the medication including timeliness of refills, side effects, etc.; and

v) whether the patient has been given sufficient opportunity to ask questions or discuss potential issues.

e) All patient consultations must be documented and retained in accordance with section 1.6 c). The pharmacist should use professional judgement when determining the information to be documented, but it should include, at a minimum, the name of the pharmacist involved and the date the consultation took place.

f) If the patient refuses to participate in a consultation offered by a pharmacist, the pharmacist should document the refusal in the patient record.

3.10. Non-Prescription Medication Consultation

a) Pharmacists must consult with patients regarding the selection and use of Schedule 2 medications and be available to consult with patients regarding the selection and use of Schedule 3 medications and unscheduled products.

b) Such consultations must include, but not be limited to:

i) assessing the patient's knowledge about a medication when they ask for a specific product by name;

ii) assessing whether a medication is safe and appropriate for the patient by collecting information appropriate to the circumstances, using a combination of patient interview, review of the patient's electronic health record, and other sources, as appropriate;

iii) considering whether it would be more appropriate to prescribe the medication;

iv) referring the patient to another health care professional as required;

v) if a therapy is recommended,

- providing the patient with information about the medication, considering the general principles outlined in sections 3.9 a) and b), and
- advising the patient to follow up with the pharmacist or another health care professional if there is no improvement or worsening of symptoms; and

vi) documenting the consultation and/or the medication provided on the patient profile, as appropriate.

3.11. Transferring Prescriptions

a) Pursuant to a request from a patient, a pharmacist or pharmacy technician may request a transfer of a prescription from a pharmacist or pharmacy technician at another pharmacy, in accordance with section C.01.041.1 of the *Food and Drug Regulations*

(Canada), or, if the prescription is for a controlled substance, in accordance with section 102 of the *Controlled Substances Regulations (Canada)*.

b) To reduce the likelihood of transcription errors and avoid duplicate records within the provincial electronic health record, a transferred prescription must be processed using the Pharmacy Network, which will record the transfer on the patient's provincial electronic health record. In special circumstances where this is not possible (i.e., if the Pharmacy Network is not available and the patient requires medication immediately), the information required for the prescription transfer may be communicated verbally or by fax and entered manually. In this case, the existing prescription must be manually inactivated to ensure that there are not multiple prescriptions for the same medication on the patient's provincial electronic health record.

c) When a pharmacist or pharmacy technician receives a request from another pharmacist or pharmacy technician to transfer a prescription to another pharmacy:

   i) The pharmacist or pharmacy technician must, in a timely manner and in accordance with CPNL's *Code of Ethics*, transfer the prescription to the registrant requesting the transfer.

   ii) The pharmacist or pharmacy technician transferring the prescription must document in the patient record that the prescription was transferred, and include the following information:

      - date of the transfer;
      - identity of the transferring pharmacist or pharmacy technician;
      - identity of the receiving pharmacist or pharmacy technician and pharmacy; and
      - any other relevant information; and

   iii) Once the transfer has been completed, the prescription may no longer be filled at the transferring pharmacy.

d) When receiving a prescription that has been transferred from another pharmacy:

   i) The pharmacist or pharmacy technician receiving the transfer must confirm the accuracy of demographic (e.g., full name, MCP number) and prescription information prior to the transfer, including confirmation that the prescription is still active and is the most recent prescription available for the drug.

   ii) The pharmacist or pharmacy technician receiving the transfer must ensure that all necessary information for a valid prescription is obtained and documented, as well as the following:

      - date the prescription was written;
      - date the prescription was first filled;

- date of the most recent refill;
- date of the transfer;
- identity of the transferring pharmacist or pharmacy technician;
- identity of the receiving pharmacist or pharmacy technician; and
- any other relevant information.

iii) The transferred prescription is limited to the number of refills remaining on the original prescription and must not be filled or refilled beyond one year from the date it was originally written.

e) If, while performing a prescription transfer, a pharmacy technician identifies a situation that requires patient assessment, clinical analysis, or application of therapeutic knowledge, they must consult with a pharmacist before continuing with the request.

3.12. Communicating Within the Circle of Care

a) Sharing information related to patient care activities with other health care professionals in the patient's circle of care enhances the opportunity for collaboration and supports the principles of patient safety and continuity of care.

i) Information may be shared:

- verbally;
- via facsimile;
- via the provincial electronic health record or another appropriate patient care record; or
- via another appropriate method determined in collaboration with the other health care professional.

i) When sending information via facsimile, pharmacy staff must ensure that the correct fax number is being used and that the transmission is being sent to the intended recipient.

ii) If information is inadvertently transmitted to the incorrect recipient, this would be considered a privacy breach and must be communicated to the patient, in accordance with the *Personal Health Information Act* (PHIA).

b) Patients are also considered part of their circle of care and effective communication between the patient and the pharmacy team enhances patient care. The following should be considered when communicating with patients and determining appropriate communication methods:

i) patient preferences;

ii) accommodation for language barriers, hearing and speech impairments, and other unique patient needs;

iii) access to and understanding of technological methods;

iv) security of technological methods, including consideration of privacy-related safeguards, the need for a formal privacy impact assessment and/or consultation with Office of the Information and Privacy Commissioner NL, and the expectation that the patient has given informed consent for their use.

APPENDIX A

Policy and Procedure Template Table of Contents

1. General Pharmacy Information
   a. Contact Information
   b. Pharmacy / Dispensary Hours
   c. Pharmacy Layout

2. Human Resources
   a. Pharmacy Staff Information
   b. Job Descriptions
   c. Supervision
   d. Staffing Levels
   e. Training/Orientation
   f. Performance Appraisal
   g. Sick Leave/Vacation Leave

3. Security
   a. Security System
      i. Equipment
      ii. Maintenance
      iii. Data Retrieval
   b. Alarm Company Contacts
   c. Key/Alarm Code Holders
   d. Dispensary Access (including lock and leave procedures, if applicable)
   e. Opening and Closing Procedures
   f. Storage of Records
   g. Hardware and Software Security
   h. Responding to Burglaries or Robberies

4. Dispensary Equipment and Supplies
   a. Computers/Software
      i. System and Software Training
      ii. Data Back-up and Retrieval
      iii. User ID and Password Security
   b. Hardware (printer, scanner)
   c. Fax Machine (location, access, etc.)
   d. Internet Access
   e. Compounding Equipment
   f. Refrigerator
      i. Specifications
      ii. Temperature Monitoring Equipment
      iii. Maintenance
   g. Shredder or Shredding Service
   h. Safe (location, access, etc.)
   i. Other Equipment and Consumable Supplies
   j. Required Reference Material
      i. List of Required References and their Location
      ii. Reference Review Processes

5. Dispensary Operation
   a. Workflow Diagram
   b. Prescription Entry (scanning of original prescriptions, information collection, wait times)
   c. Prescription Packaging
   d. Prescription Checking Procedures
      i. Clinical/Therapeutic Check
      ii. Technical Check
   e. Prescription Release
   f. Prescription Filing
   g. Prescription Balances or Owings
   h. Prescriptions Not Picked-up
   i. Inventory Management
      i. Prescription Stock
      ii. Non-Prescription Stock
      iii. Consumable Supplies
      iv. Identification of Expired Stock
   j. Cold Chain Management
   k. Pharmacist Consultation
      i. Prescriptions
      ii. Exempted Codeine
      iii. Schedule 2 and 3 Products
   l. Prescription Delivery
   m. Record Retention

6. Controlled Substances
    a. Inventory Management
    b. Storage and Access
    c. Physical Inventory Counts and Reconciliation
    d. Internal Diversion Monitoring
    e. Provincial TRPP and PMP
    f. Health Canada Reporting

7. Occupational Health and Safety
    a. Hazardous/Cytotoxic Medications Handling and Storage
    b. Needle Stick Injury
    c. Staff with CPR and First Aid Training

8. Waste Management
    a. Paper
    b. Packaging Materials
    c. Expired Drugs/Returned Medications
    d. Biomedical Waste

9. Privacy
    a. Privacy Policy
    b. Confidentiality Agreements
    c. Documentation of Personal Health Information Disclosure

10. Quality Assurance
    a. Drug Error/ Near Miss Reporting
    b. Disclosure and Patient Follow-up
    c. Incident Analysis
    d. Quality Improvement
    e. Adverse Event Reporting to Health Canada

11. Emergency Preparedness (continuity of care during service disruptions, pandemic planning, etc.)

12. In accordance with section 1.1, if the pharmacy offers any special services, the pharmacy's Policy and Procedure Manual must also contain information pertaining to each of the services provided.

APPENDIX B

Protecting the Cold Chain

Introduction

Pharmacy professionals have a responsibility to ensure that all pharmaceutical products are stored in a manner that ensures the integrity and security of the drug. This responsibility requires particular 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 in order 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-Charge3

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 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. These policies and procedures should be reviewed at least yearly.

The pharmacist-in-charge must ensure that pharmacy staff members 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[3] **PHARMACIES MUST BE EQUIPPED WITH ONE OF THE FOLLOWING REFRIGERATORS FOR THE EXCLUSIVE STORAGE OF PHARMACEUTICAL PRODUCTS:** • (PREFERRED) A "Purpose-Built" Refrigerator (pharmacy or vaccine refrigerators) – a specialized refrigerator that responds to fluctuations in temperature; or • A "Modified" Frost-Free Domestic Refrigerator - A typical household refrigerator that has had the following modifications:	Small, single-door refrigerators (under-counter "bar fridges") are NOT to be used to store temperature-sensitive products. All refrigerators, regardless of type, 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

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

• The crisper has been removed from the bottom of the unit • Large water bottles have been placed in the crisper area, in the door and against the walls of the unit • Freezer packs or ice cube trays are kept in the freezer section of the unit, if present If a modified domestic refrigerator is used, staff must be aware of the various temperature zones within the unit as well as the location of the air vent in the unit. All drugs should be kept away from the air vent to avoid freezing.	surrounding temperatures change or after opening the door to remove a product; • dedicated to the storage of temperature-sensitive products; and • located within the dispensary, or another secure area that has access restricted to authorized personnel (e.g., private consultation rooms, prescription storage area for lock and leave hours).
THERMOMETER **ALL REFRIGERATORS, REGARDLESS OF TYPE, 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 remain 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 in order 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 closing time. • The min/max thermometer must be reset regularly (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 regarding 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 C

Required Reference Materials

In accordance with sections 1.5 a) i) and xii), pharmacies must have access to the CPNL website as well as **current versions** of at least **ONE** reference 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, OAMT).

CATEGORY	EXAMPLES
Canadian Compendium	CPS: Drug Information (text or online), Health Canada's Drug Product Database, RxVigilance
Drug Interactions	Lexicomp online, MedicinesComplete, Micromedex Pharmaceutical Knowledge, RxVigilance
General Drug Information Reference	Lexicomp online, 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)
Natural Health Products	Lexicomp online, TRC Natural Medicines, The Review of Natural Products
Pediatrics	Lexicomp online, Micromedex Pharmaceutical Knowledge, RxVigilance, Sick Kids Drug Handbook and Formulary (text or online)
Pregnancy and Lactation	Lexicomp online, Drugs in Pregnancy and Lactation (text or online), Hale's Medications and Mother's Milk (text or online), MedicinesComplete
Therapeutics	Applied Therapeutics: The Clinical Use of Drugs (text), Compendium of Therapeutic Choices (text or online), Pharmacotherapy: A Pathophysiologic Approach (text)