

# Newfoundland and Labrador Pharmacy Board



## Standards of Pharmacy Operation Community Pharmacy

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## 1) General Standards of Pharmacy Operation

These standards of pharmacy operation apply to ALL licensed community pharmacies in Newfoundland and Labrador. A person or corporation shall not be permitted to operate a pharmacy in Newfoundland and Labrador unless the board is satisfied that the pharmacy meets all of the following requirements.

### 1.1 Operational Policies & Procedures

- a) *Policy and Procedure Manual.* The pharmacy must develop, maintain, and regularly review a policy and procedure manual that is accessible to all pharmacy staff (see Appendix I for a Policy and Procedure Manual template Table of Contents).
- b) *Hours of Operation*
  - i) Reasonable hours of operation of a pharmacy shall be considered to be a minimum of 36 hours per week. Hours of operation should be stable and must be posted in full view at the public entrance of the pharmacy.
  - ii) Pharmacies with an approved Lock and Leave enclosure (see section 2.1) may have dispensary hours that vary from the pharmacy hours. In this case, hours of operation must be posted in full view at both the public entrance of the pharmacy and at the dispensary.

### 1.2 Staffing and Supervision

- a) *Staffing Complement.* The pharmacy must have an adequate staffing complement for safe practice.
- b) *Name Tags.* All persons working in the dispensary, whether registrants or not, must wear a suitable name tag that identifies to the public that person's name and position.
- c) *Training and Orientation.* All persons working in the dispensary should be appropriately educated, trained, and oriented to ensure an understanding of the pharmacy's policies and procedures as well as the legislative environment under which a pharmacy must operate.
- d) *Supervision.* The pharmacist-in-charge must ensure that:
  - i) adequate levels of supervision are provided to all pharmacy staff including pharmacy assistants, pharmacy technicians, pharmacy students, and pharmacy interns; and
  - ii) registrants do not delegate tasks to any person, unless that person is reasonably qualified and competent to engage in the specified task.

### 1.3 Physical Layout and Security

- a) *Signage*
  - i) There shall be a sign showing the trading name of the pharmacy which shall be affixed to the exterior of the premises.
  - ii) There shall be a sign inside the premises which clearly defines the dispensary area.
- b) *Security*
  - i) Both the pharmacy as a whole and the dispensary area must be equipped with a security system that provides suitable protection against theft, diversion, and tampering with drugs and other health care products. A combination of alarms, cameras, and motion detectors must be utilized to meet this requirement.

- ii) Access to exterior and interior keys and/or codes should be limited to a minimum number of appropriately authorized persons. The policy and procedure manual should include a policy on how key assignments are made and a documented paper trail of persons with authorized access.
- c) *Dispensary Area*
- i) The dispensary area shall be at least 9.29 square metres, including the “No Patient Access” area, but excluding the Professional Products area, patient consultation area(s), and appropriate patient waiting area.
  - ii) The dispensary must be self-contained and designed in such a way as to discourage entrance by other than authorized persons, but shall also be set up to facilitate discussion between the pharmacist and the patient.
  - iii) The dispensary must be able to be secured against entry by the public or other staff when a pharmacist or a pharmacy technician is not present in the pharmacy.
  - iv) If the pharmacy is accessible to the public or other staff at any time when a pharmacist or pharmacy technician is not present (such as for cleaning, inventory, or overnight stocking), a lock and leave enclosure must be installed (see section 2.1 for more information on lock and leave).
  - v) The dispensary should be well ventilated, appropriately lighted, and clean and tidy at all times.
  - vi) There must be at least 1.2 square metres of working counter space, excluding counter space occupied by equipment.
  - vii) Schedule II products must be located in an appropriate “No Public Access” area within the dispensary that provides no opportunity for patient self-selection.
- d) *Professional Products Area.* The pharmacy must have a designated professional products area for the sale of Schedule III products that is visually distinctive from the rest of the premises, identified with signage, and located immediately adjacent to the dispensary under the supervision of a pharmacist.
- e) *Patient Consultation Area.* The pharmacy must have a designated area for patient consultation that ensures visual and acoustical privacy and confidentiality and that is clean, safe, and comfortably furnished for the patient.

**PLEASE NOTE:** This requirement must be implemented by January 1, 2017.

#### 1.4 Dispensary Equipment and Supplies

- a) The dispensary must have:
  - i) a secure computer system with:
    - practice management software that meets the requirements of the *NAPRA Pharmacy Practice Management Systems: Requirements to Support NAPRA’s “Model Standards of Practice for Canadian Pharmacists”*;

- a connection to the provincial electronic health record through the Pharmacy Network<sup>1</sup>;

**PLEASE NOTE:** This requirement must be implemented by January 1, 2017.

- suitable internet access to allow staff access to NLPB email as well as other electronic resources appropriate to pharmacy practice; 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);

**PLEASE NOTE:** This requirement must be implemented by January 1, 2017.

- v) a prescription filing system that is readily accessible to appropriate pharmacy staff, but secured against unauthorized access;
- vi) a refrigerator for the exclusive storage of drugs requiring refrigeration that meets the cold chain requirements defined by the board in Appendix II;

**PLEASE NOTE:** This requirement must be implemented by January 1, 2017.

- vii) a safe or lockable cabinet that is appropriately anchored to the floor to be used for the secure and exclusive storage of narcotics and controlled drugs;
- viii) 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;
- ix) a shredder or service for the safe disposal of confidential information;
- x) a telephone that has a number listed in an appropriate telephone directory;
- xi) a sanitary sink with a supply of hot and cold water;
- xii) sanitary waste disposal;
- xiii) an appropriate method to dispose of hazardous waste;
- xiv) adequate shelf and storage space;
- xv) a sufficient supply of prescription and non-prescription drugs to support the professional services provided by the pharmacy;
- xvi) required and recommended reference material, as defined by the board in Appendix III;

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<sup>1</sup> The Pharmacy Network is a province-wide drug information system that integrates medication profiles from connected pharmacies. It is a key component of the provincial Electronic Health Record (EHR). The EHR provides health care professionals with more comprehensive patient information when and where it is needed, at the point of care. It supports timely and more informed decision-making and care delivery across the health system. Connected pharmacies contribute to, and utilize the information in, the patient's electronic health record through the Pharmacy Network in real-time via pharmacy practice management systems (PPMS) that are conformance tested and approved for connection to the provincial electronic health record by the NL Centre for Health Information.

- xvii) other suitable equipment (for example, graduated cylinders, mortars and pestles, spatulas, counting trays, funnels, stirring rods, and ointment pads); and
- xviii) other consumable supplies (for example, prescription and auxiliary labels, safety and non-safety vials, liquid medication bottles, ointment jars, and distilled water) required to support the professional services provided by the pharmacy.

## 1.5 Record Keeping and Information Management

### a) *Documentation*

- i) The pharmacist-in-charge shall ensure that all records required by legislation, these Standards of Pharmacy Operation, and the Standards of Practice are documented appropriately and retained for the appropriate time period.
- ii) Documentation shall 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 shall 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 fireproof and theft-resistant safe.

### c) *Record Storage and Security*

- i) Physical patient records required by legislation, these Standards of Pharmacy Operation, and the Standards of Practice (such as original written prescriptions, copies of verbal prescriptions, documentation forms, delivery records, compounding, or packaging records) must be retained in a secure, but readily accessible format for a minimum of three years after being scanned and stored electronically. Records that have not been scanned for electronic storage must be retained for a minimum of ten years.
- ii) Electronic patient records, including patient profiles, patient medication profiles, and scanned copies of the records identified in 1.5c)i) must be retained in a secure, but accessible format for a minimum of ten years.
- iii) All physical and electronic records (including backups) must be adequately secured to protect them from unauthorized access, theft, use, or loss.
- iv) 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.
- ii) Electronic records must be erased or destroyed in such a manner that the information cannot be reconstructed.

1.6 Security and Accountability of Narcotics and Controlled Drugs

a) *Storage and Security.* All narcotics and controlled drugs, including liquids, exempted codeine products, and prepared doses of methadone must be stored in a safe or cabinet that can be securely locked and is appropriately anchored to the floor and used for the exclusive storage of these drugs. Such safes or cabinets should be concealed from public view where possible.

b) *Perpetual Inventory.* Pharmacies must maintain either a computerized or manual perpetual inventory of narcotics and controlled drugs. If a manual system is utilized, a separate record must be maintained for each drug where each received quantity (including medication dispensed, but not picked-up) and each sale/transaction is recorded with a resulting running balance.

c) *Physical Inventory Counts*

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

- All narcotics and controlled drugs in the active inventory should be counted, including expired or damaged stock, products awaiting destruction, prescriptions with a balance owing, and any compounded mixtures containing a narcotic or controlled drug.
- 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 active 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, and
  - the date the count was taken.
- The physical count must be reconciled with the perpetual inventory count and any discrepancy must be investigated by reviewing records of purchases and sales. A record of identified discrepancies and their resolution should be maintained, filed with the inventory record, and retained for two years.
- Any unexplained discrepancies must be treated as a loss/theft and reported to the Office of Controlled Substances at Health Canada within 10 days in accordance with section 42. of the Narcotic Control Regulations. A copy of this report should be sent to the NLPB office and also filed with the inventory record and retained for two years.

ii) Additional physical inventory counts of narcotics and controlled drugs should also be conducted:

- 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 (either separately or together) and the signatures of each pharmacist-in-charge shall be recorded and retained for two years;
- 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.

d) *Maintenance and Auditing of Purchase Records*

- i) A book, register, or other record of all receipts of narcotics and controlled drugs, including store-to-store transfers and receipt of "Emergency Supplies", must be maintained in an organized manner in the pharmacy in accordance with section 30. of the Narcotic Control Regulations.
- ii) Purchase invoices must be retained in a readily retrievable format, filed in order by date and invoice number.
- iii) Random audits of purchase records must be conducted on a monthly basis in accordance with the following:
  - A random selection of 10% of narcotic and controlled drug invoices received each month should be selected for audit to ensure they have been accurately recorded in the Perpetual Inventory Record.
  - The date and time of the audit should not be predictable.
  - Any discrepancies should be investigated, addressed, and documented. A record of identified discrepancies and their resolution should be maintained, filed with the inventory record and retained for two years.
  - Any unexplained discrepancies must be treated as a loss/theft and reported to the Office of Controlled Substances at Health Canada within 10 days in accordance with section 42. of the Narcotic Control Regulations. A copy of this report should be sent to the NLPB office and also filed with the inventory record and retained for two years.

e) *Maintenance and Auditing of Sales Records*

- i) A book, register, or other record of all sales of narcotics and controlled drugs, including store-to-store transfers and provisions of "Emergency Supplies" (for example, a computer-generated Narcotic and Controlled Drug Sales Report), must be maintained in an organized manner in the pharmacy in accordance with section 38. of the Narcotic Control Regulations.
- ii) Random audits of sales records must be conducted on a monthly basis in accordance with the following:
  - A random selection of 10% of narcotic and controlled drug prescriptions filled each month should be selected for audit to ensure they have been accurately recorded in the Perpetual Inventory Record. The review will include obtaining the original written prescription and reconciling it with the computer record of the dispensing.
  - Any discrepancies should be investigated, addressed, and documented. A record of identified discrepancies and their resolution should be maintained, filed with the inventory record and retained for two years
  - Any unexplained discrepancies must be treated as a loss/theft and reported to the Office of Controlled Substances at Health Canada within 10 days in accordance with section 42. of the Narcotic Control Regulations. A copy of this report should be sent to the NLPB office and also filed with the inventory record and retained for two years.



- f) *Filing and Storage of Narcotic and Controlled Drug Prescriptions.* Prescriptions for Narcotics and Controlled Drugs (including pharmacist-authorized exempted codeine products) must be filed in a separate file in sequence by date and number (either transaction or prescription number) in accordance with section 40. of the Narcotic Control Regulations.

## 2) Supplemental Standards of Pharmacy Operation

These standards of pharmacy operation apply only to those pharmacies that choose to offer the particular service.

### 2.1 Lock and Leave

- a) *Intended Use.* If the pharmacy is accessible to the public or other staff at any time when a pharmacist or pharmacy technician is not present, a lock and leave enclosure must be installed and utilized.
- b) *Prior Approval.* Prior to operating a pharmacy with a lock and leave enclosure, the pharmacist-in-charge must first apply to the Board for approval using the designated form, indicating the anticipated hours of closure and describing the construction of the enclosure.
- c) *Physical Construction.* The lock and leave enclosure should be constructed in such a way to physically and securely separate the dispensary from the rest of the pharmacy.
- d) *Staff Access.* When the lock and leave enclosure is secured, only pharmacists or pharmacy technicians may enter the dispensary for any reason.
- e) *Prescription Pick-up.* Previously-prepared prescriptions may be made available for pick-up when the lock and leave enclosure is secured, in accordance with the following:
  - i) Such prescriptions must be stored in a secured area outside of the lock and leave enclosure that also takes into account any special storage considerations including breakage and refrigeration.
  - ii) The patient's confidentiality must be protected at all times by ensuring the outer package contains only the patient's name and address.
  - iii) Any patient (or designated agent) who picks up a prescription during these times must still be provided with proper and sufficient counseling.
  - iv) A documented "paper trail" (either physical or electronic) of all prescriptions picked up, including patient or designated agent signatures must be retained in the pharmacy.

### 2.2 Prescription Delivery

- a) *Intended Use.* These standards must be met in any situation where a prescription is hand or mail-delivered to a patient or an agent of the patient.
- b) Prescription delivery must take place in accordance with the following:
  - i) All storage considerations must be taken into account including breakage and refrigeration.
  - ii) The patient's confidentiality must be protected at all times by ensuring the outer package contains only the patient's name and address.
  - iii) Patients requesting delivery of prescriptions to a person other than themselves must provide the pharmacy with written delegation of authority for that person to act as the patient's agent. The written delegation of authority to an agent must include the name of the designated agent and the

name and signature of the patient, and must be kept on file in the pharmacy and noted in the patient's profile.

- iv) Any patient to whom a prescription is delivered must still be provided with proper and sufficient counseling.
- v) A documented "paper" trail (either physical or electronic) of all prescriptions delivered, including patient or designated agent signatures must be retained in the pharmacy.

### 3) Pharmacy Practice

These standards of pharmacy practice apply to ALL licensed community pharmacies in Newfoundland and Labrador. Any person or corporation who operates a pharmacy in Newfoundland and Labrador must meet all of the following practice requirements.

#### 3.1 Professional Responsibilities

- a) *Professional Responsibility of the Pharmacist.* Before a prescription is dispensed or a Schedule II medication is provided to a patient, it is the pharmacist's responsibility to review the patient profile and patient medication profile and to 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.
- b) *Role of the Pharmacy Technician.*
  - i) A pharmacy technician may:
    - obtain, enter, and record patient profile information;
    - receive, transcribe, and record verbal prescriptions from prescribers, in accordance with federal and provincial legislation;
    - transfer prescriptions to and receive prescriptions from other pharmacies (see section 3.3);
    - ensure that a prescription is complete and authentic;
    - prepare and compound prescriptions;
    - ensure the accuracy of a prepared prescription, including performing the final technical check; and
    - provide technical information to a patient when a therapeutic assessment or clinical judgment by the pharmacist is not required. (for example, a pharmacy technician could demonstrate the use of an EpiPen as a device, but not discuss the effects of epinephrine, specifically)

- ii) A pharmacy technician may assist in gathering information from a patient about a drug or a medical condition if necessary to assess the appropriateness of drug therapy, but the pharmacist remains responsible for obtaining sufficient information to assess the patient and the appropriateness of drug therapy.
  - iii) A pharmacy technician must not counsel a patient, directly or indirectly, about a drug or a medical condition, and a pharmacist may not delegate the responsibility to counsel a patient to a pharmacy technician.
  - iv) A pharmacy technician must recognize when the professional expertise of a pharmacist is required and consult with a pharmacist in that case.
- c) *Role of the Pharmacy Assistant.* A pharmacy assistant may participate in administrative or technical functions related to the operation of a community pharmacy where the pharmacy assistant is directly supervised 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 Prescription Legality/Eligibility Requirements

- a) Prior to preparing any prescription for dispensing, the pharmacist or pharmacy technician is responsible for ensuring that the prescription is authentic and clear with regards to the following:
  - i) when the prescription was written;
  - ii) the intended patient;
  - 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 identity and eligibility of the prescriber.
- b) Each time a prescription is dispensed or a Schedule II medication is provided to a patient, it must be recorded in the patient's electronic health record.
- c) Prescriptions may not be filled beyond one year from the date on which the prescription was originally written.
- d) If the prescription is received verbally from the prescriber, the information noted in 3.2 a) must be recorded in an accessible and auditable manner and the pharmacist or pharmacy technician must sign, initial or otherwise identify him- or herself on the prescription.

**PLEASE NOTE:** At this time, pharmacy technicians may not accept verbal prescriptions for narcotics, controlled drugs, benzodiazepines or targeted substances.

- e) If the prescription is written for a narcotic or controlled drug that is subject to the Government of Newfoundland and Labrador's Tamper Resistant Prescription Drug Pad Program, the pharmacist or pharmacy technician must ensure that all requirements of that program are met.

- f) If the prescription is received via facsimile transmission, the pharmacist or pharmacy technician must ensure that all requirements of the *Standards of Practice – Facsimile Transmission of Prescriptions* are met.
- g) If the prescription is written by a prescriber who is not licensed to practice in Newfoundland and Labrador, the prescription may be dispensed so long as the pharmacist takes all 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 would be entitled to prescribe the medication in question in Newfoundland and Labrador.
- h) If the prescription is being logged for dispensing at a later time:
  - i) The pharmacist must take all reasonable steps to ensure therapeutic appropriateness of drug therapy, in consideration of their assessment of the patient at that time, and take the necessary steps to address and resolve any identified drug related problems;
  - ii) The pharmacist or pharmacy technician must ensure that the prescription is accurately entered into the patient's medication profile, as if it were to be dispensed that day, and checked within a timely manner; and
  - 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, 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.

### 3.3 Transferring Prescriptions

- a) In accordance with the *Food and Drugs Act (Canada)*, pharmacists and pharmacy technicians may transfer prescriptions to another pharmacist or pharmacy technician, with the exception of prescriptions for narcotics and controlled drugs and prescriptions for benzodiazepines that have been previously transferred. To ensure patient safety, completeness of patient profiles, and to avoid duplication of records, the following requirements must be met.

**PLEASE NOTE:** At this time, pharmacy technicians may not participate in prescription transfers for benzodiazepines or targeted substances.

- b) When prescriptions are 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 shall not be filled or refilled beyond one year from the date it was originally written.
- c) When prescriptions are transferred to another pharmacy:
- i) The pharmacist or pharmacy technician will, in a timely manner and in accordance with the *Code of Ethics*, transfer a prescription to another registrant.
  - 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) All remaining refills at the transferring pharmacy must be cancelled and the prescription may no longer be filled.
- d) If, while performing a prescription transfer, a pharmacy technician identifies a situation that requires patient assessment, clinical analysis, or application of therapeutic knowledge, he or she must consult with a pharmacist before continuing with the request.
- e) Prescription transfers may be completed via fax as long as the transmitted document contains all the required information including:
- i) identity of the transferring pharmacist or pharmacy technician;
  - ii) name and address of the originating pharmacy;
  - iii) identity of the receiving pharmacist or pharmacy technician; and
  - iv) name and address of the receiving pharmacy.

### 3.4 Patient Profile

- a) A patient profile must be prepared and maintained for each patient to whom:
  - i) a prescription is dispensed;
  - ii) a Schedule II medication is provided;
  - iii) an inhalation or injection is administered; or
  - iv) other pharmacist-administered assessment or activity is performed.

- b) The profile must include the following patient information:
  - i) full name;
  - ii) medical care plan (MCP) number;
  - iii) mailing and/or street address;
  - iv) home and/or cell phone number, when available;
  - v) date of birth;
  - vi) gender; and
  - vii) documentation of any notable clinical conditions, allergies, intolerances or adverse drug reactions.
  
- c) The profile may also include other relevant information such as:
  - i) clinical observations (height, weight, blood glucose, blood pressure, etc.);
  - ii) lifestyle status (smoking status, alcohol and/or caffeine intake, etc.);
  - iii) use of known over-the-counter medications, clinical evaluation packages, or special access medications; and
  - iv) any other relevant clinical notes.

### 3.5 Patient Medication Profile

- a) For each prescription that is dispensed or Schedule II medication provided, the following information must be documented and maintained:
  - 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) In each case, the preceding information should print or be visually displayed for the pharmacist and pharmacy technician (if applicable) to utilize to complete the dispensing and checking process.
- c) Each record must also contain documentation of:
- i) any interactions that were detected, how they were addressed, and who addressed them;
  - ii) the identity of all staff members involved in the dispensing and checking processes; and
  - iii) the name of the pharmacist who delivered patient counselling and the date and time the counselling was given.

### 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.
- 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 pursuant to a prescription or provided pursuant to a Schedule II request 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) local prescription number and DIS 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);
    - xiv) the initials of the pharmacist responsible for the prescription; and
    - xv) appropriate auxiliary labels, as indicated.
- d) Where a drug container size is too small to accommodate a full label, a trimmed prescription label must be affixed to the small container. This label must include, at a minimum, the
  - i) prescription number;
  - ii) dispensing date;
  - iii) full name of the patient; and
  - iv) name of the drug; 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.

### 3.7 Final Check and Prescription Release

- a) A pharmacist or pharmacy technician must ensure that a final check is performed to ensure that each step in the dispensing process has been completed properly by verifying that:
  - i) the drug, dosage form, strength, manufacturer and quantity dispensed are correct according to the prescription; and
  - ii) the prescription label is accurate according to the prescription and contains the information required under these Standards and under federal and provincial legislation.

### 3.8 Pharmacist-Patient Consultation

- a) Pharmacists shall promote the safe and effective use of medication by educating and counselling patients about their drug therapy on the original filling of each prescription, while also giving the patient the opportunity to ask questions.
- b) Such counselling shall include, but not necessarily be limited to:
  - i) confirming the identity of the patient;
  - ii) the identity and strength of the medication;



- iii) the purpose 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) Such counselling should occur in person, whenever possible. If this is not possible due to the prescription being delivered to or picked up by an agent, patient counselling should occur by telephone.
  - d) While specific patient counselling is not required for repeat and refill prescriptions, pharmacists are expected to gauge the need for such counselling by asking questions regarding changes to dosage regimens, compliance, efficacy, and the presence of adverse effects and counsel accordingly.
  - e) All patient counselling must be documented. The pharmacist should use professional judgement when determining the information to be contained in the counselling record, but it should include, at a minimum, the name of the pharmacist who delivered the counselling and the date and time the counselling was given.
  - f) If the patient refuses to participate in patient counselling, the pharmacist should document the refusal in the patient record.

### 3.9 Miscellaneous

- a) *Return to Stock.* A pharmacy shall 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 it is in the pharmacist's professional judgment that it is appropriate to do so.

**Appendix I**  
**Policy and Procedure Manual Template Table of Contents**

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  - b. Pharmacy / Dispensary Hours
  - c. Pharmacy Layout
  
2. Human Resources
  - a. Pharmacy Staff Information
  - b. Job Descriptions
  - c. Supervision
  - d. Staffing Levels
  - e. Dress Code
  - f. Training and Orientation
  - g. Performance Appraisal
  - h. Sick Leave
  - i. Leaves of Absence
  - j. Vacation Requests
  
3. Security
  - a. Security System
    - i. Equipment
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  - b. Alarm Company Contacts
  - c. Key/Alarm Code Holders
  - d. Dispensary Access Restrictions
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  - f. Storage of Electronic Records
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## Appendix II Protecting the Cold Chain

### Introduction

Pharmacists 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 document is intended to help pharmacists meet their obligation to 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 ultimately 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

Category	Equipment	Notes
<b>REFRIGERATOR</b>	<b>PHARMACIES MUST BE EQUIPPED WITH ONE OF THE FOLLOWING REFRIGERATORS FOR THE EXCLUSIVE STORAGE OF PHARMACEUTICAL PRODUCTS:</b>	Small, single-door refrigerators (under-counter “bar fridges”) are <u>NOT</u> to be used to store temperature-sensitive products.
	A “Purpose-Built” Refrigerator (pharmacy or vaccine refrigerators) – a specialized refrigerator that responds to fluctuations in temperature	All refrigerators, regardless of type, must be: <ul style="list-style-type: none"> <li>• 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,</li> <li>• dedicated to the storage of temperature-sensitive products, and</li> <li>• located within the dispensary.</li> </ul>
	A “Modified” Frost-Free Domestic Refrigerator - A typical two-door household refrigerator that has had the following modifications: <ul style="list-style-type: none"> <li>• The crisper has been removed from the bottom of the unit</li> <li>• Large water bottles have been placed in the crisper area, in the door and against the walls of the unit</li> <li>• Freezer packs or ice cube trays are kept in the freezer section of the unit</li> </ul> If this type of 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.	

Required Equipment (continued)		
Category	Equipment	Notes
THERMOMETER	<b>ALL REFRIGERATORS, REGARDLESS OF TYPE, MUST BE EQUIPPED WITH EITHER:</b>	<ul style="list-style-type: none"> <li>Separate thermometers must be used to monitor the refrigerator and freezer compartments, if applicable.</li> <li>Thermometers should be calibrated to +/- 1°C accuracy.</li> <li>Ideally, select a thermometer that can be mounted on the outside of the refrigerator with a probe on a cord that is placed inside a vaccine or diluent box in the refrigerator, allowing the temperature to be monitored without opening the door.</li> </ul>
	A Thermometer that provides continuous monitoring (i.e. digital data loggers).	
	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. The min/max thermometer must be reset regularly (after properly recording temperatures) for meaningful readings.	

Operational Requirements	
<b>GENERAL EQUIPMENT USAGE</b>	<ul style="list-style-type: none"> <li>The refrigerator must be well maintained and free from excessive frost build up.</li> <li>Frequent opening of the door can lead to temperature instability, so the door should be opened only when absolutely necessary.</li> <li>Ensure the refrigerator is properly installed with appropriate clearance around the unit.</li> <li>Connect the unit to a dedicated circuit that is not required for other appliances.</li> <li>Label the refrigerator electrical outlet and the power breaker switch to alert others that it belongs to the refrigerator.</li> <li>A new refrigerator may take 2-7 days after turning on to reach a steady temperature range of +2°C to +8°C. Ensure the unit is reliably maintaining a steady temperature before stocking the unit.</li> <li>Do not overstock the refrigerator. Filling the unit too full prevents proper air circulation around the product thus affecting the product temperature.</li> </ul> <p><u>Temperature Range</u></p> <ul style="list-style-type: none"> <li>Refrigerator's central temperature must 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.</li> <li>Freezer compartments must be kept at -15°C or colder.</li> <li>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.</li> </ul> <p><u>Recording Temperatures</u></p> <ul style="list-style-type: none"> <li>The minimum and maximum temperatures should be recorded on a temperature log, placed on the door of the unit, at the time of pharmacy opens as well as closing time.</li> <li>It is important to reset the minimum/maximum temperatures to the current temperature after recording to obtain meaningful records.</li> </ul>
<b>RECEIVING</b>	<ul style="list-style-type: none"> <li>Protect deliveries from poor weather during unloading and examine containers to ensure there is no damage.</li> <li>Establish and follow internal procedures for good cold chain receiving: <ul style="list-style-type: none"> <li>Ensure that temperature-sensitive products received by or distributed from the pharmacy are suitably packaged in containers that maintain an appropriate environment during extreme weather conditions;</li> <li>Examine delivery documents to ensure product was not subjected to distribution delay;</li> <li>Identify products that should not be stored at room temperature on receipt; and</li> <li>Document information about ordered products that were unusable because they were exposed to temperatures outside the recommended range.</li> </ul> </li> <li>Transfer the contents of a shipment promptly to the appropriate, environmentally controlled storage area.</li> </ul>

<p><b>STORAGE</b></p>	<ul style="list-style-type: none"> <li>• Establish and follow internal procedures for good cold chain storage: <ul style="list-style-type: none"> <li>○ Identify products to be stored in a frozen state or those within a specific temperature range;</li> <li>○ Check freezer sections for products that should not be frozen;</li> <li>○ Check refrigerator and other locations for inappropriately stored products;</li> <li>○ Store products in a manner that does not block air flow within refrigerator; Ensure that drug storage refrigerators are dedicated to drugs; and</li> <li>○ Establish schedule to check expiration date and rotation of temperature controlled products.</li> </ul> </li> <li>• Products should not be stored on the doors, in the crisper area, or close to the walls of the refrigerator where the temperature fluctuations are the greatest.</li> <li>• Products should be stored in their original boxes with caps on. Light exposure may cause loss of potency of the product.</li> <li>• Products should be stored with space between each large box or tray to allow proper air circulation between the products to maintain consistent temperatures. No more than 50% of the internal volume of the refrigerator should be filled with stock.</li> <li>• Rotate stock; use stock that will expire first.</li> <li>• Document the date of opening for a multi-use vial. Also document the date of reconstitution. Store any opened vial within the original box to protect from light.</li> </ul>
<p><b>DISPENSING</b></p>	<ul style="list-style-type: none"> <li>• Educate patients regarding the cold chain and appropriate handling, storage and use of medications: <ul style="list-style-type: none"> <li>○ Identify differences in proper handling and storage in the home, at the workplace and while traveling;</li> <li>○ Provide written instructions if necessary;</li> <li>○ Instruct patients to avoid unintended exposure of drugs to abnormal temperatures; and</li> <li>○ Instruct patients to avoid exposure and storage in high humidity environments (e.g. bathroom).</li> </ul> </li> <li>• Ensure that packaging for home delivery meets the specifications required for the product.</li> </ul>



## Appendix III Required and Recommended Reference Materials

### Text versus Electronic Sources

Electronic sources are readily available and acceptable for any of the required references, provided they are as comprehensive as the printed version and meet the same requirements for currency. As with hard-copy references, when electronic references are the source of information, they must be accessible and available to the pharmacist working in the dispensary when the pharmacy is open for business.

### Sources and Suppliers

Pharmacy reference texts can be obtained from several suppliers. Some of the primary sources are listed below:

Canadian Pharmacists Association (CPhA) <a href="http://www.pharmacists.ca">www.pharmacists.ca</a>	Facts & Comparisons (FC) <a href="http://www.factsandcomparisons.com">www.factsandcomparisons.com</a>	Lexi-Comp Inc. (LC) <a href="http://www.lexi.com">www.lexi.com</a>
Login Canada (LBC) <a href="http://www.lb.ca">www.lb.ca</a>	Micromedex (MM) <a href="http://www.micromedex.com">www.micromedex.com</a>	

### Required References

At least **ONE** from **each** of the following categories:

Category	Versions	Examples	Comments/Availability
<b>CANADIAN COMPENDIUM</b>	current year	Compendium of Pharmaceuticals and Specialties (CPS)	Text, online or app (CPhA) <i>If the pharmacy is using an online or app version, it is <b>recommended</b> to also have the text version as the content is not always equivalent between these versions</i>
<b>COMPLEMENTARY/ ALTERNATIVE/ NATURAL HEALTH</b>	within the last 4 years	Alt-Med-Dex® System	Online or app (MM) - individually or as part of a bundle
		Lexi-Natural Products	Online or app (LC) - individually or as part of a bundle
		Natural Medicines Comprehensive Database	Text, online or app ( <a href="http://www.naturaldatabase.com">www.naturaldatabase.com</a> )
		The Review of Natural Products	Text, loose-leaf binder (with updates) or online (FC)
<b>DRUG INTERACTIONS</b>	current year or previous year with continuous updates	Drug Interactions Analysis & Management	Text, loose-leaf binder (with updates) (FC)
		Drug Interaction Facts	Text, loose-leaf binder (with updates) or online (FC)
		Drug-Reax® System	Online or app (MM) - individually or as part of a bundle
		Evaluations of Drug Interactions	Text ( <a href="http://www.firstdatabank.com">www.firstdatabank.com</a> )
		Lexi-Drug Interactions	PDA (LC) - individually or as part of a bundle

<b>Required References (continued)</b>			
At least <b>ONE</b> from <b>each</b> of the following categories:			
<b>Category</b>	<b>Versions</b>	<b>Examples</b>	<b>Comments/Availability</b>
<b>GENERAL DRUG INFORMATION REFERENCE</b>	current edition or next to current edition	AHFS Drug Information	Text ( <i>LBC</i> )
		Drug Facts & Comparisons	Text, loose-leaf binder (with updates) or online ( <i>FC</i> )
		Drug-Dex® System	Online or app ( <i>MM</i> ) - individually or as part of a bundle
		Lexi-Drug Information	Text, online or app ( <i>LC</i> ) - individually or as part of a bundle
<b>MEDICAL DICTIONARY</b>	within the last 10 years	<i>Dorland's, Mosby's, Stedman's, Tabor's</i> or any equivalent professional medical dictionary	Text
<b>MINOR AILMENTS</b>	current edition	Compendium of Therapeutics for Minor Ailments (CTMA) – formerly “Patient Self-Care”	Text or online ( <i>CPhA</i> )
	<b><i>BOTH</i></b> references are required	Compendium of Products for Minor Ailments (CPMA) – formerly “Compendium of Self-Care Products”	Text or online ( <i>CPhA</i> )
<b>PEDIATRICS</b>	within the last 4 years	Lexi-Pediatric and Neo-Natal Dosage Handbook	Text or electronically ( <i>LC</i> ) - individually or as part of a bundle
		Sick Kids Drug Handbook and Formulary	Text ( <a href="mailto:druginfo@sickkids.ca">druginfo@sickkids.ca</a> )
<b>PREGNANCY AND LACTATION</b>	within the last 3 years	Drugs in Pregnancy and Lactation, <i>Briggs</i>	Text ( <i>LBC</i> )
		Lexi-Pregnancy and Lactation	Electronically ( <i>LC</i> ) - as part of a bundle
<b>THERAPEUTICS</b>	within the last 4 years	Applied Therapeutics: The Clinical Use of Drugs, <i>Koda-Kimble</i>	Text ( <i>LBC</i> )
		Clinical Pharmacy and Therapeutics, <i>Walker</i>	Text ( <i>LBC</i> )
		Compendium of Therapeutic Choices (CTC)	Text, online or app ( <i>CPhA</i> )
		Pharmacotherapy: A Pathophysiologic Approach, <i>DiPiro</i>	Text ( <i>LBC</i> )
		Textbook of Therapeutics: Drug & Disease Management, <i>Helms</i>	Text ( <i>LBC</i> )
<b>REGULATORY INFORMATION</b>	current access to the NLPB website including the NLPB Pharmacy Practice Manual, newsletters and advisories ( <a href="http://www.nlpb.ca">www.nlpb.ca</a> )		
<b>PHARMACY PROFESSIONAL JOURNALS</b>	current subscriptions to at least <b>three</b> relevant pharmacy journals (e.g. Canadian Pharmacists Journal, Pharmacy Practice+, The Pharmacist's Letter)		

<b>Additional Recommended References</b>	
<b>COMPOUNDING</b>	Sick Kids Pharmacy Compounding Service website ( <a href="http://www.sickkids.ca/pharmacy/compounding-service/index.html">http://www.sickkids.ca/pharmacy/compounding-service/index.html</a> )
<b>GERIATRICS</b>	Lexi-Geriatric Dosage Handbook (LC)
<b>LACTATION</b>	LactMed website ( <a href="http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT">toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT</a> ) Medications and Mother's Milk ( <a href="http://www.ibreastfeeding.com">www.ibreastfeeding.com</a> ) Motherisk website ( <a href="http://www.motherisk.org">www.motherisk.org</a> )
<b>PHARMACOLOGY</b>	Basic & Clinical Pharmacology, <i>Katzung</i> (LBC) Goodman & Gillman's The Pharmacological Basis of Therapeutics, <i>Brunton</i> (LBC)
<b>OTHER</b>	Clinical Handbook of Psychotropic Drugs, <i>Bezchlibnyk-Butler</i> (LBC) Lexi-Infectious Diseases (LC) Remington: The Science and Practice of Pharmacy ( <a href="http://www.lww.com">www.lww.com</a> ) Sanford Guide to Antimicrobial Therapy (LBC)

<b>Additional Required References for Specific Practice Areas</b>	
For pharmacies administering drug therapy by inhalation or injection	Canadian Immunization Guide ( <a href="http://www.phac-aspc.gc.ca/im/professionals-professionnels-eng.php">www.phac-aspc.gc.ca/im/professionals-professionnels-eng.php</a> ) Newfoundland and Labrador Immunization Manual ( <a href="http://www.health.gov.nl.ca/health/publichealth/cdc/health_pro_info.html#immunization">www.health.gov.nl.ca/health/publichealth/cdc/health_pro_info.html#immunization</a> )
For pharmacies providing opioid dependence treatment services	College of Physicians and Surgeons of Newfoundland and Labrador Methadone Maintenance Treatment Standards and Guidelines ( <a href="http://www.cpsnl.ca">www.cpsnl.ca</a> ) Health Canada Best Practices: Methadone Maintenance Treatment ( <a href="http://www.hc-sc.gc.ca/hl-vs/pubs/adp-apd/methadone-bp-mp/index-eng.php">www.hc-sc.gc.ca/hl-vs/pubs/adp-apd/methadone-bp-mp/index-eng.php</a> ) Methadone Maintenance: A Pharmacist's Guide to Treatment, 2nd edition ( <a href="http://store.camh.ca/product.php?productid=36&amp;cat=0&amp;page=2">store.camh.ca/product.php?productid=36&amp;cat=0&amp;page=2</a> ) Centre for Addictions and Mental Health (CAMH) Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice Guideline ( <a href="http://knowledgex.camh.net/primary_care/guidelines_materials/Documents/buprenorphine_naloxone_gdlns2012.pdf">knowledgex.camh.net/primary_care/guidelines_materials/Documents/buprenorphine_naloxone_gdlns2012.pdf</a> )