Newfoundland and Labrador Pharmacy Board

Standards of Pharmacy Operation

Hospital Pharmacy

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1) General Standards of Pharmacy Operation

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

A hospital pharmacy may provide drugs in the following circumstances:

   a)   where the drugs are only available through a hospital;

   b)   where government- or regional health authority-sponsored programs require the drugs to be dispensed by a regional health authority;

   c)   to admitted patients receiving treatment in the hospital;

   d)   to ambulatory patients receiving treatment in specialized hospital clinics;

   e)   to residents of the hospital;

   f)   to other hospitals;

   g)   to members of the public in an emergency; or

   h)   in other special circumstances, following consultation with the board.

1.1   <u>Operational Policies & Procedures</u>

   a)   *Oversight*. Each licenced hospital pharmacy must be under the oversight and supervision of an approved Pharmacist-in-Charge who has the appropriate knowledge and skills to be responsible and accountable for the practice of pharmacy at that pharmacy.

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

   If 24-hour pharmacy services are not available on-site, the hospital pharmacy's pharmacist-in-charge must ensure that urgently needed drugs and patient-oriented pharmacy services are available at all times by:

   i)   providing a locked, secure area (i.e. "night cupboard") outside of the hospital pharmacy which must:

   - be accessible only by authorized persons;

   - be stocked with a minimum supply of drugs most commonly required for urgent use;

   - only contain controlled drugs (narcotics, controlled drugs, benzodiazepines or other targeted substances) if they are provided by an automated dispensing system, wherever possible, or alternatively, a double-locked cabinet;

   - contain drugs that are packaged to ensure integrity of the drug and labeled with the drug name, strength, quantity (if not unit dose), expiry date and lot number; and

   - include a log in which drug withdrawals are documented; and

   ii)   arranging for a pharmacist to be available for consultation on an on-call basis.

   c)   *Policy and Procedure Manual*. The pharmacy must have a well-organized and easily accessible policy and procedure manual that is familiar to all pharmacy staff. It shall be reviewed on an ongoing basis and revised, as needed.

   The policy and procedure manual shall include information relating to the administrative and procedural aspects of pharmacy services, as well as copies of guidelines for medication-related activities in the hospital that have been approved by hospital administration, pharmacy administration, or the Pharmacy and Therapeutics Committee.

d) *Committees and Programs*. Committees responsible for establishing or monitoring medication- or pharmacy-related policies and procedures (e.g. Pharmacy and Therapeutics Committee, Patient Safety and Incident Reporting) must have pharmacists as members and active participants.

e) *Continuous Quality Improvement*. The pharmacist-in-charge must participate in the development, documentation and implementation of an ongoing quality management program that:

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

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

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

   iv) documents periodic audits of the drug distribution process;

   v) includes a process to review pharmacist's recommendations related to patient care;

   vi) includes a process that reviews a pharmacist's documentation notes in the patient health record;

   vii) includes a process to evaluate drug use; and

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

1.2 Staffing and Supervision

a) *Staffing Complement*. The pharmacy must have an adequate staffing complement for safe practice. There should be sufficient numbers of professional, technical and other support personnel to meet the goals and objectives of the department and of the hospital.

b) *Name Tags*. All pharmacy personnel, whether registrants or not (including students and interns), must wear a suitable name tag that identifies to the public and other hospital staff that person's name and position.

c) *Position Descriptions*. There shall be written position descriptions for all pharmacy personnel containing detailed information on the knowledge, skills, experience, and abilities that should be maintained by pharmacists, pharmacy technicians, pharmacy assistants and other pharmacy support personnel.

d) *Training and Orientation*. All pharmacy personnel 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.

   i) All orientation and training processes are documented in a readily retrievable manner.

   ii) Staff performances are regularly assessed for continued demonstrated competency and the audit is appropriately documented.

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

   i) adequate levels of supervision and/or oversight are provided to all pharmacy staff including pharmacy assistants, pharmacy technicians, pharmacy students and interns and pharmacists; 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) *Physical Space.* The pharmacy must have sufficient physical space and be designed in such a way to facilitate a safe, healthy and effective working environment for all staff.

   i) The pharmacy should be well ventilated, appropriately lighted, and clean and tidy at all times.

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

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

   iv) Access to medication storage areas must be restricted to designated personnel.

b) *Security.* The pharmacy must be self-contained and secured against entry by the public or non-authorized staff when a pharmacist or a pharmacy technician is not present in the pharmacy.

   This includes the installation and use of a security system that provides suitable protection against theft, diversion, and tampering with drugs and other health care products.

   This system must be separate from the system that secures the remainder of the premises and include:

   i) high quality cameras and recording equipment;

   ii) motion detectors; and

   iii) panic buttons, if appropriate and necessary.

c) *Access*. Keys, access cards and/or codes should be limited to a minimum number of appropriately authorized registrants (i.e. pharmacists and pharmacy technicians). Access may be provided to other pharmacy personnel as long as such access is limited to when a pharmacist or pharmacy technician is present in the pharmacy. 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.

1.4 Equipment and Supplies

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

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

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

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

b) *Required Equipment and Supplies.* The pharmacy must have appropriate equipment to support safe medication practice including:

   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 HEALTHe NL Viewer[1];

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[1] HEALTHe NL is the provincial electronic health record (EHR) - a secure and private lifetime record of select information about an individual's health care. HEALTHe NL consolidates information from a variety of source systems across the province. The HEALTHe NL Viewer is a portal

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

iv) suitable equipment (for example a scanner) that allows staff to scan documents (including prescriptions and other patient records) and store them electronically;

> **PLEASE NOTE**: This requirement must be implemented by January 1, 2019.

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 I;

vii) an appropriately anchored safe, lockable cabinet or storage area, that is 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 contracted, secure 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) required and recommended reference material, as defined by the board in Appendix II;

xvi) other suitable equipment (for example, graduated cylinders, mortars and pestles, spatulas, counting trays, funnels, stirring rods, and ointment pads); and

xvii) other consumable supplies (for example, distilled water, prescription and auxiliary labels, medication packaging supplies, etc.) required to support the professional services provided by the pharmacy.

c) *Optional Equipment and Supplies*.

i) Prepackaging Machines. Pharmacies that utilize prepackaging machines must have appropriate policies and procedures in place including those related to:

- determining the appropriateness of medications to be utilized in each machine;
- how medications are added to the units, including initial setup and replenishment;
- calibration and recalibration of the cells or cassettes;

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that provides authorized health care professionals with one point of access into the EHR to view important patient information such as patient medications, lab results and clinical reports available in the EHR.

- the maintenance of accountability logs (including date machine was replenished, identification of the pharmacist or pharmacy technician who checked the stock);
- 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 all reports related to the prepackaging machines to ensure patient safety.

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

1.5 Inventory Management

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

b) All pharmaceuticals shall be delivered unopened to the pharmacy department.

c) *Return to Stock.* Unused dispensed drugs must be returned to the hospital pharmacy. Previously dispensed drugs must not be re-dispensed unless

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

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

    iii) the integrity of the drug can be verified.

1.6 Drug Distribution Systems

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

    i) provides drugs in identified dosage units ready for administration whenever possible and practical,

    ii) protects drugs from contamination,

    iii) provides a method of recording drugs at the time of administration, and

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

> **PLEASE NOTE**: A unit dose, monitored dose, multiple pouch packaging or individual patient prescription drug distribution system must be used for dispensing drugs.

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

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

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

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

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

    v) levels of access and training for nursing staff before they perform medication administration and on an ongoing basis to ensure safe medication practice;

vi)   review of all appropriate reports at least monthly to ensure inventory is within the "use by" date; and

vii)   contingency procedures for system down-time or machine failure.

1.7 Record Keeping and Information Management

a)   *Documentation*

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

ii)   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, pharmacy technician's or pharmacy's activities.

b)   *Medication Administration Records*

i)   Pharmacists must collaborate with nursing and medical staff to develop written policies and procedures regarding documentation related to the administration of drugs.

ii)   The medication administration record must include:

- the patient's full name and identification number;
- the patient's location in the hospital;
- the presence or absence of known allergies, adverse drug reactions, and intolerances;
- the date or period for which the drug administration record is to be used;
- the name, dosage and form of all drugs currently ordered;
- complete directions for use for all drugs;
- stop or expiry dates for drug orders for which there is an automatic stop policy (if not reported by another means);
- predetermined, standard medication administration times for regularly scheduled drugs; and
- changes to drug orders.

c)   *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.

d) *Record Storage and Security*

    i) Patient records, including:

        i. prescriptions,

        ii. written copies of verbal prescriptions, and

        iii. 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.

e) *Destruction of Records*

    i) Physical records must be destroyed using an in-pharmacy shredder, a contracted, secure service for the safe disposal of confidential information, or by complete incineration. To ensure that the requirement for record retention outlined in section 1.6 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.

1.8 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 secure cabinet that can be appropriately anchored to the floor, or in a separate secure room used for the exclusive storage of these drugs.

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 and each 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 monthly 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, 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:
  - o the name, strength, form, and quantity of the drug counted,
  - o the signature(s) of the counter, and
  - o 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 must be maintained in an organized manner in the pharmacy in accordance with section 63. 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 target percentage of 5% of narcotic and controlled drug invoices received each month should be randomly 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 63. 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 Dispensing Records*

i) A book, register, or other record of all narcotics and controlled drug dispenses (including the sale of a narcotic or controlled drug to another pharmacist pursuant to an emergency request) must be maintained in an organized manner in the pharmacy in accordance with section 63. of the Narcotic Control Regulations.

ii) Random audits of dispensing records must be conducted on a monthly basis in accordance with the following:

- A random selection of narcotic and controlled drug transactions (issued and returned) each month should be selected for audit to ensure the amount dispensed to the patient care area has been accurately recorded in the Perpetual Inventory Record. The review will generally include obtaining the original written requisition and reconciling it with the computer record of the amount dispensed to the patient care area and the nursing unit narcotic register.

- 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 63. 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 must be filed in a readily retrievable manner.

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 Investigational and Special Access Program Drugs

Registrants must comply with the policies and directives of Health Canada with respect to storage and dispensing of Special Access Program or investigational drugs.

2.2 Service to Clinics or Other Hospitals

a) Service to clinics or other hospitals must be performed in accordance with established policies and procedures that are not inconsistent with these Standards.

b) Any clinics or hospitals serviced by the pharmacy must be visited on a regular basis.

2.3 Service to Long-Term Care Facilities

Service to provincially-licensed long-term care facilities must be performed in accordance with the *Standards for the Provision of Pharmaceutical Care to Long-Term Care Facilities* as well as established policies and procedures.

2.4 Service to Personal Care Homes

Service to provincially-licenced personal care and community care homes must be performed in accordance with the *Standards for the Provision of Pharmaceutical Care to Personal Care Homes* as well as established policies and procedures.

2.5 Out-Patient Services

Service to out-patients must be performed in accordance with the *Standards of Pharmacy Operation – Community Pharmacy* as well as established policies and procedures.

2.6   Sterile Compounding

Sterile compounding must be performed in accordance with either the *Standards for Pharmacy Compounding of Non-Hazardous Sterile Preparations* or the *Standards for Pharmacy Compounding of Hazardous Sterile Preparations*, as appropriate, as well as established policies and procedures.

2.7   Opioid Agonist Maintenance Treatment

Opioid Dependence Treatment services must be performed in accordance with the *Standards for the Safe and Effective Provision of Opioid Agonist Maintenance Treatment* as well as established policies and procedures.

2.8   Off-Site Delivery to Patients

a)   Any off-site delivery of medications 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 in accordance with section 1.7 d).

2.9   Inpatient Leave of Absence (Pass) Medications

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

b)   Labels for leave of absence medications must include:

   i)   the hospital's name,

   ii)   the patient's name,

   iii)   the practitioner's name,

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

   v)   identification of the person preparing the drug, and

   vi)   the date the drug is issued.

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

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

   ii)   in the registrant's judgment it is not advisable to use a child-resistant container,

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

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

3)   Pharmacy Practice

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

3.1   Patient Record

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

i)   surgical day care,

ii)   ambulatory care,

iii)   emergency short-stay, or

iv)   other short-stay diagnostic or treatment units.

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

i)   full name;

ii)   medical care plan (MCP) number;

iii)   hospital number and location;

iv)   admission date;

v)   attending physician's name;

vi)   date of birth;

vii) gender;

viii) weight and height, if applicable to therapy;

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

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

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

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

c) Auditable and traceable documentation must be maintained of:

    i) the identity of all staff members involved in the order entry, dispensing and checking processes;

    ii) any interactions that were detected at the time of filling, how they were addressed, and who addressed them; and

    iii) any patient counselling or drug consultation that took place, the name of the pharmacist who delivered patient counselling and the date and time the counselling was given.

d) Each time a prescription is dispensed, the patient profile information should print or be visually displayed for the pharmacist and/or pharmacy technician to utilize to complete the dispensing and checking process.

e) The pharmacist shall also have access to other relevant clinical information such as:

    i) medication history prior to hospital admission;

    ii) diagnosis on admission and updates, where applicable;

    iii) other pertinent clinical or drug-related monitoring data (e.g. drug serum concentrations, renal function, etc.);

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

    v) any other relevant clinical information.

3.2 Prescription Legality/Eligibility Requirements

a) Prior to dispensing any prescription, the pharmacist or pharmacy technician is responsible for ensuring that the prescription is authentic and clear with regards to the following:

    i) the intended patient;

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

    iii) the route and frequency of administration;

    iv) the duration of therapy;

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

    vi) when the medication was prescribed; and

    vii) the identity and eligibility of the prescriber.

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

c) 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.

d) 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, wherever possible.

e) 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.

f) 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.

g) 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.

3.3 Professional Responsibilities

a) *Professional Responsibility of the Pharmacist*.

    i) Before a prescription is dispensed to a patient, it is the pharmacist's responsibility to review the patient profile, including the electronic health record, where necessary, and to take appropriate action, where applicable, with respect to:

- appropriateness of drug therapy;
- drug interactions;
- allergies, intolerances or adverse drug reactions;
- therapeutic duplication;
- correct dosage, route, frequency and duration of administration and dosage form;
- contraindicated drugs;
- intravenous administration problems including potential incompatibilities, drug stability, dilution volume and rate of administration; and
- any other potential drug-related problems.

    ii) After-hours or ward stock prescriptions must be reviewed by a pharmacist at the earliest opportunity. The pharmacist must notify the prescriber or nursing staff immediately if a problem with a prescription is detected.

    iii) A pharmacist must monitor drug therapy to detect, resolve and prevent drug-related problems at a frequency appropriate to the medical condition being treated.

    iv) When a pharmacist gathers a medication history from the patient or patient's representative, the following information must be obtained:

- medical conditions and physical limitations;
- allergies, adverse drug reactions, and idiosyncratic responses;

- past and current prescribed drug therapy including the drug name, strength, dosage, frequency and duration and effectiveness of therapy;

- compliance with the prescribed drug regimen; and

- Schedule II and III and unscheduled drug use.

v) A pharmacist must provide drug information, including patient-specific information to health care personnel, as appropriate.

vi) A pharmacist must provide information about the assessment, management and prevention of drug-related adverse events within the hospital.

vii) When a pharmacist provides patient counselling or drug consultation to patients, the following information must be included:

- the name and strength of the medication;

- the purpose and the therapeutic goals of the medication;

- directions for use of the drug including the frequency, duration and route of therapy;

- action to be taken in the event of a missed dose;

- how to monitor the response to therapy;

- how to properly store the medication;

- common adverse effects, drug and food interactions or therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur; and

- any other information unique to the specific medication or patient.

b) *Role of the Pharmacy Technician.*

i) A pharmacy technician may:

- receive, transcribe, and record verbal prescriptions from prescribers, in accordance with federal and provincial legislation;

- transfer prescriptions to and receive prescriptions from other pharmacies;

- ensure that a prescription is complete and authentic;

- ensure the accuracy of drug and personal health information in the patient record;

- record patient and prescription information in the patient record;

- 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 about a drug or medical condition or provide therapeutic or clinical information or advice to another health professional, and a pharmacist may not delegate either of these responsibilities 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 drug distribution-related activities where the pharmacy assistant is directly supervised[2] 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.

3.4 Prescription Labelling Requirements

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

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

ii) generic name, strength and dosage form of the drug.

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

b) If not available on the patient medication administration record, the following information must also be included on the label:

i) directions for use including frequency and route of administration;

ii) appropriate auxiliary or cautionary statements, as indicated;

iii) date of dispense; and

iv) a way of identifying the pharmacist responsible for the prescription.

c) Only pharmacists or pharmacy technicians may alter a prescription label.

3.5 Final Check and Prescription Release

a) Before being released to be administered to the patient, 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, strength, dosage form, route 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.

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[2] 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.

Appendix I
Protecting the Cold Chain

Introduction

Pharmacists have a responsibility to ensure that all pharmaceutical products (including those stored in patient care areas) are stored in a manner that ensures the integrity and security of the drug. This responsibility requires 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

Equipment	Notes
REFRIGERATOR A "Purpose-Built" Refrigerator (pharmacy or vaccine refrigerators) – a specialized refrigerator that responds to fluctuations in temperature	All refrigerators must be: • unaffected by outside temperatures and able to maintain temperature within the recommended storage range without deviation (between 2°C and 8°C for most temperature-sensitive products) even when surrounding temperatures change or after opening the door to remove a product, and • dedicated to the storage of temperature-sensitive products.
THERMOMETER All refrigerators must be equipped with either: • A Thermometer that provides continuous monitoring (i.e. digital data loggers); 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. The min/max thermometer must be reset regularly (after properly recording temperatures) for meaningful readings	• Separate thermometers must be used to monitor the refrigerator and freezer compartments, if applicable. • Thermometers should be calibrated to +/- 1°C accuracy. • 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.

Operational Requirements	
GENERAL EQUIPMENT USAGE	• The refrigerator must be well maintained and free from excessive frost build up. • Frequent opening of the door can lead to temperature instability, so the door should be opened only when absolutely necessary. • Ensure the refrigerator is properly installed with appropriate clearance around the unit. • The unit should be connected to a dedicated circuit that is not being used for other appliances. • The refrigerator electrical outlet and the power breaker switch should be labelled to alert others that it belongs to the refrigerator. • A new refrigerator may take 2-7 days after turning on to reach a steady temperature range of $+2^0C$ to $+8^0C$. Ensure the unit is reliably maintaining a steady temperature before stocking the unit. • Do not overstock the refrigerator. Filling the unit too full prevents proper air circulation around the product thus affecting the product temperature. Temperature Range • 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. • Freezer compartments must 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, placed on the door of the unit, at the time of pharmacy opens as well as at closing time. Alternatively, continuous temperature monitoring could be met through a remote alarm system that notifies a pharmacist if the temperature goes outside of the designated range. • It is important to reset the minimum/maximum temperatures to the current temperature after recording to obtain meaningful records.

RECEIVING	• Protect deliveries from poor weather during unloading and examine containers to ensure there is no damage.
	
	• Establish and follow internal procedures for good cold chain receiving:
	
	   o 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;
	
	   o Examine delivery documents to ensure product was not subjected to distribution delay;
	
	   o Identify products that should not be stored at room temperature on receipt; and
	
	   o Document information about ordered products that were unusable because they were exposed to temperatures outside the recommended range.
	
	• Transfer the contents of a shipment promptly to the appropriate, environmentally controlled storage area.

STORAGE	• Establish and follow internal procedures for good cold chain storage:
	
	    ○ Identify products to be stored in a frozen state or those within a specific temperature range;
	
	    ○ Check freezer sections for products that should not be frozen;
	
	    ○ Check refrigerator and other locations for inappropriately stored products;
	
	    ○ Store products in a manner that does not block air flow within refrigerator; Ensure that drug storage refrigerators are dedicated to drugs; and
	
	    ○ Establish schedule to check expiration date and rotation of temperature controlled products.
	
	• Products should not be stored on the doors or close to the walls of the refrigerator where the temperature fluctuations are the greatest.
	
	• Products should be stored in their original boxes with caps on. Light exposure may cause loss of potency of the product.
	
	• Products should be stored with space between each large box or tray to allow proper air circulation between the products to maintain consistent temperatures.
	
	• Rotate stock; use stock that will expire first.
	
	• 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.

DISPENSING	• Educate patients and other health professionals regarding the cold chain and appropriate handling, storage and use of medications.

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 pharmacy 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)* www.pharmacists.ca	Facts & Comparisons *(FC)* www.factsandcomparisons.com	Lexi-Comp Inc. *(LC)* www.lexi.com
Login Canada *(LBC)* www.lb.ca	Micromedex *(MM)* www.micromedex.com	

Required References
Pharmacies should have, or have access to, at least **ONE** reference from **each** of the following categories:
PLEASE NOTE: Additional references may be required in accordance with specific Standards of Practice.

Category	Versions	Examples	Comments/Availability
CANADIAN COMPENDIUM	current edition	Compendium of Pharmaceuticals and Specialties (CPS)	Text, online or app (e.g. CPS All Access, CPS e-suite, RxTx) *(CPhA)* *If the pharmacy is using an online or app version, it is **recommended** to also have the text version as the content is not always equivalent between these versions*
COMPLEMENTARY/ ALTERNATIVE/ NATURAL HEALTH	current edition or next to current edition	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 (www.naturaldatabase.com)
		The Review of Natural Products	Text, loose-leaf binder (with updates) or online *(FC)*
DRUG INTERACTIONS	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 (www.firstdatabank.com)
		Lexi-Drug Interactions	PDA *(LC)* - individually or as part of a bundle

Required References (continued)			
Pharmacies should have, or have access to, at least **ONE** reference from **each** of the following categories:			
Category	**Versions**	**Examples**	**Comments/Availability**
GENERAL DRUG INFORMATION REFERENCE	current edition or next to current edition	AHFS Drug Information	Text *(LBC)*
		Drug Facts & Comparisons	Text, loose-leaf binder (with updates) or online *(FC)*
		Drug-Dex® System	Online or app *(MM)* - individually or as part of a bundle
		Lexi-Drug Information	Text, online or app *(LC)* - individually or as part of a bundle
GERIATRICS *(where applicable)*	current edition or next to current edition	Lexi-Geriatric Dosage Handbook	Text, online or app (LC) - individually or as part of a bundle
MINOR AILMENTS **BOTH** *references are required*	current edition	Compendium of Therapeutics for Minor Ailments (CTMA) – *formerly "Patient Self-Care"*	Text or online as part of RxTx *(CPhA)*
		Compendium of Products for Minor Ailments (CPMA) – *formerly "Compendium of Self-Care Products"*	Text or online as part of RxTx *(CPhA)*
PARENTERAL PRODUCTS	current edition or next to current edition	Extended Stability for Parenteral Products, *Dellamorte-Bing*	Text or electronically (https://store.ashp.org/default.aspx)
		King Guide to Parenteral Admixtures	https://www.kingguide.com/index.html
		Lexi-IV	Text, online or app (LC) - individually or as part of a bundle
		Pediatric Injectable Drugs, *Phelps (LBC)*	Text or electronically *(LBC)*
		Trissel's IV Compatibility	Electronically as part of a bundle *(LC, MM)*
PEDIATRICS *(where applicable)*	current edition or next to current edition	Lexi-Pediatric and Neo-Natal Dosage Handbook	Text or electronically *(LC)* - individually or as part of a bundle
		Sick Kids Drug Handbook and Formulary	Text (druginfo@sickkids.ca)
PREGNANCY AND LACTATION	current edition or next to current edition	Drugs in Pregnancy and Lactation, *Briggs*	Text *(LBC)*
		Lexi-Pregnancy and Lactation	Electronically as part of a bundle *(LC)*
REGULATORY INFORMATION	current access to the NLPB website including the NLPB Pharmacy Practice Manual, newsletters and advisories (www.nlpb.ca)		
THERAPEUTICS	current edition or next to current edition	Applied Therapeutics: The Clinical Use of Drugs, *Koda-Kimble*	Text *(LBC)*
		Clinical Pharmacy and Therapeutics, *Walker*	Text *(LBC)*
		Compendium of Therapeutic Choices (CTC)	Text or online (CTC online, RxTx) *(CPhA)*
		Pharmacotherapy: A Pathophysiologic Approach, *DiPiro*	Text *(LBC)*
		Textbook of Therapeutics: Drug & Disease Management, *Helms*	Text *(LBC)*

Additional Recommended References	
LACTATION	LactMed website (toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT) Medications and Mother's Milk (www.ibreastfeeding.com) Motherisk website (www.motherisk.org)
NON-STERILE COMPOUNDING	Sick Kids Pharmacy Compounding Service website (http://www.sickkids.ca/pharmacy/compounding-service/index.html)
ONCOLOGY	BC Cancer Agency (http://www.bccancer.bc.ca/) Cancer Care Ontario (https://www.cancercare.on.ca/)
PHARMACOLOGY	Basic & Clinical Pharmacology, *Katzung (LBC)* Goodman & Gillman's The Pharmacological Basis of Therapeutics, *Brunton (LBC)*
OTHER	Clinical Handbook of Psychotropic Drugs*, Bezchlibnyk-Butler (LBC)* Institute for Safe Medication Practices (ISMP) Canada website (https://www.ismp-canada.org/index.htm) Lexi-Infectious Diseases *(LC)* Remington: The Science and Practice of Pharmacy (www.lww.com) Sanford Guide to Antimicrobial Therapy *(LBC)*