Newfoundland and Labrador Regulation 2024

NEWFOUNDLAND AND LABRADOR
REGULATION 62/24

Pharmacy Regulations, 2024
under the
Pharmacy Act, 2024

(Filed September 27, 2024)

Under the authority of section 71 of the *Pharmacy Act, 2024,* the Board of Directors of the College of Pharmacy of Newfoundland and Labrador, with the approval of the Minister of Health and Community Services, makes the following regulations.

Dated at St. John's, September 27, 2024.

Henry White
Chair of the Board of Directors of the College of Pharmacy of Newfoundland and Labrador

John Hogan K.C.
Minister of Health and Community Services

REGULATIONS

Analysis

Short title

1. These regulations may be cited as the *Pharmacy Regulations, 2024*.

Interpretation

2. (1) In these regulations

(a) "Act" means the *Pharmacy Act, 2024*;

(b) "ailment" means a common or uncomplicated health condition listed in Schedule A that

can be managed with self-care strategies or minimal treatment or both;

(c) "pharmacy network" means the component of the province-wide electronic health record that allows authorized health care providers to contribute to and access patient medication profiles in real-time;

(d) "prescriber" means a person authorized by an Act of the province to provide an instruction directing that a drug be dispensed to or for a person, which instruction may be given

(i) orally,

(ii) in writing, or

(iii) by an electronic means;

(e) "preventable disease" means a disease listed in Schedule B;

(f) "regional medical officer of health" means a person appointed under section 11 of the *Public Health Protection and Promotion Act*;

(g) "Schedule I drug" means a drug or device listed in Schedule I of a drug schedule referred to in subparagraph 2(z)(iii) or (iv) of the Act;

(h) "Schedule II drug" means a drug or device listed in Schedule II of a drug schedule referred to in subparagraph 2(z)(iii) or (iv) of the Act;

(i) "Schedule III drug" means a drug or device listed in Schedule III of a drug schedule referred to in subparagraph 2(z)(iii) or (iv) of the Act;

(j) "standards advisory committee" means the standards advisory committee established under section 10;

(k) "therapeutic substitution" means substituting a prescribed drug with a different drug that has an equivalent therapeutic effect; and

(l) "unscheduled drug" means a drug or device that is not listed on a drug schedule referred to in paragraph 2(z) of the Act and is available for sale at any retail outlet.

(2) For the purposes of the Act and these regulations, "inspector" means

(a) a person or class of persons designated under subsection 57(1) of the Act; and

(b) the registrar.

(3) For the purpose of subparagraph 2(z)(iii) of the Act, the following drugs shall be excluded from the definition of "scheduled drug":

(a) naloxone hydrochloride injection, when indicated for emergency use for opioid overdose; and

(b) naloxone hydrochloride nasal spray, when indicated for emergency use for opioid overdose.

(4) For the purposes of subsection 31(5) of the Act,

(a) "sale of the pharmacy" means the sale of all or substantially all of the assets of the pharmacy;

(b) "sale of shares in the pharmacy" means

(i) where a pharmacy owner is a corporation, other than a publicly traded corporation where the sale of shares has no impact on any individual with significant control of the pharmacy owner,

(A) a sale, issuance, or cancellation of any shares in the pharmacy owner, or

(B) a merger or amalgamation of the pharmacy owner which impacts upon the ownership of shares in the pharmacy owner,

(ii) where a pharmacy owner is a partnership, a sale, issuance or cancellation of any partnership units directly held in the pharmacy owner, or

(iii) a plan of arrangement or reorganization of the pharmacy owner under an order of a court of competent jurisdiction; and

(c) "sale of shares in a corporation that holds shares in the pharmacy" means

(i) where a pharmacy owner is a corporation, any of the following that leads to a change in any individual with significant control of the pharmacy owner,

(A) any sale, issuance or cancellation of shares in a corporation which directly or indirectly holds shares in the corporation that holds shares in the pharmacy owner,

(B) any sale, issuance, or cancellation of partnership units in a partnership which directly or indirectly holds shares in the corporation that holds shares in the pharmacy owner, or

(C) a merger or amalgamation of a corporation that directly or indirectly holds shares in the pharmacy owner, and

(ii) where a pharmacy owner is a partnership, any of the following that leads to a change in any individual with significant control of the pharmacy owner,

(A) any sale, issuance or cancellation of shares in a corporation which directly or indirectly holds partnership units in the partnership that holds shares in the pharmacy owner,

(B) any sale, issuance or cancellation of partnership units in a partnership which directly or indirectly holds partnership units in the partnership that holds shares in the pharmacy owner, or

(C) a merger or amalgamation of a corporation that directly or indirectly holds partnership units in the pharmacy owner.

(5) For the purposes of subsection (4), "individual with significant control of the pharmacy owner",

(a) for the purposes of subparagraphs (b)(i) and (c)(i), has the same meaning as "individual with significant control over a corporation" in section 45.1 of the *Corporations Act*; and

(b) for the purposes of subparagraph (c)(ii), means an individual who

(i) controls 25% or more of the votes of the pharmacy owner, either

(A) alone, or

(B) jointly with one or more individuals or by arrangement or agreement for such rights to be exercised jointly or in concert with those individuals,

(ii) controls 25% or more of the fair market value of the pharmacy owner, either

(A) alone, or

(B) jointly with one or more individuals or by arrangement or agreement for such rights to be exercised jointly or in concert with those individuals; or

(iii) has any direct or indirect influence that, where exercised, would result in control of the pharmacy owner.

PART I
REGISTRATION AND RENEWAL

Practical training - pharmacists

3. The practical training referred to in paragraph 16(1)(h) of the Act shall be

(a) in addition to any pharmacy practice experience required as part of the applicant's pharmacy education program;

(b) completed in accordance with the policies and guidelines established by the college;

(c) conducted at a pharmacy or other facility approved by the college; and

(d) completed under the preceptorship of a pharmacist approved by the college.

Practical training – pharmacy technicians

4. The practical training referred to in paragraph 20(1)(h) of the Act shall be

(a) in addition to any pharmacy technician practice experience required as a part of the applicant's pharmacy technician education program;

(b) completed in accordance with the policies and guidelines established by the college;

(c) conducted at a pharmacy or other facility approved by the college; and

(d) completed under the preceptorship of a pharmacist or pharmacy technician approved by the college.

Certificate of registration – validity period and renewal requirements

5. (1) A certificate of registration, except for a certificate of registration issued to a pharmacist or pharmacy technician registered under section 17 or 21 of the Act, is valid for one year.

(2) The college shall renew a registrant's certificate of registration, except for a certificate of registration issued to a pharmacist or pharmacy technician registered under section 17 or 21 of the Act, where the registrant

(a) submits a completed application for renewal in a form and manner set by the college;

(b) provides proof, satisfactory to the college, that the registrant continues to have professional liability insurance coverage in a form and amount satisfactory to the college;

(c) provides proof, satisfactory to the college, that the registrant's licence or registration in another jurisdiction has not been revoked, suspended or restricted or has conditions attached by reasons of disciplinary measures in another jurisdiction, where the registrant is currently, or was previously, licensed or registered in another jurisdiction; and

(d) pays

(i) the annual registration fee set by the board, and

(ii) any outstanding amounts that are owed to the college.

(3) Notwithstanding paragraph (2)(c), the college may renew the certificate of registration of a registrant whose licence or registration in another jurisdiction has been revoked, suspended or restricted or has conditions attached by reasons of disciplinary measures in the other jurisdiction where

(a) the registrant provides details of any revocation or suspension of or restriction or conditions on the person's licence or registration in the other jurisdiction;

(b) the college is satisfied, after consideration of the details provided under subparagraph (i), that the registrant is entitled to have the registrant's certificate of registration renewed; and

(c) the registrant satisfies the other requirements in this section.

(4) Where the college renews a certificate of registration under subsection (3), the college may impose terms, conditions or restrictions on the certificate of registration.

(5) In addition to the renewal requirements under subsection (2), a pharmacist or a pharmacy technician who is applying for a renewal of a certificate of registration shall provide proof, satisfactory to the college, that the registrant has completed the continuing professional development requirements set by the board.

(6) In addition to the other renewal requirements in this section, a pharmacist or pharmacy technician referred to in subsection 26(5) of the Act who is applying for a renewal of a certificate of registration shall

(a) complete a period of supervised practice as required by the college; and

(b) successfully complete any examinations or other qualifications required by the college.

PART II
PHARMACY LICENSING, RENEWAL AND CLOSURE

Pharmacy licences

6. (1) The college shall issue a licence in respect of a proposed pharmacy where

(a) the owner and pharmacist in charge of the proposed pharmacy submit an application in a form and manner specified in the by-laws;

(b) the owner of the proposed pharmacy provides a current certificate of conduct satisfactory to the college;

(c) the owner of the proposed pharmacy submits a declaration, satisfactory to the college, stating that the owner of the proposed pharmacy

(i) will comply with the Act and all regulations under the Act,

(ii) will comply with the board's standards of pharmacy operation and standards of practice,

(iii) will cooperate with an inspector carrying out inspections of the pharmacy under the Act and comply with an order of an inspector,

(iv) will participate in the quality assurance program established under the Act,

(v) will not direct, control or manage the proposed pharmacy,

(vi) will not impede, through action nor inaction, the ability of the pharmacist in charge to ensure that the proposed pharmacy is operated in compliance with this Act, and

(vii) is authorized to sign a declaration in respect of the proposed pharmacy;

(d) an inspector completes an inspection of the proposed pharmacy, and the college is satisfied that

(i) the proposed pharmacy complies with the board's standards of pharmacy operation and standards of practice, or

(ii) the pharmacy owner and pharmacist in charge will rectify any deficiencies noted in the inspection to the satisfaction of the college; and

(e) the proposed pharmacy is connected to the provincial electronic health record via the pharmacy network and the pharmacy network is fully operational within the pharmacy.

(2) The college shall renew a licence in respect of a pharmacy where the pharmacist in charge

(a) applies in the form and manner specified in the by-laws;

(b) submits a declaration, satisfactory to the college, stating that the pharmacist in charge will

(i) continue to fulfill the duties of a pharmacist in charge in accordance with section 9,

(ii) comply with the Act and all regulations under the Act,

(iii) comply with the board's standards of pharmacy operation and standards of practice,

(iv) cooperate with an inspector carrying out inspections of the pharmacy under the Act and comply with an order of an inspector, and

(v) participate in the quality assurance program established under the Act; and

(c) pay the annual licence fee set by the board.

Cessation of operation

7. Before a pharmacy owner and a pharmacist in charge cease operation of a pharmacy, the pharmacist in charge shall

(a) submit an application to close the pharmacy in the form and manner set by the college;

(b) ensure that all narcotic, controlled and other drugs are disposed of in accordance with laws relating to disposal of those drugs;

(c) ensure that prescription records are available through another pharmacy; and

(d) comply with other requirements set by the college.

PART III
PHARMACIST IN CHARGE

Designation of pharmacist in charge

8. The college may designate a pharmacist as a pharmacist in charge where the pharmacist

(a) applies in a form and manner set by the college; and

(b) satisfies other requirements set by the college.

Duties of pharmacist in charge

9. In addition to the responsibilities set out in the Act, a pharmacist in charge shall be responsible for the following:

(a) actively directing, controlling and managing the pharmacy;

(b) prohibiting an owner or other person from directing, influencing, controlling or participating in the management or operation of the pharmacy;

(c) practising in the pharmacy for the minimum number of hours set by the college;

(d) where required by the college, ensuring that another pharmacist is designated as pharmacist in charge when the pharmacist in charge is away from the pharmacy;

(e) developing, maintaining and enforcing written policies and procedures for pharmacy staff in accordance with applicable legislation and the board's standards of pharmacy operation and standards of practice;

(f) ensuring that persons who are employed by the pharmacy to engage in the practice of pharmacy are registered with the college;

(g) notifying the college when a person registered with the college begins or ceases employment with the pharmacy;

(h) notifying the college of any changes to information included on the pharmacy licence application;

(i) notifying the college of a contravention of the board's standards of pharmacy operation or standards of practice;

(j) ensuring that the pharmacy has an adequate staffing complement for the safe practice of pharmacy;

(k) ensuring that confidentiality is maintained with respect to all pharmacy and patient records in accordance with all applicable legislation and the board's standards of pharmacy operation and standards of practice;

(l) ensuring correct usage of the operating name of the pharmacy with regard to prescription labels, contact information, interior and exterior signs or media advertising;

(m) ensuring that the pharmacy is appropriately secured against loss, theft and diversion;

(n) ensuring that the pharmacy has the facilities, space, equipment, resources and systems in place to support the safe and effective operation of the pharmacy, in accordance with the board's standards of pharmacy operation and standards of practice;

(o) cooperating with any person appointed by the board or college in accordance with the Act or any regulations under the Act; and

(p) ensuring compliance with all federal and provincial legislation pertaining to the practice of pharmacy and licensing of pharmacies including the Act, all regulations under the Act, the by-laws and the board's standards of pharmacy operation and standards of practice.

PART IV
SCOPE OF PRACTICE

Division 1
Standards

Standards advisory committee

10. (1) The board shall appoint a standards advisory committee which shall consist of

(a) a person nominated by the college;

(b) a person nominated by the College of Physicians and Surgeons of Newfoundland and Labrador;

(c) a person nominated by the College of Registered Nurses of Newfoundland and Labrador; and

(d) other members the board considers appropriate to appoint.

(2) The standards advisory committee shall make recommendations to the board respecting standards for the purposes of this Part.

Standards

11. (1) The board shall establish standards relating to the following:

(a) the administration of drug therapy by inhalation or injection by registrants for the purposes of Division 2; and

(b) the prescribing of drugs by pharmacists for the purposes of Division 3.

(2) The board shall consider the recommendations of the standards advisory committee in establishing the standards under subsection (1).

Division 2
Administration of Drug Therapy by Inhalation or Injection

Prohibition

12. A pharmacist or pharmacy technician shall not administer drug therapy by inhalation or injection to a person unless

(a) the pharmacist's or pharmacy technician's certificate of registration includes an authorization granted under section 13;

(b) the requirements set out in the standards established by the board under section 11 are met; and

(c) either,

(i) the drug therapy does not require a prescription, or

(ii) where it does require a prescription, it has been prescribed by a person authorized to prescribe it.

Authorization to administer drug therapy by inhalation or injection

13. (1) The college shall add an authorization to administer drug therapy by inhalation or injection to the certificate of registration of a pharmacist or pharmacy technician where the pharmacist or pharmacy technician

(a) applies in the form and manner directed by the college;

(b) provides proof, satisfactory to the college, that the pharmacist or pharmacy technician has completed the educational and training requirements approved by the college;

(c) provides proof, satisfactory to the college, of current training in CPR and first aid; and

(d) pays the application fee.

(2) An authorization added under subsection (1) expires on the same date as the pharmacist's

or the pharmacy technician's certificate of registration.

Delegation

14. (1) Where a pharmacist is authorized to administer drug therapy by inhalation or injection under subsection 13(1), the pharmacist may delegate the administration of drug therapy by inhalation or injection to a pharmacy intern or pharmacy student.

(2) Where a pharmacy technician is authorized to administer drug therapy by inhalation or injection under subsection 13(1), the pharmacy technician may delegate the administration of drug therapy by inhalation or injection to a pharmacy technician intern or pharmacy technician student.

Requirement to follow standards

15. A registrant who administers drug therapy by inhalation or injection under subsection 13(1) or through a delegation under section 14 shall do so in accordance with the standards established under section 11.

Division 3
Prescribing by Pharmacists

Prescribing by pharmacist

16. A pharmacist may prescribe a drug to a person in accordance with these regulations where

(a) the requirements set out in the standards established by the board under section 11 are satisfied; and

(b) the prescribing falls into one or more of the following categories:

(i) providing an interim supply of drugs,

(ii) extending a prescription,

(iii) adapting a prescription,

(iv) therapeutic substitution,

(v) prescribing Schedule II drugs, Schedule III drugs and unscheduled drugs,

(vi) prescribing for ailments,

(vii) prescribing for preventable diseases,

(viii) prescribing hormonal contraceptives, and

(ix) prescribing post-exposure prophylaxis.

Interim supply

17. (1) A pharmacist who meets the requirements of section 16 may prescribe an interim supply of drugs to a person.

(2) A pharmacist who prescribes an interim supply of drugs under subsection (1) may provide the person with a minimum amount of previously prescribed drugs required in order to allow the person time to visit a prescriber or the person's usual pharmacy in order to obtain a renewal.

Extending prescriptions

18. (1) A pharmacist who meets the requirements of section 16 may extend a prescription one or more times.

(2) Notwithstanding subsection (1), where a pharmacist extends a prescription under this section, the pharmacist shall not

(a) extend a prescription beyond 12 months after the date that the prescription was first extended; or

(b) prescribe, at any one time, more than a 90 days' supply.

Adapting prescriptions

19. (1) A pharmacist who meets the requirements of section 16 may adapt a prescription.

(2) A pharmacist who adapts a prescription under subsection (1) may do the following:

(a) change the brand of the prescribed drug;

(b) change the dose of the prescribed drug;

(c) change the duration of the prescription;

(d) change the formulation of the prescribed drug; and

(e) change the regimen of the prescribed drug.

Therapeutic substitution

20. A pharmacist who meets the requirements of section 16 may substitute a drug within a defined therapeutic class with another drug which would have, in the opinion of the pharmacist, an equivalent therapeutic effect in order to meet the therapeutic needs of the person for whom the drug has been prescribed.

Ailments, preventable diseases and other Schedule I prescribing

21. A pharmacist who meets the requirements of section 16 may prescribe a Schedule I drug where

(a) the drug is indicated for the treatment of an ailment;

(b) the drug is indicated for the prevention of a preventable disease; or

(c) the prescribing falls into a category referred to in subparagraph 16(b)(i), (ii), (iii), (iv), (viii) or (ix).

Prescribing post-exposure prophylaxis

22. A pharmacist who meets the requirements of section 16 may only prescribe post-exposure prophylaxis with a referral from a regional medical officer of health or a designate of a regional medical officer of health.

Drugs listed in the Controlled Drugs and Substances Act (Canada)

23. (1) A pharmacist who meets the requirements of section 16 may only prescribe a drug listed in the *Controlled Drugs and Substances Act* (Canada) or the regulations under that Act where the pharmacist is authorized to prescribe the drug under the *Controlled Drugs and Substances Act* (Canada), the regulations under that Act or an exemption issued under that Act.

(2) Where a pharmacist prescribes a drug in accordance with an authorization referred to in subsection (1), the pharmacist shall comply with the terms and conditions of the authorization.

PART V
TRANSITIONAL, CONSEQUENTIAL AMENDMENTS, REPEAL AND

COMMENCEMENT

Transitional

24. (1) A person who was authorized to administer drug therapy by inhalation or injection under the *Administration of Drug Therapy by Inhalation or Injection Regulations*, Newfoundland and Labrador Regulation 82/14, immediately before the coming into force of these regulations, continues to be authorized to administer drug therapy by inhalation or injection under these regulations.

(2) A person who was authorized to prescribe under the *Authorization to Prescribe Regulations*, Newfoundland and Labrador Regulation 73/15, immediately before the coming into force of these regulations, continues to be authorized to prescribe under these regulations.

NLR 33/12 Amdt.

25. Subsection 10(1) of the *Animal Health Regulations* under the *Animal Health and Protection Act* is amended by deleting the words "section 45 of the *Pharmacy Regulations* and".

NLR 90/12 Amdt.

26. Paragraph 3.1(2)(b) of the *Diagnostic and Therapeutic Drug Regulations, 2012* under the *Optometry Act, 2012* is repealed and the following substituted:

> (b) administer and prescribe a Schedule I drug and Schedule II drug as defined in the *Pharmacy Regulations, 2024*, to treat and manage ocular disease, except for narcotics and other controlled pharmaceutical agents;

NLR 94/14 Rep.

27. The *Pharmacy Regulations, 2014*, Newfoundland and Labrador Regulation 94/14, are repealed.

NLR 82/14 Rep.

28. The *Administration of Drug Therapy by Inhalation or Injection Regulations*, Newfoundland and Labrador Regulation 82/14, are repealed.

NLR 73/15 Rep.

29. The *Authorization to Prescribe Regulations*, Newfoundland and Labrador Regulation 73/15, are repealed.

Commencement

30. These regulations come into force on September 30, 2024.

SCHEDULE A
Approved Ailments and Conditions

Acne, Mild

Allergic Rhinitis

Aphthous Ulcers

Atopic Dermatitis, Mild-Moderate

Callouses and Corns

Conjunctivitis

Contact Dermatitis

COVID-19

Dandruff and Seborrhea

Diarrhea (non-infectious)

Dry Eyes

Dysmenorrhea

Dyspepsia

Emergency Contraception

Fungal Nail Infections

Fungal Skin Infections (including athlete's foot)

Gastroesophageal Reflux Disease

Headache, Mild

Hemorrhoids

Herpes Simplex (cold sores)

Herpes Zoster (shingles)

Impetigo

Insomnia, Mild

Joint Pain, Mild

Musculoskeletal Pain, Mild

Nausea and Vomiting

Oral Candidiasis

Pinworms

Nicotine Dependence

Upper Respiratory Conditions, Mild (cough, nasal congestion, sore throat)

Urinary Tract Infections, uncomplicated

Urticaria, Mild (including bites and stings)

Vaginal Candidiasis

Viral Skin Infections (common and flat warts)

SCHEDULE B
Preventable Diseases

COVID-19

Hepatitis A

Hepatitis B

Herpes Zoster (shingles)

Human Papillomavirus (HPV)

Respiratory Syncytial Virus (RSV)

Varicella Zoster (chickenpox)