



PRINCE EDWARD ISLAND
ÎLE-DU-PRINCE-ÉDOUARD

PHARMACY ACT GENERAL REGULATIONS

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For more information concerning the history of these regulations, please see the *Table of Regulations* on the Prince Edward Island Government web site (www.princeedwardisland.ca).

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Legislative Counsel Office
Tel: (902) 368-4292
Email: legislation@gov.pe.ca



PHARMACY ACT
Chapter P-6.1

GENERAL REGULATIONS

Pursuant to section 51 of the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6.1, the Council of the College of Pharmacy, with the approval of the Lieutenant Governor in Council, made the following regulations:

PART I – PERMIT AND OPERATING REQUIREMENTS

Interpretation

1. Definitions

In these regulations,

- (a) “**facsimile transmission**” means a transmission of the exact image of a document using a facsimile machine;
- (b) “**package**”, as a verb, includes to label;
- (c) “**professional service**” means a service, other than a pharmacy service, provided by a member, including
 - (i) administering a drug or vaccine, and
 - (ii) conducting a medication review. (EC527/14; 870/24)

Administration

2. Registrar records

The Registrar shall keep and maintain a record of the following for a period of 20 years after receipt:

- (a) applications and any supporting documentation submitted for a permit or an endorsement or to renew a permit or an endorsement;
- (b) reports, written submissions and orders related to or resulting from an inspection. (EC527/14)

Requirements for Permit Holder

3. Requirements for applicant, permit

- (1) For the purposes of obtaining a permit under section 8 of the Act, an applicant shall meet the following requirements:
- (a) the applicant has not been found guilty of an offence or disciplined by a professional regulatory body for conduct that, in the opinion of the Registrar or the Council, as the case may be, renders the applicant unsuitable to operate a pharmacy;
 - (b) where the applicant is a corporation,
 - (i) the corporation is in good standing under the enactment or Act of the Parliament of Canada under which it was incorporated or registered, and
 - (ii) the letters patent or articles of incorporation of the corporation permit the corporation to carry on the business of operating a pharmacy;
 - (c) hold public liability insurance with coverage in the amount of at least five million dollars for the pharmacy to be operated under the permit.

Requirements for permit holder, renewal

- (2) For the purposes of renewing a permit under section 11 of the Act, the permit holder shall
- (a) continue to meet the requirements in clauses 1(a), (b), if applicable, and (c), if applicable, for an applicant; and
 - (b) meet the following requirements:
 - (i) the permit holder is not in default in the payment of any fees required to be paid to the College,
 - (ii) the permit holder is operating the pharmacy to which the permit applies in accordance with the Act and these regulations. (EC527/14; 870/24)

Requirements for Pharmacy

4. Design and equipment

For the purposes of sections 8 and 11 of the Act and as a term and condition of the operation of a pharmacy under a permit, a pharmacy shall be equipped with

- (a) a well-defined and sufficiently sized dispensary area that is inaccessible to the public and equipped for the safe and proper compounding and dispensing of drugs and the delivery of other pharmacy services;
- (b) an area for confidential patient consultation;
- (c) a reference library of, or unrestricted internet access to, current references relevant to compounding and dispensing drugs and other pharmacy services;
- (d) a computer system capable of storing, retrieving, reporting and auditing information with sufficient speed, efficiency and security; and
- (e) a security system to prevent and detect unauthorized access to the premises. (EC527/14; 870/24)

Operation of a Pharmacy

5. Insurance

A permit holder shall hold and maintain public liability insurance with coverage in the amount of at least five million dollars for the pharmacy operated under the permit. (EC527/14)

6. Requirements on ceasing to operate, exception

Clause 21(1)(a) of the Act does not apply where another permit holder intends to operate a pharmacy under a permit in the same location. (EC527/14)

Drug Schedules

7. Designating drug as unscheduled

The following are designated as unscheduled drugs when indicated for emergency use for opioid overdose:

- (a) Naloxone hydrochloride injection;
- (b) Naloxone hydrochloride nasal spray. (EC527/14; 494/24)

Dispensing and Supplying Drugs

7.1 Exempted codeine product

Revoked by EC870/24 (EC460/15; 870/24)

7.2 Dispensing activities, employees other than members

For the purpose of subsections 18(1) and 24(2) of the Act, an employee who is not a member may, under the direct supervision of a pharmacist who is physically present, perform the following activities related to dispensing a Schedule I drug or a Schedule II drug in a pharmacy:

- (a) collecting information from a patient for a patient profile;
- (b) recording and retrieving data about a patient or a prescription;
- (c) entering prescription information into a database;
- (d) non-sterile compounding, if a member has approved the formulation and process;
- (e) selecting an appropriate container for a drug;
- (f) preparing and packaging a drug for dispensing;
- (g) attaching the prescription label and any other labels to a container;
- (h) replenishing drug storage containers and dispensing machines;
- (i) managing drug inventory;
- (j) implementing quality assurance and risk management policies. (EC460/15)

Prescriptions

8. Manner of giving prescriptions

- (1) For the purposes of subsection 25(3) of the Act, a prescriber may give a prescription
- (a) in writing,
 - (i) to a patient or a representative of the patient, or
 - (ii) to a pharmacist or a pharmacy technician at a pharmacy, directly, by electronic transmission or by facsimile transmission; or
 - (b) verbally, directly to a pharmacist or a pharmacy technician at a pharmacy.

Prescription for methadone

- (2) Revoked by EC228/20.

Transcription required

- (3) A pharmacist or pharmacy technician who receives a prescription verbally from a prescriber shall transcribe the prescription in writing.

Information required

- (4) For the purposes of subsection 25(3) of the Act, a prescription shall contain the following information:
- (a) the date the prescription is given;
 - (b) the name of the patient;
 - (c) the name, business address and business contact information of the prescriber;
 - (d) the name, quantity, form, and strength of the drug prescribed;
 - (e) directions for the use of the drug prescribed;
 - (f) the number of refills and the minimum interval between refills, if applicable;
 - (g) the signature of the prescriber or the transcriber, as the case may be.

Time limit for submission

- (5) A prescription given in writing is valid for submission to a pharmacy for up to one year after the date it is given.

Refills up to one year

- (6) A prescription is valid for refill, if applicable, for one year after the date it is given or until the refills run out, whichever occurs sooner.

Refills, no time limit

- (6.1) Despite subsection (6), a prescription given on or after the date this subsection comes into force is valid for refill, if applicable, until the refills run out unless
- (a) the prescriber provides for an earlier expiry on the prescription; or
 - (b) the prescription is for a monitored drug, as defined in the *Narcotics Safety and Awareness Act* R.S.P.E.I. 1988, Cap. N-.01.

Initials required

- (7) and (8) revoked by EC870/24. (EC527/14; 228/20; 239/21; 870/24)



9. Prescription sent by facsimile

Revoked by EC870/24. (EC527/14; 870/24)

Packaging Prescription Drugs**10. Individual container or package labels**

For the purposes of clause 26(a) of the Act, the following information shall be recorded on the drug container or drug package label for a prescription drug dispensed in an individual container or drug package in a pharmacy:

- (a) the date the drug is dispensed;
- (b) the name of the patient;
- (c) the name of the prescriber;
- (d) the name, business address and business contact information of the pharmacy;
- (e) the identification number of the prescription;
- (f) the following information about the drug dispensed:
 - (i) the brand or generic name of the drug,
 - (ii) the manufacturer of the drug,
 - (iii) the drug information number or natural product number assigned to the drug by Health Canada,
 - (iv) the strength, dosage form and quantity of the drug;
- (g) the number of refills remaining, if applicable;
- (h) directions respecting the use of the drug dispensed. (EC527/14)

11. Multiple drug package

- (1) A member or other employee in a pharmacy may, with the approval of the patient or representative of the patient, package in a multiple drug package two or more drugs in solid form that are to be taken orally, if a pharmacist or pharmacy technician is satisfied it is appropriate to do so.

Compartments

- (2) A person who packages drugs in a multiple drug package in a pharmacy shall ensure that the compartments of the multiple drug package are
 - (a) sealed without the application of heat; and
 - (b) either
 - (i) designed to show any resealing, or
 - (ii) not resealable.

Multiple drug package label

- (3) For the purposes of clause 26(a) of the Act, the following information shall be recorded on a multiple drug package label:
 - (a) the date the multiple drug package is dispensed;
 - (b) the name of the patient;
 - (c) the name, business address and business contact information of the pharmacy dispensing the multiple drug package;
 - (d) the identification number of the multiple drug package;

- (e) instructions respecting when each compartment is to be accessed and the drug or drugs contained within taken;
- (f) any other necessary instructions respecting the multiple drug package, including instructions respecting storage; and
- (g) in respect of each type of drug contained in the multiple drug package
 - (i) the name of the prescriber,
 - (ii) the identification number of the prescription for the drug,
 - (iii) the brand or generic name of the drug,
 - (iv) the manufacturer of the drug,
 - (v) the drug information number or natural product number assigned to the drug by Health Canada,
 - (vi) the strength, dosage form and quantity of the drug,
 - (vii) a description of the form of the drug by size, shape, colour and markings,
 - (viii) the number of refills remaining, if applicable, and
 - (ix) directions respecting the use of the drug. (EC527/14; 460/15; 870/24)

12. Prepared or repackaged drug labels

Where a drug is prepared or repackaged in a pharmacy for later use, the person who prepares or repackages the drug shall ensure the following information is recorded on the container or package in which the drug is stored in the dispensary:

- (a) the name of the drug;
- (b) the strength or concentration of the drug, if applicable;
- (c) recommended dosages of the drug;
- (d) the manufacturer's identification number, the lot number and the expiry date of the drug, if applicable;
- (e) the drug information number or natural product number assigned to the drug by Health Canada;
- (f) any special instructions respecting preservation of the drug;
- (g) any special precautions respecting the drug, including side effects or interactions. (EC527/14; 460/15; 870/24)

Patient Record

13. Electronic patient record

For the purposes of clause 26(b) of the Act, an electronic patient record shall be maintained in a pharmacy respecting each patient for whom a prescription drug is dispensed, containing

- (a) information respecting the patient, including his or her
 - (i) name,
 - (ii) address and contact information,
 - (iii) date of birth,
 - (iv) known allergies and allergic reactions,
 - (v) primary medical practitioner or nurse practitioner, if applicable, and
 - (vi) provincial health number, if necessary for purposes permitted under the *Provincial Health Number Act* R.S.P.E.I. 1988, Cap. P-27.01;

- (b) information respecting each prescription submitted for the patient during the past ten years, including
 - (i) the name of the prescriber,
 - (ii) the name of the drug prescribed,
 - (iii) the identification number of the prescription,
 - (iv) directions for the use of the drug prescribed,
 - (v) the number of refills and the minimum interval between refills, if applicable;
 - (vi) with respect to each time a drug is dispensed pursuant to the prescription,
 - (A) the date the drug is dispensed,
 - (B) the brand or generic name of the drug,
 - (C) the manufacturer of the drug,
 - (D) the drug information number or natural product number assigned to the drug by Health Canada,
 - (E) the strength, dosage form and quantity of the drug,
 - (F) the number of refills remaining , if applicable, and
 - (G) the name of the person who prepared and packaged the drug; and
- (c) where any prescription drugs have been dispensed to the patient in a multiple drug package, with respect to each multiple drug package dispensed during the past ten years
 - (i) the multiple drug package number,
 - (ii) the prescription number of each drug contained in the multiple drug package,
 - (iii) a description of the multiple drug package sufficient to enable its duplication, and
 - (iv) the name of the person who prepared and packaged the drugs. (EC527/14; 460/15)

Transfer of Prescription

14. Method of transfer

- (1) A pharmacist or a pharmacy technician in a pharmacy may, pursuant to section 30 of the Act, transfer a prescription to another pharmacy
 - (a) by facsimile transmission or electronic transmission, to a pharmacist or pharmacy technician at the other pharmacy; or
 - (b) verbally, directly to a pharmacist or a pharmacy technician at the other pharmacy.

Duties of transferring member

- (2) The pharmacist or pharmacy technician transferring the prescription shall
 - (a) provide the following information to the pharmacist or pharmacy technician receiving the prescription:
 - (i) the date the prescription was given,
 - (ii) the name of the patient,
 - (iii) the name, business address and business contact information of the prescriber,
 - (iv) the identification number of the prescription,

- (v) the name, quantity, form, and strength of the drug prescribed,
 - (vi) directions for the use of the drug prescribed,
 - (vii) the number of refills and the total quantity of the drug remaining to be dispensed under the prescription,
 - (viii) the minimum interval between refills, if applicable,
 - (ix) the date the drug was first dispensed and the date of the last refill,
 - (x) the quantity most recently dispensed, if different from the quantity prescribed,
 - (xi) the name, business address and business contact information of the pharmacy from which the prescription is being transferred,
 - (xii) the name of the pharmacist or pharmacy technician transferring the prescription; and
- (b) make a record of
- (i) the date the prescription is transferred,
 - (ii) the name, business address and business contact information of the pharmacy the prescription is transferred to,
 - (iii) the name of the pharmacist or pharmacy technician who transferred the prescription, and
 - (iv) the name of the pharmacist or pharmacy technician at the other pharmacy who received the transfer.

Information required

- (3) A pharmacist or pharmacy technician transferring a prescription by facsimile transmission or electronic transmission shall include the following information in the transmission:
- (a) the name of the pharmacy and the facsimile number or electronic address to which it is being sent;
 - (b) an indication that the transmission is confidential.

Verification

- (4) The pharmacist or pharmacy technician receiving a prescription transferred by facsimile transmission shall verify the origin of the transmission and be satisfied as to its authenticity before the prescription is dispensed at that pharmacy.

Transcription

- (5) The pharmacist or pharmacy technician receiving a prescription transferred verbally shall transcribe the prescription in writing. (EC527/14; 870/24)

PART II – CENTRALIZED PRESCRIPTION PROCESSING

Interpretation

15. Definitions

In this part,

- (a) “**central-fill pharmacy**” means a pharmacy in which central-fill services are provided;

- (b) “**central-fill services**” means the preparation and packaging of a prescription drug on behalf of a pharmacy to which the prescription is submitted or a hospital in which the prescription is ordered;
- (c) “**originating pharmacy**” means a pharmacy in which central-fill services are utilized in relation to some or all prescriptions submitted to it. (EC527/14)

Notice Requirements

16. Notice to Registrar

- (1) A permit holder shall provide notice to the Registrar, in the form required by the Council, at least 30 days in advance of commencing to provide or utilize central-fill services in the pharmacy operated under the permit.

Notice to public

- (2) A permit holder shall provide notice to the public, in accordance with subsection (3),
 - (a) for at least 30 days in advance of commencing to utilize central-fill services in the pharmacy operated under the permit; and
 - (b) each day thereafter until central-fill services cease to be utilized in the pharmacy.

Form and manner of notice

- (3) The notice required under subsection (2) shall
 - (a) be in writing;
 - (b) be posted in the area of the pharmacy where prescriptions are submitted by patients or representatives of patients to the dispensary; and
 - (c) indicate
 - (i) that prescription drugs dispensed in the pharmacy may be prepared and packaged in a central-fill pharmacy,
 - (ii) that personal information of the patient that is necessary to facilitate the provision of central-fill services may be shared with a central-fill pharmacy, and
 - (iii) the name, business address and business contact information of each central-fill pharmacy to which requests for central-fill services are submitted from the originating pharmacy.

Implied consent

- (4) Where a prescription is submitted to a pharmacy that gives notice as required in subsections (2) and (3), the patient is deemed to consent to
 - (a) the disclosure, from the originating pharmacy to a central-fill pharmacy listed in the notice, of the personal information of the patient that is necessary to facilitate the provision of central-fill services; and
 - (b) the preparation and packaging of the drug prescribed in the prescription in a central-fill pharmacy listed in the notice.

Transitional

- (5) A permit holder who, immediately before these regulations come into force, having notified the Prince Edward Island Pharmacy Board as it existed under the former Act, operates a class I pharmacy in which central-fill services are utilized or provided, is deemed to meet subsection (1) and clause (2)(a), if applicable. (EC527/14)

Request for Central-fill Services

17. Request for central-fill services

- (1) A pharmacist at an originating pharmacy shall submit a request for central-fill services to a central-fill pharmacy, in the form required by the Council, directly or by facsimile transmission or other electronic means.

Information required

- (2) A request for central-fill services shall contain:
- (a) the name of the patient;
 - (b) the address and contact information of the patient;
 - (c) the date of birth of the patient;
 - (d) the name, business address and business contact information of the originating pharmacy;
 - (e) the name of the pharmacist submitting the request;
 - (f) the name, business address and business contact information of the central-fill pharmacy.

Facsimile or electronic transmission

- (3) In addition to the information required in subsection (2), a request for central-fill services submitted by facsimile transmission or electronic transmission shall contain
- (a) the facsimile number or electronic address to which it is being sent; and
 - (b) an indication that the transmission is confidential.

Record of request

- (4) The pharmacist who submits a request for central-fill services shall ensure a copy of the request is maintained in the originating pharmacy for a period of at least ten years after the drug is dispensed. (*EC527/14; 460/15; 870/24*)

Labels and Records

18. Interpretation

- (1) Where a prescription drug is prepared and packaged in a central-fill pharmacy, “pharmacy” in sections 10 and 11 means the originating pharmacy.

Additional information on labels

- (2) Where a prescription drug is prepared and packaged in a central-fill pharmacy, in addition to the information required in section 10 or subsection 11(3), as the case may be, the name, business address and business contact information of the central-fill pharmacy or a code representing the central-fill pharmacy shall be recorded on the label.

Additional information in patient record

- (3) Where a prescription drug is prepared and packaged in a central-fill pharmacy, in addition to the information required in paragraphs 13(b)(vi)(A) to (G) and subclauses 13(c)(i) to (iv), the name, business address and business contact information of the central-fill pharmacy or a code representing the central-fill pharmacy shall be recorded in the patient record. (*EC527/14*)

19. Central-fill services records

- (1) With respect to each request for central-fill services received in a central-fill pharmacy, the person who prepares and packages the drug or drugs pursuant to the request shall ensure a record is maintained in the central-fill pharmacy containing
- (a) a copy of the request;
 - (b) the lot number and expiry date of each drug prepared and packaged pursuant to the request; and
 - (c) the name of the person who prepared and packaged the drug or drugs.

Separate records

- (2) Records referred to in subsection (1) shall be maintained
- (a) separately from records respecting patients of the pharmacy; and
 - (b) for a period of at least ten years. (EC527/14; 460/15)

PART III – STANDARDS**Compliance****20. Compliance with standards**

- (1) The permit holder, managing pharmacist of the pharmacy operated under the permit and members and other employees providing pharmacy services in that pharmacy shall comply with standards for the operation of a pharmacy and the sale of drugs to the public established or adopted under these regulations.

Idem

- (2) The permit holder and the managing pharmacist of the pharmacy operated under the permit shall ensure that all members and other employees providing pharmacy services in that pharmacy comply with standards for the operation of a pharmacy and the sale of drugs to the public established or adopted under these regulations. (EC527/14; 460/15)

Advertising**21. Application**

- (1) This section establishes standards that apply to advertisements in any form or medium respecting a pharmacy or members employed or engaged at a pharmacy.

Advertising requirements

- (2) Advertisements shall
- (a) contain information that is factual, clear and verifiable; and
 - (b) maintain the honour and integrity of member professions.

Prohibited content

- (3) Advertisements shall not
- (a) contain descriptive or qualifying words, including “professional”, “trusted”, “prompt”, “licensed”, “accurate”, “cheap”, or words of similar meaning or intent;
 - (b) contain the words “specialist” or “expert” or words of similar meaning or intent;

- (c) claim or imply exclusivity of any aspect of the practice of pharmacy;
- (d) compare, directly or indirectly, the services of pharmacies or the abilities of members;
- (e) promise more effective services or better results;
- (f) express disapproval of, or criticize services provided in or by, other pharmacies or members employed or engaged in other pharmacies;
- (g) disclose personal information respecting patients without express consent;
- (h) advertise Schedule I drugs;
- (i) offer any inducement, including a gift, prize, rebate, bonus or loyalty points, in relation to prescription drugs, pharmacy services or professional services; or
- (j) in the opinion of the Council,
 - (i) be inaccurate or misleading due to the inclusion or exclusion of information,
 - (ii) misrepresent pharmaceutical knowledge or fact, or
 - (iii) create unrealistic expectations respecting services or outcomes.

Advertisement respecting Schedule II drug

- (4) An advertisement respecting a Schedule II drug may only contain
 - (a) the name of the drug;
 - (b) the classification of the drug;
 - (c) the quantity of the drug available for sale; and
 - (d) the price of the drug. (EC527/14)

PART IV - GENERAL

22. Fine

For the purposes of clause 35(1)(b) of the Act, the Council may impose a minimum fine of \$2,000 and a maximum fine of \$10,000. (EC527/14)

23. Revocation

The following regulations are revoked:

- (a) *Pharmacy Act Authorization Regulations (EC575/92);*
- (b) *Pharmacy Act Drug Schedule Regulations (EC287/05);*
- (c) *Pharmacy Act Standards Regulations (EC618/87). (EC527/14)*

SCHEDULE

Revoked by EC228/20

(EC527/14; 228/20)