



## **PLEASE NOTE**

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For more information concerning the history of these regulations, please see the [Table of Regulations](#).

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## CHAPTER P-6

### PHARMACY ACT

#### STANDARDS REGULATIONS

Made by the Prince Edward Island Pharmacy Board, after consultation with the Council of the Prince Edward Island Pharmaceutical Association pursuant to section 8 of the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6, and approved by the Lieutenant Governor in Council

1. (1) In these regulations
- |   | Definitions             |
|---|-------------------------|
| (a) "Act" means the <i>Pharmacy Act</i> R.S.P.E.I. 1988, Cap. P-6;  | Act                     |
| (a.1) "CE unit" means one hour of a continuing education program approved by the Board pursuant to subsection 25(1.2);  | CE unit                 |
| (b) "dispensary" means that section of a pharmacy to be used, under the direct supervision of a dispenser, specially for the keeping, preparation and furnishing to clients of prescription and closely restricted non-prescription products; | dispensary              |
| (c) "dispenser" means a person qualified under the Act to practise pharmacy;  | dispenser               |
| (d) "inspector" means a person appointed in accordance with section 30;   | inspector               |
| (e) "Investigation Committee" means the persons appointed in accordance with section 35;  | Investigation Committee |
| (e.1) "multiple drug package" means a container with individual compartments containing different drugs;  | multiple drug package   |
| (f) "No Public Access" means, in relation to a drug or product, that, while not requiring a prescription, it is specified in the regulations as being required to be kept within a dispensary;  | No Public Access        |
| (f.1) "preceptor" means a preceptor approved by the Board under section 29.2;   | preceptor               |
| (f.2) "prescriber" means  | prescriber              |
| (i) a person authorized by the law of any province to practice medicine, dentistry or veterinary medicine and to prescribe any Schedule I drugs,  |                         |
| or  |                         |

	(ii) a person or class of persons authorized by the Minister to prescribe the drugs referred to in subclause (i);
provincial health number	(f.3) “provincial health number” means the number assigned to a person pursuant to the <i>Provincial Health Number Act</i> R.S.P.E.I. 1988, Cap. P-27.01;
PPRA	(f.4) “PPRA” means a Provincial Pharmacy Regulatory Authority from another jurisdiction;
Public Access - Pharmacy Only	(g) “Public Access - Pharmacy Only” means, in relation to a drug or product that, while not requiring a prescription, it is specified in the regulations as being required to be available to the public only through acquisition from a pharmacy.
Application	(2) These regulations (a) apply to all pharmacists and pharmacies in the province, except as provided in clause (b); and (b) apply, except for sections 9, 19, 20 and 22, to all hospital pharmacies and pharmacists that provide pharmacy services to a hospital. (EC618/87; 289/05)

#### PART I REQUIREMENTS OF A PHARMACY

Discretionary application	<b>2.</b> The Board may, if safety is not thereby endangered, relax the application of requirements in relation to certain classes of permit or in particular cases where it considers that strict compliance would be unproductive or unrealistic. (EC618/87)
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#### FACILITIES

Hygienic, etc.	<b>3.</b> A pharmacy shall be kept weatherproof, dry, free of pests, ventilated, heated, lighted, in a state of good repair and sanitation and otherwise hygienic, to the satisfaction of the Board, so as to prevent potential harmful effect on the storage, preparation and provision of drugs. (EC618/87)
Dispensary	<b>4.</b> A pharmacy shall have a dispensary that is distinct from other areas and enclosed by physical barriers to prevent public access. (EC618/87)
Dispensary, physical requirements	<b>5.</b> (1) A dispensary shall (a) have a lockable cupboard for the keeping of narcotic and controlled drugs in accordance with the relevant federal legislation; (b) have surfaces that are all readily cleanable, and that are kept sanitary; (c) be kept free of tobacco smoke;

- (d) have a sanitary sink with potable hot and cold running water;
- (e) have a working refrigerator that is exclusively for keeping drugs and is not accessible to patients or the public; and
- (f) be furnished with equipment, instruments, other aids, materials and supplies sufficient for the person in charge to demonstrate, to the satisfaction of the Board, the capability to perform the services offered by the pharmacy.

(2) Class I, II, III and V pharmacies shall have on their premises reference sources as compiled on a list maintained by the Board and as amended by it from time to time. (EC618/87; 289/05)

**6.** A Class I pharmacy shall, where beginning operation in a formerly unlicensed facility or carrying on operation following major renovation, provide for wheelchair approach to the dispensary. (EC618/87)

#### OPERATIONAL PRACTICES

**7.** (1) In the case of a Class I, II or V pharmacy,

- (a) a pharmacist shall have charge in accordance with section 23 of the Act; and
- (b) all dispensing shall be done by a qualified dispenser.

(2) Notwithstanding clause (1)(b), a person who does not hold an authorization to practise pharmacy may perform particular steps in the dispensing process, if a qualified dispenser

- (a) checks and confirms the work;
- (b) himself performs the aspects of assessing appropriateness and giving professional advice that may be involved in the dispensing; and
- (c) assumes responsibility for the dispensing. (EC618/87)

**8.** In the case of a Class IV or VIII pharmacy, a pharmacist is not required to be in charge, and dispensing may be performed by persons who do not hold an authorization to practise pharmacy, if the pharmacy, unless exempted by the Board, has a formally established consultancy arrangement with a pharmacist for purposes of professional advice. (EC618/87; 289/05)

**8.1** Every person working in a dispensary shall wear identification indicating whether that person is qualified to dispense drugs or to engage in patient counselling. (EC289/05)

**9.** In the case of a Class I pharmacy, all prescription and No Public Access products shall be kept within the dispensary unless being held in some other storage area that is securely inaccessible to persons other than staff of the pharmacy. (EC618/87; 289/05)

- Loosely restricted display
- 10.** In a Class I pharmacy, Public Access - Pharmacy Only products, unless being held in storage, shall be kept distinct from unrestricted products, in an area adjacent to the dispensary to allow visual supervision by a dispenser. (EC618/87)
- Dispenser required
- 11.** In a Class I pharmacy, a dispenser shall
- (a) continuously supervise the dispensary, by presence in it or in adjacent areas allowing direct visual or auditory monitoring, unless the dispensary is made inaccessible, by locked physical barrier, to all persons unqualified to dispense;
  - (b) be actively involved in any sale of a No Public Access product; and
  - (c) receive any prescription submitted orally and, if necessary, discuss any pharmacological or therapeutic aspect of a prescription with prescriber or patient. (EC618/87)
- Out-of-province prescription
- 12.** A dispenser may fill a prescription given in writing or orally by a prescriber who practises legally in a jurisdiction other than Prince Edward Island, if it is the professional judgment of the dispenser that the prescription is valid. (EC618/87)
- Prescription time limits
- 13.** A dispenser shall not fill a prescription if
- (a) it is undated;
  - (b) it is presented more than ninety days after the date of issue, unless the prescriber verifies the continuing validity; or
  - (c) it is presented for refill more than one year after original issue. (EC618/87)
- Prescription information
- 14.** (1) Before filling a prescription, a dispenser shall ensure that there is recorded on it or in the patient record required by section 22, in legible and permanent form, the
- (a) date of issue;
  - (b) name and address of the patient for whom the prescription is given;
    - (b.1) provincial health number of the patient, if any;
  - (c) name, quantity, form and, where applicable, the strength of the drug;
  - (d) identity of the manufacturer;
  - (e) directions for use as prescribed;
  - (f) name and address of prescriber;
  - (g) date on which dispensed;
  - (h) handwritten initials of the dispenser and the handwritten initials of the person who received the prescription, if that person is not the dispenser; and
  - (i) refill information, if applicable.

(2) A dispenser shall, when refilling a prescription, comply with subsection (1). (EC618/87; 289/05) Refills information

**15.** (1) Where a prescription is transmitted orally to a dispenser at a pharmacy, the dispenser shall not fill the prescription unless Orally transmitted prescription

- (a) the prescriber has personally transmitted the prescription; and
- (b) the dispenser records the prescription in a legible and permanent form as required by section 14.

(2) Notwithstanding subsection (1), where a prescription is transmitted orally to a dispenser at a Class II or Class III pharmacy, the dispenser may fill the prescription if it has been transmitted directly to the dispenser by a registered nurse who undertakes to send to the dispenser the written prescription within seven days of the oral order. (EC618/87; 289/05) Exception

**16.** (1) The patient for whom a prescription is given, or a person he designates as his representative, is entitled to receive, upon request, a copy of the prescription, unless the prescriber expressly directs otherwise. Copy

(2) Any copy so provided shall have clearly inscribed on it “Copy: For Information Only” or a similar phrase to indicate that the copy is not to be construed as a valid prescription. *Idem*

(3) The issuance of a copy, including the date and the name of the recipient, shall be recorded on the original prescription or in the patient record. (EC618/87) *Idem*

**17.** (1) Upon presentation to a dispenser, a prescription becomes the property of and shall be retained by the dispensing pharmacy. Retention and disposal of prescription

(2) The dispensing pharmacy shall, with respect to any prescription it has filled, *Idem*

- (a) retain it for at least two years from the date of last dispensing, in such manner as to protect it against loss or destruction;
- (b) make it available at any reasonable time for inspection upon request by the prescriber, the patient for whom it was given or his designated representative, or an inspector;
- (c) dispose of it in such manner as to ensure confidentiality; and
- (d) where the pharmacy closes, ensure that any prescription less than two years old is given to the prescriber or another pharmacy or, failing these, to the Registrar, within thirty days of the closing.

(3) Class I and Class V pharmacies shall ensure that all prescription records are stored in an easily retrievable manner. (EC618/87;289/05) Records easily retrievable

- Transfer **18.** (1) Where a prescription authorizes refilling, it may be refilled upon the patient's request by a pharmacy other than the originally dispensing pharmacy, if the latter
- (a) relays to the refilling pharmacy the full information of the prescription as required by section 14, indicating the number of refills originally authorized, the date of the most recent refill and the number of authorized refills remaining; and
  - (b) records the refill transfer on the original prescription or in the patient record.
- Provincial pharmacy, transfer of service (2) Notwithstanding subsection (1), the Provincial Pharmacy may transfer a prescription to a Class I pharmacy without the patient's request, provided that
- (a) the transfer includes the information required by clauses (1)(a) and (b); and
  - (b) where the patient expresses a preference for a Class I pharmacy, that the transfer is made to that pharmacy. (EC618/87; 329/00)
- Prescription labels **19.** The dispenser shall ensure that the container of a drug dispensed by prescription is labelled with the following information:
- (a) the name, address and telephone number of the dispensing pharmacy;
  - (b) the name of the prescriber;
  - (c) the date the drug was dispensed;
  - (d) the identification number of the prescription;
  - (e) information identifying the drug by
    - (i) the brand or generic name of the drug,
    - (ii) the manufacturer, if necessary to identify the drug, and
    - (iii) the strength, dosage form, and quantity dispensed;
  - (f) the number of refills, if any, remaining in the prescription;
  - (g) the name of the patient;
  - (h) directions and cautions respecting the use of the drug;
  - (i) the initials of the dispenser. (EC618/87; 289/05)
- Repackaged restricted drug **20.** Where a No Public Access or Public Access - Pharmacy Only drug is provided that has been prepared or repackaged in the pharmacy, it shall bear a label with at least the following information:
- (a) the name of the drug or, if not a commonly recognized name, such other identification as may be satisfactory to the Board;
  - (b) the strength or concentration, where applicable;
  - (c) recommended dosages;
  - (d) identification of the manufacturer, the lot number and expiry date, as may be applicable;
  - (e) any special instructions regarding preservation; and

(f) any applicable special precautions, including side effects and interactions. (EC618/87)

**21.** (1) Subject to section 22.6, a pharmacist may place an unused, returned drug in the inventory of the pharmacy and redispense it, if Dispensing  
returned, unused  
drugs

(a) the drug was originally provided to a hospital, nursing home or similarly controlled environment under the direct supervision of health care professionals;

(b) the container of the drug as dispensed was sealed in such a way as to make evident any opening, access or tampering and the pharmacist is satisfied that the seal has not been opened or tampered with;

(c) the receiving pharmacy dispensed the drug;

(d) the lot number and expiry date of the drug is known;

(e) the pharmacist is satisfied that the drug has not been in contact with other drugs or substances; and

(f) the pharmacist is satisfied that the stability, quality, safety and efficacy of the drug have not been compromised between the initial dispensing and the redispensing of the drug.

(2) Clause (1)(b) does not apply to Class II and Class III pharmacies. Exception  
(EC618/87; 289/05)

**22.** (1) A pharmacy, or the health-care establishment of which the Board considers it an integral part, shall have and keep current a patient record system, on an individualized or family basis, for purpose of professionally monitoring the prescribed drugs and significantly related services provided. Patient record

(2) A patient record shall include at least the following types of information: Idem

(a) basic facts about the patient, including

(i) the patient's name and year of birth, and the patient's provincial health number, if any,

(ii) the patient's address and contact telephone number,

(iii) the name and contact telephone number of the patient's regular physician, if any, and

(iv) any allergies of the patient; and

(b) facts about each prescription filled at the pharmacy during at least the two preceding years, including

(i) the date and identification number of the prescription,

(ii) identification of the prescriber,

(iii) description of the drug, as applicable, by name, strength, form, manufacturer, generic name, and quantity, and

(iv) the date of filling and of refills provided, with a means of identifying the responsible dispenser on each occasion.

Computerized records	(3) A pharmacy shall use a computerized patient record system that meets the guidelines adopted by the Board from time to time. (EC618/87; 289/05)
Oral multiple drug package	<p><b>22.1</b> Subject to subsection 22.2(1), a dispenser may dispense, in a multiple drug package, two or more solid, oral drugs for an individual patient, where the dispenser is satisfied that it is appropriate to do so after considering</p> <ul style="list-style-type: none"> <li>(a) the directions of the manufacturer;</li> <li>(b) the reference sources required by these regulations;</li> <li>(c) the physical or chemical form of the drug;</li> <li>(d) the sensitivity of the drug to light;</li> <li>(e) the therapeutic incompatibility of any of the drugs with another drug in the package;</li> <li>(f) the risk of chemical interaction with another drug in the package; and</li> <li>(g) such other factors as the dispenser considers relevant. (EC289/05)</li> </ul>
Patient consent to multiple drug package	<b>22.2</b> (1) A dispenser shall not dispense drugs in a multiple drug package unless such packaging is acceptable to the patient or to the representative of the patient.
Explanation to patient	(2) The dispenser shall ensure that the patient or the representative of the patient understands how to use the multiple drug package properly. (EC289/05)
Multiple drug package not recloseable	<p><b>22.3</b> The compartments of a multiple drug package</p> <ul style="list-style-type: none"> <li>(a) shall be sealed without the application of heat; and</li> <li>(b) shall not be recloseable or shall be designed in a manner that will show any reclosure. (EC289/05)</li> </ul>
Labelling	<p><b>22.4</b> (1) In addition to the labelling required by section 19, a multiple drug package shall,</p> <ul style="list-style-type: none"> <li>(a) in respect of the package as a whole, be labelled with <ul style="list-style-type: none"> <li>(i) the name, address and telephone number of the dispensing pharmacy,</li> <li>(ii) the name, initials or other indicator of the dispenser,</li> <li>(iii) the name of the patient,</li> <li>(iv) the date of dispensing,</li> <li>(v) a multiple drug package number assigned to uniquely identify the package, and</li> <li>(vi) any necessary storage or other instructions respecting the package; and</li> </ul> </li> <li>(b) in respect of each drug contained in the package, be labelled distinctly with</li> </ul>

- (i) the identification number of the prescription,
- (ii) information identifying the prescriber,
- (iii) information identifying the drug by
  - (A) the brand or generic name of the drug,
  - (B) the manufacturer, if necessary to identify the drug, and
  - (C) the strength, dosage form, and quantity dispensed,
- (iv) a description of the drug enabling it to be clearly recognizable to a layperson, according to such attributes as size, shape, colour and markings,
- (v) directions for use as prescribed, and
- (vi) any further instructions or cautions as may be warranted according to the directions of the prescriber, manufacturer and references, and as necessary in the professional judgment of the dispenser; and
- (c) be labelled with an indication of the timing of the opening of the compartments of the package and the taking of the drugs.

(2) If a multiple drug package is divisible or allows for separation of compartments from the whole body of the package, each division or removable part shall contain all of the information required by subsection (1). Parts of multiple drug package

(3) Where it is essential for a drug study or similar purpose to which the patient has consented that the identity of the drug not be disclosed, the label may omit the information required by subclause (1)(b)(iii) with respect to that drug. (EC289/05) Drug studies

**22.5** (1) A dispenser who prepares a multiple drug package shall ensure that the patient record required to be kept under section 22 contains the following information: Patient record

- (a) the multiple drug package number assigned pursuant to subclause 22.4(1)(a)(v);
- (b) the prescription numbers of each drug associated with the multiple drug package number;
- (c) a description of the type of multiple drug package, including any characteristics, specifications and special labelling, that is sufficient to enable the duplication of the multiple drug package by a dispenser.

(2) A pharmacy shall retain the information recorded pursuant to subsection (1) for at least two years after the authorization for all refills has expired. (EC289/05) Retention of information

**22.6** (1) Drugs dispensed in a multiple drug package that are unused and returned, in whole or in part, shall not be returned to the inventory of the pharmacy or redispensed by the pharmacy. No return, exception

- Exception (2) Notwithstanding subsection (1), the drugs referred to in that subsection may be
- (a) returned to the inventory of the pharmacy for the purpose of re-dispensing them to the same patient if the drugs are sealed in the original container; and
  - (b) redispensed to the same patient, if it is appropriate in the professional judgment of the dispenser to do so. (EC289/05)

## PART II REQUIREMENTS OF A DISPENSER

- Application **23.** (1) This Part applies with the necessary changes to a certified clerk or a registered student as to a pharmacist, except insofar as the Board may determine otherwise, recognizing the nature of shared responsibility in a supervisory arrangement.
- Idem* (2) The following clauses of section 29, with the necessary changes may be applied to the holder of permit: (a), (e), (h), (i), (j), (k), (m), (o), (q), and (r). (EC618/87)
- Accepted standards of practice **24.** Pharmacists and pharmaceutical clerks shall follow accepted standards of practice as set out in the NAPRA publication, Model Standards of Practice for Canadian Pharmacists, as amended by it from time to time. (EC618/87; 289/05)
- Renewal requirements **25.** (1) An applicant for renewal of a license or certificate shall
- (a) have completed at least 15 CE units during the year preceding the application; or
  - (b) provide evidence satisfactory to the Board that the applicant has successfully met the standards set out in the NAPRA publication, National Model Continuing Competence Program for Canadian Pharmacists, as amended by it from time to time.
- Exception (1.1) Clause (1)(a) does not apply where the NAPRA National Model Continuing Competence Program for Canadian Pharmacists is implemented.
- Approval of CE units (1.2) The Board may approve CE units that are suitable for the purposes of subsection (1).
- Failure to comply (2) The Board may require an applicant who fails to comply with subsection (1), within such period as may be specified by the Board, to
- (a) successfully complete a continuing professional education program approved by the Board; or
  - (b) pass an examination administered or approved by the Board; or
  - (c) fulfil both (a) and (b).

(3) The Board may refuse to renew or impose a condition on the license of a person who fails to comply with subsection (2). *Idem*

(4) This section shall have effect from July 1, 2001. (EC618/87; 289/05) *Effective date*

**26.** The Board may find a pharmacist guilty of professional incompetence if it concludes, without any negative vote, that a patient suffered demonstrable harm or serious risk of harm which can reasonably be attributed to something which the pharmacist did or failed to do or failed to take into account, which act or omission was inconsistent with generally accepted standards of practice and procedures, and cannot be justified by the pharmacist to the satisfaction of the Board. (EC618/87) *Incompetence*

**27.** A pharmacist shall follow such code of ethics as is produced by the Canadian Pharmaceutical Association and adopted by the Prince Edward Island Pharmaceutical Association. (EC618/87) *Code of ethics*

**28.** It is a conflict of interest for a pharmacist to place himself in or accept a situation which, in the Board's judgment, *Conflict of interest*

(a) results, by connection with his pharmaceutical practice, in monetary or other personal gain other than that earned from the sale of products and the performance of professional services in his practice, or in gain for a prescriber of drugs as a consequence of his prescribing; or

(b) puts his professional integrity or his rendering of services at risk of being controlled or detrimentally influenced by other persons or by factors other than his professional judgment of what is best for the patient. (EC618/87)

**29.** Without limiting the generality of subsection 18(1) of the Act, the Board may find a pharmacist guilty of professional misconduct for any of the following reasons: *Misconduct*

(a) failing to abide by the terms of his license;

(b) failing to abide by the code of ethics;

(c) exceeding the lawful scope of practice, as defined by the Act, and as amplified by the generally accepted norms of current Canadian professional literature, university teaching, and common practice of peers;

(d) having a conflict of interest;

(e) failing to maintain current patient records;

(f) attempting to deal with a patient's problem which the pharmacist recognizes or should, according to his qualification, recognize as being beyond the scope of his competence or expertise;

- (g) failing to refer a patient appropriately when the pharmacist recognizes, or should in the Board's judgment recognize, a condition requiring the attention of another professional;
- (h) permitting, in circumstances within his control, an unauthorized person to perform any of the functions of a pharmacist except as may be provided under the Act;
- (i) maintaining in his records, signing, issuing or submitting a record, report, certificate, claim or similar document which the pharmacist knows or should know contains false or misleading information or which, by omitting significant information, may give a misleading impression;
- (j) giving information regarding a patient's condition or treatment to a person other than the patient without the consent of the patient, unless required to do so by law or for a purpose directly related to the patient's care;
- (k) purporting to have a qualification or special expertise which he does not in fact possess and which has not been recognized by the Board;
- (l) engaging in practice while ability to perform any professional act is impaired by alcohol or other drug;
- (m) failing to cooperate with an appraisal or investigation duly authorized by the Board;
- (n) failing to dispense a prescription with full labelling information and such other instruction or advice as is warranted;
- (o) advertising that is, in the judgment of the Board with reference to such written guidelines as may be developed, improper or misleading;
- (p) attempting or carrying out, without previously informing and obtaining the advice of the Board, research based on methods which do not conform to his training or to generally recognized contemporary custom;
- (q) failing to comply with directions issued by the Board in accordance with the Act and regulations;
- (r) performing an act associated with practice which in the judgment of the Board, without any negative vote, would reasonably be regarded by the vast majority of pharmacists as dishonourable or seriously offensive to a patient. (EC618/87)

Student  
requirements

**29.1** (1) Every student shall, before commencing a training period in a pharmacy,

- (a) apply as a registered student pursuant to section 12 of the Authorization Regulations;
- (b) enter into an apprenticeship agreement with a preceptor; and
- (c) file a copy of the apprenticeship agreement with the Registrar.

(2) An apprenticeship agreement between a preceptor and a student continues in effect from the date of filing with the Registrar until March 31 of the following year, unless it is sooner terminated

Term of  
apprenticeship  
agreement

- (a) by a party;
- (b) on the preceptor's ceasing to be licensed under the Act or the preceptor's license being suspended; or
- (c) on the student's ceasing to be registered.

(3) A registered student shall enter into a new apprenticeship agreement with another preceptor before applying to transfer to that preceptor. (EC289/05)

New agreement  
before transfer

**29.2** (1) Subject to subsection (2), the Board, on application, shall approve a pharmacist as a preceptor where the Board is satisfied that the pharmacist

Approval of  
preceptor

- (a) has practised pharmacy for at least two years;
- (b) is licensed under the Act; and
- (c) has entered into an apprenticeship agreement with a registered student under which the pharmacist agrees to provide immediate and continuous supervision of the registered student for at least half of the time the student works in the pharmacy during the term of agreement.

(2) The Board shall refuse to approve a pharmacist as a preceptor where the Board is satisfied that

Refusal to approve  
preceptor

- (a) a PPRA or other professional regulatory body made a finding against the pharmacist of professional misconduct, negligence or incompetence; or
- (b) the pharmacist does not meet the requirements of subsection (1).

(3) For the purposes of subsection (4), a preceptor ceases to be qualified as a preceptor if

Preceptor no longer  
qualified

- (a) the preceptor's license expires, is suspended or is revoked; or
- (b) the preceptor is the subject of a finding described by clause (2)(b).

(4) The Registrar shall, where a preceptor ceases to be qualified as such, notify a registered student with whom the preceptor signed an apprenticeship agreement, of the loss of qualification, by a letter mailed to the most recent address in the records of the Registrar.

*Idem*

(5) A preceptor shall

Preceptor's duties

- (a) act as preceptor under an apprenticeship agreement with not more than one registered student during the same time period;
- (b) carry out the responsibilities of preceptor in accordance with the Act and these regulations; and

(c) ensure that the student has the opportunity to complete the prescribed practice experience. (EC289/05)

### PART III MAINTENANCE OF STANDARDS

#### APPRAISAL

- 30.** The Board may appoint one or more inspectors to carry out an appraisal of a pharmacy and the general characteristics of its operation, with reference to the prescribed standards. (EC618/87)
- Idem* **31.** Normally such appraisal shall be carried out after a six-month period following the initial granting of a permit, and at such intervals thereafter as the Board considers advisable. (EC618/87)
- 32.** The permit holder and staff of a pharmacy shall cooperate fully in such an appraisal, including making available all records required by an inspector. (EC618/87)
- 33.** The inspector shall inform the permit holder or pharmacist of his findings and submit a report of the appraisal for consideration by the Board. (EC618/87)
- 34.** The Board shall as soon as possible inform the permit holder and pharmacist in charge of the general results of the appraisal; it shall in writing direct them to remedy any failure to meet the prescribed standards within a time period considered reasonable by the Board, and shall conduct a reinspection on expiry of the time allowed. (EC618/87)

#### INVESTIGATION AND DISCIPLINE

- 35.** (1) The Board shall appoint, with a normal membership term of three years, a standing Investigation Committee comprising
- (a) a pharmacist who is not a Board member as chair of the Committee,
  - (b) one, two or three other pharmacists who are not Board members,
  - (c) a layperson who may or may not be a member of the Board, and
  - (d) such other persons as may be considered necessary.
- (2) Normally the Registrar shall act as resource assistant to the Investigation Committee and the Committee may, subject to approval by the Board, engage the assistance of such other persons as it considers necessary for an investigation. (EC27/98)

- 36.** (1) Upon receiving a complaint or a direction from the Board which appears to warrant investigation of an alleged incident or the practice of a pharmacist, the Registrar shall refer the matter to the Investigation Committee and shall inform the complainant, if any, concerning the prescribed investigation process and what action is being undertaken. Referral to Investigation Committee
- (2) The Investigation Committee shall conduct a preliminary inquiry to determine whether there is cause for full investigation. Preliminary inquiry
- (3) If the Committee finds that there is not a sufficient basis for proceeding, it shall so notify the Board and unless the Board otherwise directs, there shall be no further action. No basis for action
- (4) If the Committee finds that there is cause to proceed, it shall inform the affected person and carry out such further investigation as it considers appropriate. (EC27/98) Further investigation
- 37.** (1) During the investigation, and at the discretion of the Investigation Committee also during the preliminary inquiry, the Investigation Committee shall ensure that any complainant and the pharmacist under investigation is each permitted to be heard and to submit evidence. Parties to be heard
- (2) The pharmacist under investigation shall, if required, give full cooperation to the Investigation Committee, including the provision of such records as may be requested. (EC618/87) Cooperation
- 38.** The Investigation Committee shall report its findings and conclusions to the Board, which shall provide a copy to the pharmacist under investigation. (EC618/87) Report
- 39.** (1) The Board shall give the pharmacist under investigation, by ten days written notice of a hearing delivered by hand or registered mail to his last known address, the opportunity to be heard, with legal counsel of both parties present if desired by either. Hearing
- (2) If the pharmacist under investigation does not attend the announced hearing, the Board may nonetheless proceed. (EC618/87) *Idem*
- 40.** The Board shall consider the report of the Investigation Committee and the outcome of the hearing, and shall by vote determine Judgment by Board
- (a) whether to accept the findings of the Investigation Committee;
  - (b) whether to accept, reject or modify the conclusions of the Investigation Committee; and
  - (c) the disciplinary action, if any, to be taken. (EC618/87)
- 41.** The Board shall forthwith notify the affected pharmacist in writing of its decisions, and any requirements of him, specifying the time allotted for compliance. (EC618/87) Notification of outcome

Compliance	<b>42.</b> The pharmacist against whom disciplinary action is taken shall comply with the Board's directions; should he fail to do so within the specified time, the Board may apply an additional penalty. (EC618/87)
Re-instatement	<b>43.</b> The Board, may upon application and payment of the fee prescribed for re-issuance of a revoked authorization, re-instate a person whose authorization has been suspended or revoked, according to such terms and conditions as it considers appropriate for protecting the public's interest. (EC618/87)

#### REMEDIAL MEASURES AND PENALTIES

Board to determine measures	<b>44.</b> Where it finds the holder of an authorization guilty of professional misconduct, incompetence, or failure to abide by the prescribed standards or other requirements of the Act or regulations, the Board shall determine a measure of remedy or penalty which it considers appropriate to the nature and degree of the failure. (EC618/87)
Measures available	<b>45.</b> (1) Without limiting the generality of section 44, disciplinary measures may include: a reprimand, whether written or oral; a fine, to a maximum of \$500; a direction that the person fulfil a continuing professional education requirement; a term or condition imposed on the authorization, limiting the scope or independence of practice; suspension of the authorization, for a fixed period of time or until a condition has been fulfilled; revocation of the authorization; or a combination of such measures.
<i>Idem</i>	(2) As part of a penalty, the Board may require a person found guilty to pay the cost or part of the cost of the investigation and hearing. (EC618/87)
Criteria	<b>46.</b> (1) The criteria for the Board's assessment of the nature and severity of the penalty or remedial measure shall include <ul style="list-style-type: none"> <li>(a) the extent of the person's awareness of the fault;</li> <li>(b) the degree of risk or harm to the patient;</li> <li>(c) the potential further risk to the public;</li> <li>(d) the potential effect upon the profession;</li> <li>(e) the likely effect upon the disciplined person's ability to earn his livelihood;</li> <li>(f) any restitution or remediation voluntarily undertaken by the person himself.</li> </ul>
<i>Idem</i>	(2) Wherever possible, the Board shall seek, by the disciplinary action it takes, an approach and outcome of remedy or positive improvement rather than mere penalization. (EC618/87)

**47.** (1) The Board shall, in all but unusual cases, keep secret any investigation and disciplinary or remedial measures unless otherwise requested by the person affected; however, the Board may reveal such matters in any report on its operation, so long as this is done in such a way that the parties involved cannot be identified. Confidentiality

(2) In unusual cases where it appears necessary for protecting the public's welfare, the Board may choose as part of the penalty or remedy applied to reveal the nature of the case and its outcome, including the identity of the person at fault, to the complainant, the Minister, the Association, law enforcement officials or the courts, or the general public. (EC618/87) *Idem*

**48.** Investigation and disciplinary measures with respect to a permit holder or certified clerk or registered student shall be conducted, with the necessary changes, in accordance with the procedures prescribed therefor with respect to a pharmacist. (EC618/87) Application to clerk or pharmacy

**49.** A Board member shall withdraw from any official involvement as a Board member in any investigation or disciplinary matter of which he himself is the subject. (EC618/87) Disqualification of Board member

#### STATISTICAL INFORMATION

**50.** (1) The Board may compile and publish statistical information with regard to the volume and nature of manpower, professional services, patient utilization and pharmaceutical problems and comparable subjects related to patterns of service need and performance, in such form that individuals are not identifiable without their consent. Statistical information

(2) The holder of an authorization shall provide to the Registrar such information as may be requested by the Board for the purposes of this section. (EC618/87) *Idem*