PLEASE NOTE

This document, prepared by the **Legislative Counsel Office**, is an office consolidation of this regulation, current to November 8, 2005. It is intended for information and reference purposes only.

This document is ***not*** the official version of these regulations. The regulations and the amendments printed in the ***Royal Gazette*** should be consulted to determine the authoritative text of these regulations.

For more information concerning the history of these regulations, please see the ***Table of Regulations***.

If you find any errors or omissions in this consolidation, please contact:

Legislative Counsel Office
Tel: (902) 368-4291
Email: legislation@gov.pe.ca

CHAPTER P-6

PHARMACY ACT

AUTHORIZATION REGULATIONS

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

1. (1) In these regulations — Definitions

(a) "Act" means the *Pharmacy Act* R.S.P.E.I. 1988, Cap. P-6; — Act

(b) "locked dispensary approval" means the approval endorsed on a permit under section 23; — locked dispensary approval

(c) "MRA" means the Mutual Recognition Agreement for the Profession of Pharmacy in Canada, dated April 9, 2000, as amended from time to time; — MRA

(d) "PPRA" means a Provincial Pharmacy Regulatory Authority from another jurisdiction; — PPRA

(e) "refresher program" means a refresher program approved by the Board under subsection (2); — refresher program

(f) "Registrar" means the Registrar appointed pursuant to subsection 6(6) of the Act; — Registrar

(g) "Standards Regulations" means the Standards Regulations made under the Act; — Standards Regulations

(h) "university program" means an accredited university program approved by the Board under subsection (2). — university program

(2) The Board may approve — Board approvals

(a) a continuing education program in the practice of pharmacy;
(b) an accredited university program for pharmacy training;
(c) a licensing examination program;
(d) testing of English as a second language; and
(e) an examination to test professional competency. (EC575/92; 286/05)

LICENSE

Application for license

2. (1) A person seeking an initial license shall, in such manner as the Board may require, submit to the Registrar a written application including, unless the Registrar otherwise directs

(a) a description of the basic professional education program, including name and location of the school, the nature of the curriculum, and the number of and the actual years attended;

(b) proof of successful completion of the educational program;

(c) evidence of any related or subsequent educational qualification;

(d) proof of fulfilment of the practical training and professional experience requirements of section 4;

(e) an outline of the type, duration and dates of further active professional practice, if applicable, indicating how this may be confirmed if necessary;

(f) evidence of current licensure or registration and good standing in another jurisdiction, if applicable;

(g) evidence of passing the examination required in section 5;

(h) evidence of successful completion of a refresher program, with date, if applicable; and

(i) such other information or evidence as the Registrar may request for the purpose of amplifying or substantiating proof of the applicant's compliance with licensing requirements.

Licensed, registered in other jurisdiction

(2) An applicant who is a licensed or registered pharmacist in a jurisdiction of a signatory PPRA to the MRA shall be issued a license by the Board, if the applicant

(a) demonstrates, by successfully completing an examination given under section 31, knowledge of the laws directly applicable to the practice of pharmacy in the province;

(b) provides written verification of good standing in professional associations from all jurisdictions in which the applicant is currently licensed and a declaration of all jurisdictions in which the applicant was ever licensed;

(c) whose first language is not English demonstrates proficiency in English consistent with a level of testing approved by the Board; and

(d) pays the required fees. (EC575/92; 286/05)

Professional education requirements

3. The professional education requirements of clause 9(1)(a) of the Act shall be met by the successful completion of an approved university program. (EC575/92; 286/05)

Standards of practice requirements

4. Subject to the approval of the Board, knowledge of the standards of practice required by clause 9(1)(d) of the Act shall be demonstrated as set out in the NAPRA publication, Framework for Assessing Canadian

Pharmacists at Entry-to-Practice Through Structured Practical Training Programs, as amended from time to time. (EC575/92; 286/05)

Professional competency requirements

5. (1) Subject to subsection (2), the professional competency requirements of clause 9(1)(c) of the Act shall be demonstrated by the successful completion of an approved licensing examination.

Exception

(2) Subsection (1) does not apply to an applicant who was registered or licensed as a pharmacist before July 1, 2001 in a jurisdiction of a signatory PPRA to the MRA. (EC575/92; 286/05)

Knowledge of standards

6. Revoked by EC286/05. (EC575/92; 286/05)

Currency of professional knowledge

7. (1) For the purpose of determining currency of professional knowledge and skills under clause 9(1)(e) of the Act, where an application is made five calendar years or more since the year in which the applicant graduated from the prescribed educational program, a license shall not be issued unless the applicant has

(a) actively practised as a pharmacist for at least 900 hours within the five years, or 450 hours within the three years, preceding the application and met the continuing professional development requirements of the jurisdiction where the applicant was registered;

(b) successfully completed the standard examination referred to in subsection 5(1) within the three years preceding the application; or

(c) successfully completed a refresher program within the three years preceding the application.

Active practice, determination

(2) Where it is not clearly evident whether or not hours of work submitted by an applicant should be counted as active pharmacy practice for purposes of clause (1)(a), the Registrar shall refer the matter to the Board, which shall make the decision in accordance with the definition of "pharmacy" in clause 1(n) of the Act. (EC575/92; 26/98)

Good standing requirements

7.1 The good standing requirements of clauses 9(1)(f) and 10(1)(e) of the Act shall be met by compliance with clauses 2(2)(b). (EC286/05)

CERTIFICATE

Application for certificate

8. (1) A person seeking an initial certificate shall, in such manner as may be requested, submit to the Registrar a written application including, unless the Registrar otherwise directs,

(a) a copy of his or her diploma from the Maritime College of Pharmacy;

(b) evidence of any related or subsequent professional educational qualification;

(c) an outline of the type, duration and dates of active professional practice, indicating how this may be confirmed if necessary;

(d) evidence of current registration and good standing in another jurisdiction, if applicable;

(e) evidence of successful completion of a refresher program, with date, if applicable; and

(f) such other information or evidence as the Registrar may request for the purpose of amplifying or substantiating proof of the applicant's compliance with requirements.

Clerks, dispensers registered elsewhere

(2) A person who is registered as a certified clerk or certified dispenser in another province or territory may apply to the Registrar to be registered as a certified pharmaceutical clerk in the province by

(a) providing evidence satisfactory to the Registrar of good standing with the appropriate licensing body in the other province;

(b) complying with Board requirements for certified pharmaceutical clerks;

(c) providing evidence that the applicant has attained the required competencies in the province of origin in the year preceding the transfer; and

(d) successfully completing an examination given under section 31 on the laws directly applicable to the practice of pharmacy in the province. (EC575/92; 286/05)

Professional competency requirements

9. The professional competency requirements of clause 10(1)(b) of the Act shall be met by the successful completion of an examination approved by the Board. (EC575/92; 286/05)

Idem

10. The professional competency requirements of clause 10(1)(c) of the Act shall be met by compliance with clause 2(2)(a). (EC575/92; 286/05)

Currency of professional knowledge

11. (1) For the purpose of determining currency of professional knowledge and skills under clause 10(1)(d) of the Act, a certificate shall not be issued unless the applicant has

(a) actively practised pharmacy for at least 900 hours within the five years, or 450 hours within the three years, preceding the application and met the continuing professional development requirements of the jurisdiction where the applicant was registered; or

(b) successfully completed a refresher program within the three years preceding the application.

Active practice, determination

(2) Where it is not clearly evident whether or not hours of work submitted by an applicant should be counted as active pharmacy practice for purposes of clause (1)(a), the Registrar shall refer the matter to the Board, which shall make the decision in accordance with the definition of "pharmacy" in clause 1(n) of the Act. (EC575/92; 26/98)

REGISTRATION

Application for registration

12. A person seeking the status of registered student shall submit to the Registrar the prescribed fee and a testimonial letter from a university authority or such similar evidence and such other information or evidence as the Registrar may require for verifying the applicant's qualification under section 11 of the Act. (EC575/92)

Work record

13. For the purpose of earning practical experience qualifications toward licensure as a pharmacist, a registered student shall

(a) have the amount of time worked and nature of work recorded on a form supplied by the Registrar;

(b) secure signed validation by the pharmacist preceptor; and

(c) submit the form to the Registrar at the conclusion of each yearly work period. (EC575/92)

PERMIT

Classes of permit

14. The granting of permits shall be according to the following classes, based on the Board's judgment of the character of a pharmacy's function, taking into account its clientele, services, scale and mode of operation:

CLASS I - COMMUNITY PHARMACY

A retail drug store, providing for profit a non-exclusive array of services and products to the general public in a non-exclusive way

CLASS II - MAJOR HOSPITAL

Queen Elizabeth Hospital, Prince County Hospital

CLASS III - HOSPITAL

Western, Community, Stewart Memorial, Hillsborough, Kings County Memorial and Souris Hospitals

CLASS IV - NURSING HOME

Provincial government manors and homes for the aged; licensed nursing homes

CLASS V - THE PROVINCIAL PHARMACY OF THE DEPARTMENT OF HEALTH

CLASS VI - PHYSICIAN DISPENSARY

A pharmacy operated by a physician in connection with a medical practice, wherein drugs are sold, whether for profit or at cost price, to the physician's patients.

CLASS VII - COMMERCIAL

A facility wherein drugs are manufactured, compounded or otherwise prepared, including packaging, repackaging or labelling, on a wholesale basis.

CLASS VIII - RESIDENTIAL INSTITUTION

A facility not covered by another class of permit, wherein drugs subject to prescription are prepared, distributed or administered for or to residents of the institution, from bulk form and on a scale beyond mere assistance to individuals in following their personal prescriptions. (EC575/92; 286/05; 616/05)

Application for permit

15. A person applying for a permit to operate a pharmacy shall submit to the Registrar

(a) the name, address and telephone number of the person intended to be the holder of the permit and, where that person is a corporation, the names and addresses of its directors;

(b) the name by which the pharmacy is to be known to the public;

(c) the location, address and telephone number of the premises;

(d) a description of the general nature of clientele to be served and of the services to be offered;

(e) a description of the physical nature and layout of the facility, with a sketch plan;

(f) a description, if applicable, of provisions for the dispensary to have locked dispensary approval;

(g) a description of the staffing plan, including numbers of pharmacists and certified clerks presented in relation to scheduled hours of operation, with indication, if applicable, of plans to operate with locked dispensary approval;

(h) the name, address and telephone number of the person designated as pharmacist in charge in accordance with section 22 of the Act;

(i) the names of all pharmacists, certified clerks and registered students employed in the pharmacy;

(j) evidence, if requested, of compliance with any applicable legislation concerning such public safety respects as fire, electrical and public health; and

(k) such other information or evidence as the Registrar may request for the purpose of the Board's assessment of the application. (EC575/92; 286/05)

Conditional permit

16. The Board or its officer may inspect a proposed pharmacy to assess its apparent compliance with prescribed standards, and a permit may be issued subject to terms and conditions that are to be fulfilled before the permit is confirmed. (EC575/92)

Correct information

17. The holder of a permit shall

(a) within seven days of a change with respect to any of the information furnished with the application under section 15, so inform the Registrar; and
(b) within seven days of receiving a request by the Registrar, provide a current update of such information. (EC575/92)

Expiry

18. A permit ceases to have effect when
(a) the pharmacy is sold;
(b) responsibility for the pharmacy's overall management, as distinct from the management of only its pharmaceutical aspects by the pharmacist in charge, is changed to a person other than the holder of the permit; or
(c) the pharmacy operation is relocated to a different facility,
and a person seeking to continue or resume operation shall make application for a new permit. (EC575/92)

Operation suspended or altered

19. (1) The holder of a permit shall inform the Registrar if
(a) the pharmacy is closed or its pharmaceutical services are discontinued for a period exceeding thirty days;
(b) the facility is significantly renovated or rearranged; or
(c) the pharmacy's scale or method of operation, such as in patterns of staffing, clientele, record-keeping or dispensing procedures, is significantly altered.

Review of permit

(2) In such case the Board may review the status of the permit, and if it considers that applicable requirements are not fully met, it may impose conditions on or suspend the permit.

Idem

(3) In case of action taken under subsection (2), the Board may subsequently remove the conditions or suspension, thus confirming the original permit, or may revoke it and require application for a new permit. (EC575/92)

Closing of pharmacy

20. The holder of a permit who closes the pharmacy for a period exceeding thirty days shall, when the plan is definite or at the least without delay upon the actual cessation of service, so notify the Registrar and shall, within thirty days of the notification, provide the Registrar with a report of the disposition of drugs in stock or on order, of the drug register, prescription files and other records, and of signs, symbols and trademarks used in that pharmacy's operation. (EC575/92)

ISSUANCE OF AUTHORIZATIONS

Decision of eligibility

21. (1) The Board, or the Registrar on its behalf and subject to its direction, shall assess any application for an authorization and decide whether the requirements are met.

Idem, by Registrar

(2) The Registrar may decide and act accordingly in the case of an application where the requirements are clearly met or not met, and shall subsequently so inform the Board.

Idem, by Board

(3) The Registrar shall, where the eligibility of an application is questionable, present the matter to the Board for decision. (EC575/92)

Inform applicant

22. The Registrar shall in writing notify the applicant of the decision on granting the authorization and shall

(a) in the case of an application judged eligible, upon receipt of the required fee, issue the authorization; or

(b) in the case of an application judged ineligible, furnish the applicant with an outline of the reasons therefor and also any directions regarding subsequent re-application. (EC575/92)

Lock-and-leave approval

23. Where a person holding or applying for a permit demonstrates that the pharmacy's dispensary meets the relevant requirements prescribed in the Standards Regulations, the Board, or the Registrar on its behalf, shall endorse the permit to indicate locked dispensary approval. (EC575/92; 286/05)

Good standing

24. In accordance with the good standing requirement of clauses 9(1)(f) and 10(1)(e) of the Act and the condition of subsections 9(4) and 10(3) of the Act, the Board may refuse to issue a license or certificate to an applicant who

(a) has been convicted of professional misconduct, negligence or incompetence by a PPRA or other professional regulatory body; or

(b) has been convicted of an offence of such a nature and direct relevance to professional practice that, in the unanimous judgment of the Board, the applicant would pose a danger to patients in the context of practice. (EC575/92; 286/05)

Special authorization

25. (1) The Board may grant to a person a special authorization, with certain privileges or restrictions concerning such aspects as duration or scope of function permitted, for unusual circumstances.

Idem

(2) The term and the particular conditions shall be clearly inscribed on such special authorization and recorded in the register. (EC575/92)

RENEWAL OF AUTHORIZATIONS

Authorization year

26. (1) The standard year for effect and expiry of an authorization shall be from January 1 to December 31.

Idem

(2) The Board may by resolution fix dates of the authorization year in substitution for those set in subsection (1). (EC575/92)

Application for renewal

27. (1) A person seeking annual renewal of an authorization shall apply to the Registrar at least thirty days before its expiry, providing payment of the required renewal fee and such evidence of continuing compliance with prescribed standards as may be required.

Renewal

(2) If there is any evidence that the applicant for renewal is in violation of the Act, regulations or terms of the authorization, or lacking the requirements for professional currency prescribed in sections 28 (currency) and 29 (continuing professional development), the Board may refuse, suspend or impose conditions on renewal, but otherwise the authorization shall be renewed.

Late payment

(3) The prescribed penalty fee for late payment may be levied where a person fails to make application with the renewal fee before the expiry of the authorization. (EC575/92)

Currency, for renewal

28. (1) To be eligible for renewal of a license or certificate where application therefor is made five calendar years or more since the year in which the applicant graduated from the prescribed educational program, the applicant shall have

(a) actively practised pharmacy for at least 900 hours within the five years, or 450 hours within the three years, preceding the application;

(b) successfully completed the standard examination cited in subsection 5(1) within the three years preceding the application; or

(c) successfully completed a refresher program with the three years preceding the application.

Active practice, determination

(2) Where it is not clearly evident whether or not hours of work submitted by an applicant should be counted as active pharmacy practice for purposes of clause (1)(a), the Registrar shall refer the matter to the Board, which shall make the decision in accordance with the definition of "pharmacy" in clause 1(n) of the Act. (EC575/92; 26/98)

Continuing professional development

29. (1) A person who applies for renewal of a license or certificate shall demonstrate to the satisfaction of the Board that the person has maintained familiarity with current practice and endeavoured to enhance professional competency by meeting such requirements of continuing professional development as are prescribed in these regulations or in the Standards Regulations.

Idem

(2) The Board may require an applicant who fails to comply with subsection (1), within such period as it may specify, to

(a) successfully complete a continuing professional development program approved by the Board;

(b) pass an examination administered or approved by the Board; or

(c) fulfil both (a) and (b).

Idem (3) Revoked by EC286/05.

Idem (4) Revoked by EC286/05. (EC575/92; 286/05)

Lapsed authorization

30. (1) A person seeking to renew entitlement to practise whose license or certificate has lapsed under subsection 14(4) of the Act shall apply to the Registrar for re-issuance of the authorization.

Re-issue, up to two years

(2) If application is made within two years of the expiry, the authorization shall be re-issued if the applicant meets the conditions referred to in subsection 14(3) of the Act concerning currency of professional competency and compliance with the Act and regulations, and pays the fee prescribed for re-issuance.

After two years

(3) If application is made beyond two years of the date of expiry, the Board shall review the person's qualification, and shall either

(a) direct the person to re-apply as if for an initial authorization; or

(b) require the person to

(i) acquire some further educational or experience qualification in accordance with or similar to the requirements of sections 28 and 29, and

(ii) demonstrate competence by means of such examination as the Board considers appropriate,

and, following successful completion of these and payment of the prescribed fee, re-issue the authorization. (EC575/92)

EXAMINATION

Examination Committee

31. (1) Where an examination administered by the Board is necessary, the Board shall appoint an Examination Committee to set the examination and assess the candidate's performance on it.

Examination committee

(2) The Examination Committee shall comprise at least two pharmacists and a layperson, who may be but need not be Board members, and the Board shall designate one of the persons to chair the Committee.

Examiners

(3) The Examination Committee may act as examiners, but may also appoint other or additional examiners.

Design of examination

(4) The Board shall, with consideration of the purpose of the examination and of the extent and nature of an applicant's education and experience, determine in general the type of examination to be given to the applicant and the requirements for successful completion.

Arrangement with candidate

(5) The chairperson of the Examination Committee shall ensure that the candidate is informed in advance regarding the time and place of the

examination, with an explanation in general terms of its form and content.

Fee

(6) The candidate for an examination shall, at such time prior to the examination as may be directed, pay to the Registrar the examination fee.

Report

(7) Following the examination the Examination Committee, through its chairperson, the Registrar or other examiner appointed under subsection (3), shall

(a) submit to the Board a written report outlining the conduct of the examination, the exact instructions, questions or tasks set, and the results achieved by the candidate;

(b) furnish such explanatory interpretation, including particular observations by examiners, as Board members may require;

(c) recommend whether or not the candidate has satisfactorily met the examination requirement.

Supplemental examination

(8) The Board may permit an applicant who has not satisfactorily passed the examination to retake it, or a partial or modified form of it, on condition that the applicant first fulfil such educational or experience requirement as the Board may direct. (EC575/92; 286/05)

MISCELLANEOUS

Further information

32. For the purpose of assessing an application for an authorization to practise, the Board or the Registrar may seek and take into account detailed information from the applicant and from other persons or bodies concerning the applicant's training, credentials and experience, including verification of coursework, examination results, standing with another regulatory body or professional organization, circumstances of previous practice and the like. (EC575/92)

Keeping of application information

33. Written information and documents, excepting an irreplaceable original such as an actual degree, submitted in connection with an application and any written report on the applicant's eligibility shall

(a) be the property of the Board and shall be retained by the Registrar for at least one year following the decision on an authorization;

(b) during that time be available for inspection by the applicant and the applicant's authorized representative; and

(c) subject to section 34, not be accessible to any person other than the applicant or representative, the Registrar, the Board or its designate, without the express consent of both the applicant and the Board. (EC575/92)

Disclosure of information

34. The Registrar may disclose information relevant to a person's authorization, professional status or standing to another professional regulatory authority or professional organization. (EC575/92)

Registrar to be informed

35. The holder of an authorization shall without delay notify the Registrar of any change of status or change in the information provided in the most recent application that may affect the person's eligibility to practise or the Registrar's ability to contact the person. (EC575/92)

FEES

Fees

36. (1) Revoked by EC286/05.

Amendment of fees

(2) Revoked by EC286/05. (EC575/92; 286/05)