

**NEWFOUNDLAND AND LABRADOR
REGULATION 80/98**

Pharmacy Regulations
under the
Pharmacy Act

Amended by:

20/00, 18/03, 31/05, 2006 cP-12.01 s56, 34/10

(Filed September 18, 1998)

Under the authority of section 14 of the *Pharmaceutical Association Act, 1994*, I make the following regulations.
Dated at St. John's, September 18, 1998.

Joan Marie Aylward
Minister of Health and Community Services

REGULATIONS

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Short title

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

Definitions

2. In these regulations

- (a) "monitored drugs" means those drugs listed as that by the provincial drug monitoring body in consultation with other regulating authorities; and
- (b) "records" includes drugs, prescriptions, prescription containers, documents, papers, notes, records, photographs, books and films.

PART I REGISTRATION AND LICENSING

Registers and registration

3. (1) The secretary-registrar shall establish and maintain the following registers:

- (a) a register of pharmacy students;
- (b) a register of pharmacists;
- (c) an annual register of registered pharmacists;
- (d) an annual register of licensed pharmacies and of the person in whose name that licence is issued; and
- (e) an annual register of membership in the association showing each class or category of membership and the members within each class or category.

(2) The registers shall contain the proper name, address and professional qualifications of the persons registered with respect to each person and pharmacy registered.

(3) A person whose name is shown in a register shall provide to the secretary-registrar the name, address and proof of current qualifications respecting the person, the particulars of the pharmacy, if any, with respect to which that person is the pharmacist-in-charge, any changes, and for all purposes under the Act and these regulations the association may treat the particulars of a person or pharmacy as established in the registers to be the particulars respecting that person or pharmacy.

(4) The secretary-registrar may, at the request of any person, and subject to the payment of a fee, verify to that person any fact or matter appearing in a register providing it is not of a personal nature.

(5) The secretary-registrar shall not enter a name in a register, except under a resolution of the council, unless the secretary-registrar is first satisfied the person or pharmacy applying for registration is entitled to be registered.

(6) An entry in a register fraudulently or incorrectly made or omitted, shall be amended, cancelled or added by the secretary-registrar upon the written direction of the council.

(7) A person or pharmacy registered shall, after the name of that person or pharmacy has been entered in a register, receive a certificate of registration under the seal of the association and signed by the president and the secretary-registrar, or those other officers or persons that the council may prescribe.

(8) An appeal from a decision of the secretary-registrar with respect to an entry made in a register may be made to the council.

(9) A person whose right to practise pharmacy in another jurisdiction has been cancelled or suspended or in any way restricted or made subject to conditions, may be entitled to be registered in the register of pharmacists, subject to the same restrictions or conditions imposed in the other jurisdiction, at the discretion of the council.

Fees

4. (1) All fees, unless otherwise specifically provided, are due and payable before January 1 in each and every year.

(2) Every pharmacy student and every pharmacist shall pay the annual membership fee for the category of membership of those persons, in the amount and at or before the time required to the secretary-registrar, or to any other person authorized to accept payment.

(3) A pharmacist who has not paid any of the fees and dues provided for before January 1 in the year in which they are due shall be liable to have his or her name removed from the applicable register.

(4) A pharmacist whose name has been removed from a register under subsection (3) shall be reinstated upon payment of all fees and dues.

Annual certificate of registration

5. (1) In addition to the requirements imposed by the Act, an annual certificate of registration shall not be issued unless a pharmacist has complied with minimum qualifications for continuing educational training as determined by the council.

(2) A person who, although previously registered as a pharmacist, has not held an annual certificate of registration during a period exceeding one year immediately before the year for that which the person seeks a certificate of registration shall not be entitled to obtain that certificate of registration unless that person, in addition to the requirements set out in the Act,

(a) has completed a period of internship of practical work under the direct supervision of an approved preceptor for at least one month of internship, subject to increase at the discretion of the council, for each full year or part of a year, beyond one year, since the pharmacist was last licensed; and

(b) satisfactorily completes other practical and theoretical training courses and examinations that the council may require.

(3) In order to receive a certificate of registration, a person who has not been engaged in the practice of pharmacy at least 420 hours in two consecutive calendar years shall be required to complete a course of studies or a period of internship as required by the board.

(4) An annual certificate of registration shall expire on

(a) December 31 of each year; or

(b) on the effective date of cancellation or suspension of the certificate of registration, whichever date occurs first.

(5) A person who fails to apply for registration within the time prescribed by subsection 11(4) but who otherwise complies with the provisions of section 21 of the Act, may on application, be registered in the register of pharmacists on passing those examinations that the council may require.

(6) The following persons are entitled upon application to the secretary-registrar, to be registered in the register of pharmacy students:

(a) all persons considered to be students under the former or current Act; and

(b) a person who enrolls as a pharmacy student in a faculty of pharmacy approved by the council who

- (i) applies on the required form,
- (ii) pays the annual fee,
- (iii) produces documentation in the form and content satisfactory to the secretary-registrar establishing that the applicant is without a criminal record,
- (iv) has met the qualifications and other conditions that may be prescribed in these regulations, and
- (v) has paid all amounts, penalties, fines, costs and arrears due by the applicant to the association.

(7) A pharmacist who intends to change his or her place of employment for more than 30 consecutive days, shall notify the secretary-registrar in writing 7 days before a change takes place.

Pharmacy licence

6. (1) Every person who plans to operate a pharmacy at least 30 days before the pharmacy is opened for business, shall submit a notarized application together with the appropriate fee, signed by the designated pharmacist-in-charge and owner of the pharmacy, to the secretary-registrar, including the following information:

- (a) the names, addresses and professions of all persons who are shareholders except for publicly traded companies or directors, partners or the individual owner;
- (b) the business name or style of the pharmacy;
- (c) the date of the opening or acquisition of the pharmacy; and
- (d) the address of the pharmacy.

(2) Notwithstanding subsection (1), the time period referred to in subsection (1) does not apply to a hospital pharmacy and may be waived by the secretary-registrar in relation to other existing pharmacies.

(3) A change in ownership or a change in location of a pharmacy shall require verification that the minimum standards of pharmacy practice are being met.

(4) A business licence is non-transferable.

(5) All approved applications for a business licence are valid for 60 days and pharmacies that are not in operation within 60 days of the issuing of a business licence may be subject to re-inspection or other requirements that the council may require.

(6) A business licence may be amended to reflect

- (a) a change of name of the registered pharmacist-in-charge;
- (b) a change of name of the corporate or trading name of the pharmacy; or
- (c) a change of location of the pharmacy,

and those changes shall be reported to the secretary-registrar at least 7 days before that change takes place.

Annual licensing of pharmacies

7. (1) A person who wishes to obtain the annual business licence of a pharmacy shall apply to the secretary-registrar, using forms specified by the council, and submitting the required fees.

(2) An application referred to in subsection (1) shall be signed by the pharmacist-in-charge as well as the applicant.

(3) Upon being satisfied in each year

- (a) by receipt of a certificate from the pharmacist-in-charge that he or she

- (i) shall personally manage, control and supervise the pharmacy,
 - (ii) shall maintain in the pharmacy adequate and suitable stock, dispensing equipment, and a pharmaceutical reference library, that may be specified in these regulations,
 - (iii) shall maintain the pharmacy, its stock, dispensing equipment and library in a clean and sanitary condition and suitable for the practice of pharmacy, that may be specified in these regulations, and
 - (iv) shall comply with the standards of practice of pharmacy; and
- (b) that the pharmacy complies with other requirements of the Act and these regulations,

the secretary-registrar shall register the pharmacy and renew the annual business licence.

- (4) The register of licensed pharmacies, and the annual business licence shall contain
- (a) the names, addresses and professions of all persons who are shareholders, except where the company is a publicly traded corporation, and directors, partners or individual owners;
 - (b) the name of the pharmacist-in-charge of the pharmacy;
 - (c) the name and address of the owner of the pharmacy;
 - (d) the business or trade name of the pharmacy;
 - (e) the corporate name and address of the pharmacy; and
 - (f) the street and mailing address at which the pharmacy is to operate.

(5) A person to whom an annual business licence is issued shall display that annual business licence in a conspicuous part of the pharmacy in full public view.

(6) A proprietor of a pharmacy who or which uses a business name or style consisting of a name or style other than or in addition to the proper name of the proprietor shall, during the time that name or style is used, display in a conspicuous place in the pharmacy a clear indication of the actual name of the proprietor.

- (7) The pharmacist-in-charge of a licensed pharmacy shall notify in writing the secretary-registrar
- (a) of the names of the licensed pharmacists employed there; and
 - (b) of any change in the corporate name of the pharmacy.

Hospital pharmacy

8. (1) A hospital shall obtain the annual hospital pharmacy licence by making application to the secretary-registrar, using the appropriate forms and including the appropriate fee.

(2) The application referred to in subsection (1) shall be signed on behalf of the hospital by a licensed pharmacist who is to be designated as the pharmacist-in-charge of the pharmacy.

- (3) A hospital pharmacy may provide drugs only
- (a) where the drugs are only available through a hospital;
 - (b) to in-patients receiving treatment in the hospital;
 - (c) residents of the hospital;
 - (d) to other hospitals;
 - (e) to members of the public in an emergency; or
 - (f) following consultation with the council, in the other circumstances and with respect to those drugs designated by the minister.

PART II EDUCATION

Continuing education

9. (1) Commencing January 1, 1998, and continuing each year after, continuing education units, as determined by the council, shall be required for re-licence of all active licensed pharmacists.
- (2) The education committee appointed by the council shall make recommendations to the council with respect to continuing education requirements for re-licence.
- (3) The council may approve the recommendations made by the education committee and may determine other requirements with respect to continuing education.
- (4) Upon written notice being provided to all members by ordinary mail the continuing education requirements determined by the council shall be mandatory for re-licence for the period stated in the notice.

Pharmaceutical students

10. (1) The course of studies for pharmaceutical students shall be a program as approved by the Academic Council, School of Pharmacy, Memorial University of Newfoundland, provided that the Newfoundland Pharmaceutical Association is represented on the Academic Council.
- (2) At the beginning of each academic year, all pharmaceutical students shall register with the association, on the required form, and pay the appropriate fee.
- (3) All pharmaceutical students applying for registration as pharmacists shall have completed the studentship program authorized and operated by the Joint Studentship Committee of the Memorial University of Newfoundland School of Pharmacy and the Newfoundland Pharmaceutical Association, or in the case of students not enrolled with the Memorial University School of Pharmacy, another program as may be authorized by the council of the Newfoundland Pharmaceutical Association.
- (4) The terms of reference of the Joint Studentship Committee, and the Studentship Program, shall be as approved by the Academic Council, and the council of the Newfoundland Pharmaceutical Association.

Board of Examiners

11. (1) The Board of Examiners shall be appointed by the council and shall consist of not less than 3 members.
- (2) The council shall appoint a chairperson, and the secretary-registrar shall act as secretary.
- (3) The program of registration examinations shall be as approved by the council.
- (4) Candidates who successfully complete the registration examination shall apply for registration within 6 months following the date of examination.
- (5) The council may impose additional requirements for registration on a candidate who does not apply within the 6 month time frame.
- (6) Upon payment of the set fee, a candidate may appeal, in writing, the results of examinations to the secretary-registrar within 14 days after the results are made available.

PART III STANDARDS

Responsibilities of the pharmacist-in-charge

12. (1) All pharmacists who are designated and named on a business licence as the pharmacist-in-charge of that pharmacy

- (a) are accountable to the council, through its designate the secretary-registrar, for all professional activities occurring within that pharmacy; and
- (b) shall be responsible for
 - (i) personally managing, controlling, or supervising a pharmacy,
 - (ii) prohibiting an owner or other person who is not a pharmacist from directing, influencing, controlling or participating in the management or operation of a pharmacy for which the pharmacist-in-charge is responsible under the Act and these regulations,
 - (iii) establishing policies and procedures for pharmacy personnel in accordance with pharmacy law and pharmacy practice,
 - (iv) advising the secretary-registrar, upon request, of the identity of a person who contravenes established policies and procedures,
 - (v) notifying the secretary-registrar in writing of the names of pharmacists employed by that pharmacy and when a pharmacist ceases employment with that pharmacy,
 - (vi) ensuring correct usage of the operating name of the pharmacy, which may differ from the corporation name, with regard to prescription labels, telephone directory listings, interior and exterior signs or media advertising,
 - (vii) ensuring compliance with all applicable licensing requirements under sections 6 and 7 of these regulations,
 - (viii) devoting the majority of his or her working time and attention to the operation of the pharmacy in respect of which the pharmacist-in-charge is responsible under the Act and these regulations,
 - (ix) attending in the prescription department for a reasonable portion of the operating hours of the pharmacy, but this does not mean that the prescription department may not be open for business when the pharmacist-in-charge is not in attendance or on vacation, provided another licensed pharmacist is present,
 - (x) ensuring that information relating to the dispensing of monitored drugs is transmitted to the lawful monitoring body, and
 - (xi) generally ensuring that the pharmacy for which he or she is responsible complies with the Act and these regulations.

(2) A contravention of paragraph (1)(b) shall be considered professional misconduct.

Standards of Pharmaceutical Service

13. (1) A licensed pharmacy shall not accept for return to stock or re-use any drug or preparation previously dispensed, and shall not assume responsibility for a drug or preparation which has been removed from the direct supervision of a pharmacist for a period of time except for disposal.

(2) Notwithstanding subsection (1), a pharmacist may accept back drugs packaged in customized patient drug packages for dosage adjustment or reuse by the same patient.

- (3) Reasonable hours of operation of a pharmacy shall be considered to be a minimum of 36 hours per week, unless exempted by the council and those hours shall be posted in full view of the public.
- (4) Every licensed pharmacist who fills a prescription in solid dosage form shall dispense the drug in a child resistant container that is designated by the Canadian Standards Association, or some other agency acceptable to the council, unless
- (a) the prescriber, the patient or his or her agent directs otherwise;
 - (b) in the professional judgment of the pharmacist, in each instance, it is advisable not to use the child resistant containers; and
 - (c) a child resistant container is not suitable because of the physical nature of the drug.
- (5) Where under subsection (4) a child resistant container is not provided, the pharmacist filling the prescription shall at the time of dispensing it make an appropriate notation on the prescription or on the patient medication profile system to indicate that non-child resistant container was used.
- (6) Notwithstanding subsection (4), a pharmacist may dispense prescriptions in customized patient drug packages if requested by the prescribing physician and either the patient, the patient's responsible relative or the patient's care giver.
- (7) Every licensed pharmacy shall have and maintain in an electronic database a patient medication profile for each patient for whom a prescription medication is dispensed, and may include non-prescription information.
- (8) Patient medication profiles shall provide the following patient information:
- (a) surname and given names;
 - (b) address;
 - (c) telephone number;
 - (d) sex;
 - (e) date of birth;
 - (f) chronic medical conditions;
 - (g) notations of allergies and drug reactions; and
 - (h) any other notations of importance.
- (9) Patient medication profiles and labels shall provide the following prescription information:
- (a) dispensing date;
 - (b) prescription number;
 - (c) brand name of the drug, or generic name of the drug and name of manufacturer;
 - (d) quantity and strength of the drug;
 - (e) directions to the patient;
 - (f) identification of practitioner;
 - (g) number of authorized refills; and
 - (h) initials of licensed pharmacist dispensing prescription.
- (10) Each pharmacy shall ensure that the prescription information recorded in a patient medication profile is retained for 2 years from the date of entry.

(11) A pharmacist shall not fill a prescription beyond one year from the date on which the prescription was originally written, except in the circumstances outlined in the Standard of Pharmacy Practice for Medication Management adopted by the board.

(11.1) A pharmacist shall not fill a prescription other than as directed in the prescription, except in the circumstances outlined in the Standard of Pharmacy Practice for Medication Management as adopted by the board.

(12) Each pharmacy shall ensure that every original prescription is retained on file for 2 years from the date the prescription was filled or last refilled.

(13) All superfluous confidential records or labels concerning patients and prescriptions shall be destroyed either by shredding or by incineration.

(14) The patient's medication profile shall be reviewed by the pharmacist before the dispensing of a prescription to identify problems and take appropriate action where applicable.

(15) Each pharmacist shall promote the safe and effective use of medication by educating and counselling patients about their drug therapy as appropriate to the circumstances and as may be directed by the council.

(16) On the original filling of each prescription, the patient shall be counselled by the pharmacist and that counselling shall include, but is not limited to

- (a) the identity of the patient;
- (b) the identity of drugs being dispensed;
- (c) the dosage regimen and instructions required to achieve the intended therapeutic response;
- (d) storage requirements; and
- (e) major adverse side effects and cautions.

(17) Notwithstanding subsection (1), a pharmacist may accept for return to inventory, a drug previously dispensed to a nursing home licensed in the province if in the pharmacist's professional judgment it is appropriate to do so, where the following conditions are met:

- (a) the lot numbers and expiry dates of the drug, where applicable, are directly attached to the dispensed container;
- (b) each dose of the drug is individually sealed and the seal is intact at the time of return to the pharmacy;
- (c) containers are single-unit or unit-dose packages only;
- (d) the pharmacist has a personal knowledge of the storage conditions of the drug subsequent to its being dispensed or the length of time between dispensing and return is of such short duration that storage would not be material;
- (e) the patient has not been in possession of the drug; and
- (f) the drug has been under the supervision of the pharmacist directly or indirectly between the time of dispensing and the time of return to a sufficient degree to permit the exercise of professional judgment.

(18) The following requirements are applicable where drugs are repackaged into single-unit or unit dose containers:

- (a) it is the responsibility of the pharmacist, taking into account the nature of the drug repackaged, the characteristics of the containers, and the storage conditions to which the article may be subjected, to determine a suitable beyond-use date to be placed on the label and in the absence of stability data to the contrary, that date should not exceed
 - (i) 25% of the remaining time between the date of repackaging and the expiration date on the original manufacturer's bulk container, or

(ii) a 6 month period from the date the drug is repackaged, whichever is earlier; and

(b) each single-unit dose or unit dose container shall bear a separate label, unless the device holding the unit dose form does not allow for the removal or separation of the intact single unit or unit dose container.

(19) For the purpose of subsection (17) a nursing home is a facility where care is provided to individuals who are disabled to a degree that they require round-the-clock nursing care and medical supervision on a continuing basis, but do not require all the facilities of an acute care hospital.

(20) Where a restocking charge is charged by the pharmacist in regard of medications returned in accordance with subsection (17), that charge shall be reasonable, taking into consideration the work involved in returning the medications safely to inventory.

(21) Where credit is given for returned medications in accordance with the provisions of subsection (17), that credit shall only be given to the payer of the medications, which payer in the case of third parties may be an insurer or government, and it shall be considered unprofessional conduct to reimburse the patient or the patient's agent for medications paid for by a third party.

(22) It shall be considered unprofessional conduct to credit a portion of a professional fee for services rendered, or markup, to a patient, his or her agent, or a third party insurer in relation to medications returned to inventory in accordance with the provisions of subsection (17).

(23) This section does not apply to a hospital pharmacy or pharmacist practising pharmacy in a hospital pharmacy.

Standards of practice

14. (1) All pharmacists shall adhere to standards of practice approved by the council.

(2) All members shall be supplied with a copy of the standards of practice approved by the council.

Standards of pharmacy operation

15. (1) A person shall not be permitted to operate a pharmacy, unless the council is satisfied that the pharmacy complies with standards of pharmacy operation approved by the council.

(2) Before a licence is issued, an inspection shall be carried out on the proposed pharmacy.

(3) There shall be a sign showing the trading name of the pharmacy which shall be affixed to the exterior of the establishment.

(4) There shall be a sign, which clearly defines the prescription department area.

(5) The prescription department area shall

(a) contain at least 9.29 square metres, excluding the professional products area and patient waiting area;

(b) be a self-contained area, and shall be accessible to the public during normal business hours;

(c) be so designed by suitable fixtures and a lockable entrance as to discourage entrance by other than authorized persons but shall facilitate discussion between patient and pharmacist;

(d) be physically separate, in cases where it does not comprise the entire establishment, so as to clearly delineate it from the non-pharmaceutical portion of the establishment;

(e) be well ventilated, appropriately lighted, clean and tidy at all times;

- (f) have a supply of hot and cold water, a sanitary waste disposal container, a method of printing a label, adequate shelf and storage space and an approved method to dispose of confidential materials and pharmaceutical waste;
 - (g) have a refrigerator, for the exclusive storage of drugs requiring refrigeration; and
 - (h) have a telephone installed and the number listed in the appropriate telephone directory under the trading name of the pharmacy.
- (6) All persons working in the prescription department shall wear identification enabling the public to determine the name and position of that person.
- (7) Current reference material, either written or in electronic form, as defined by council in a schedule of required and suggested reference materials, shall be located in the prescription department and be accessible to a pharmacist.
- (8) Dispensing equipment, as defined by council in a Schedule of Dispensing Equipment, shall be located in the prescription department area.
- (9) A sufficient quantity of expendable material as defined by council in a Schedule of Expendable Materials shall be on hand in a prescription department.
- (10) The dispensing counter, where drugs are compounded or prepared, shall
- (a) have at least 1.2 square metres of working area to be utilized for this purpose; and
 - (b) exclude counter space occupied by equipment.
- (11) A prescription filing system shall be readily accessible to the pharmacist and shall be capable of being secured against unauthorized access.
- (12) There shall be a secure drug locker satisfactory to the inspector of the Bureau of Drug Surveillance, or its successor, and the secretary-registrar of the association.
- (13) There shall be a sufficient supply of drugs and medicines in order to provide prescription service.
- (14) There shall be a defined self-selection professional products area for Schedule III drugs, which shall be under visual supervision of the pharmacist, and shall be devoted exclusively to non-prescription medications and products which are to be sold under the supervision of a pharmacist.
- (15) The defined self-selection professional products area should contain, but not be limited to, a reasonable supply of the following:
- (a) analgesics;
 - (b) antiseptics, topical;
 - (c) antibiotics, topical;
 - (d) anti-infectives, topical;
 - (e) antacids;
 - (f) antihistamines, oral and topical;
 - (g) anti-fungals;
 - (h) anti-emetics;
 - (i) anti-diarrheals;
 - (j) cathartics;
 - (k) cough and cold remedies, including:
 - (i) antitussives,
 - (ii) decongestants,
 - (iii) expectorants, and
 - (iv) throat sprays and lozenges;
 - (l) eye and ear remedies;

- (m) first aid supplies;
- (n) hemorrhoidal preparations;
- (o) sweetening agents; and
- (p) vitamin preparations.

(16) This section does not apply to a hospital pharmacy or a pharmacist practising pharmacy in a hospital pharmacy.

Code of Ethics

16. The council may adopt a Code of Ethics which shall govern the practice of pharmacy.

Code of Advertising

17. (1) A pharmacist shall not advertise, or permit a person to advertise on behalf of a pharmacy which that pharmacist operates, using information that

- (a) is false, misleading, fraudulent, deceptive, ambiguous or confusing, or likely to mislead or deceive the public due to partial disclosure of relevant facts;
- (b) is not relevant to the public's ability to make an informed choice;
- (c) is not verifiable by facts independent of personal feelings, beliefs, opinions or interpretations;
- (d) makes comparisons either directly or indirectly with another pharmacy or pharmacist or would be reasonably regarded as suggestive of uniqueness or superiority over another pharmacy or pharmacist; or
- (e) as a result of its content, method or frequency of dissemination is such as to be reasonably regarded by pharmacists as likely to demean the integrity or dignity of the profession or bring the profession into disrepute.

(2) The council may approve and publish guidelines to assist pharmacists in complying with the requirements and prohibitions contained in this section.

(3) A person or pharmacist operating a pharmacy shall not place or allow to be placed on a prescription pad the name or address of that pharmacy.

Hospital pharmacy standards

18. (1) Hospital pharmacists shall adhere to the Standards of Practice for Hospital Pharmacies as proposed by the committee of hospital pharmacists and approved by the council.

(2) All hospital pharmacies shall be supplied with a copy of the Standards of Practice for Hospital Pharmacies as approved by the council.

PART IV INSPECTIONS

Power of registrar

19. The secretary-registrar or the secretary-registrar's designated agent may

- (a) conduct an inspection of an existing or proposed pharmacy and of the equipment and drugs contained or to be contained there, and of other contents, actual or proposed; and
- (b) require the owner to rectify deficiencies noted in the inspection.

PART V CLOSURES

Where pharmacy closes

20. (1) Where a licensed pharmacy ceases to operate as a pharmacy, the pharmacist-in-charge shall in addition to the requirements imposed by the Act, at least 5 days, if possible, before the effective date of cessation, notify the secretary-registrar on the forms that may be prescribed by council of the proposed cessation of operation of the pharmacy.

(2) In the event of a change of control or ownership of a licensed pharmacy, the pharmacist-in-charge and the owner shall deliver the pharmacy licence to the secretary-registrar for cancellation on the effective date of the change of ownership.

PART VI DISCIPLINE

Composition of disciplinary committee

21. (1) The discipline committee shall be comprised of not less than 3 nor more than 9 persons appointed from among the members of the association, and other persons as the council may determine.

(2) A member of council may not be appointed to or become a member of the discipline committee.

(3) The council shall appoint from the members of the discipline committee, a chairperson and vice-chairpersons.

(4) The vice-chairperson shall act for and has the powers of the chairperson when the chairperson is unable to act.

(5) In the event of the death, resignation or removal of a member of the discipline committee, the council may appoint a replacement for that member to serve the remainder of the term of office of the member.

(6) The term of office of a member of the discipline committee shall be for a period of 3 years from the date of appointment and members may be reappointed for additional terms.

Subcommittees

22. (1) The discipline committee may sit as a committee of the whole, or may be divided into panels of 3 members each, at the discretion of the chairperson.

(2) The chairperson of the discipline committee shall appoint one member of a panel as chairperson of the panel.

(3) Where the discipline committee is divided into panels, a panel shall be considered for all purposes as the discipline committee.

(4) A report of a panel is considered to be the report of the discipline committee.

(5) Panels may sit separately or concurrently.

Panels

23. (1) In order to comply with subsections 38(2), 39(1) and section 41 of the Act, the chairperson may appoint a panel of 3 members of the discipline committee to receive reports and information from the secretary-registrar, in order to decide whether or not a hearing should take place.

(2) The panel referred to in subsection (1) shall not take part in a discipline hearing that it determines should be held.

Panels

24. The chairperson may appoint a panel of 3 members or more of the discipline committee, other than the members of the panel referred to in section 23, to hear a complaint.

Retention of counsel

25. (1) The discipline committee may engage the services of legal counsel, consultants and experts that it considers necessary to assist and advise the discipline committee with respect to a matter dealt with by the discipline committee.

(2) The association's solicitor shall only represent the association at a hearing of the discipline committee.

Member's participation in decision

26. A member of the discipline committee shall not participate in the decision of the committee unless that member was present throughout all of the hearing and heard all of the evidence and argument of the parties presented.

Written complaint

27. A complaint made under subsection 35(1) of the Act shall be in writing.

Service of notice

28. (1) Notice under this Part shall be served in compliance with section 34 and subsection 42(2) of the Act and shall take place not less than 14 days before the date established for a hearing.

(2) Subsection (1) does not apply to a notice given under section 48 of the Act.

Content of notice

29. (1) The notice shall include a statement to the effect that the discipline committee may proceed to hear the matter in the absence of either or both of the complainant or investigated person, should either fail to appear at the time and place set for the hearing.

(2) The discipline committee, where it is satisfied that the complainant and the investigated person were served properly with notice of the hearing, may proceed with the hearing in the absence of the complainant or the investigated person.

Rules of evidence

30. (1) The rules of evidence applicable in civil proceedings in the Supreme Court are applicable at a hearing.

(2) Oral evidence given at a hearing shall be recorded and, if required, a transcript of the evidence prepared.

Hearing in public

31. An investigated person requesting that a hearing be public shall do so in writing to the secretary-registrar or the discipline committee at least 2 days before the day fixed for the hearing.

Basis of findings

32. The findings of the discipline committee shall be based exclusively on the evidence adduced at the hearing.

Return of records

33. The records placed into evidence at a hearing shall, upon the request of the person who introduced them, be returned to that person by the discipline committee within a reasonable time after the matter in issue has been finally determined, including the expiry of all permitted appeal proceedings and time limits.

Report to council

34. Following a hearing, the chairperson of the discipline committee or a panel of the committee shall, within a reasonable period, and in any event not later than 30 days following the final date of the hearing, submit a report in writing to the council containing the findings of the committee or panel and the reasons for the decision.

Release of decision

35. (1) The discipline committee shall, following final consideration of the matter, and in any event, not later than 30 days following the final date of the hearing, serve the complainant and the investigated person with a written decision in the matter, with reasons for the decision.

(2) The service of a decision may be made by personal service or by sending the decision by prepaid registered mail to the last known address of the complainant and the investigated person known to the secretary-registrar.

(3) The secretary-registrar shall give notice of a decision of the discipline committee or a panel of the committee and an order made under it to those persons stipulated in the decision and to those other persons that the council considers appropriate in the public interest.

Monetary penalty

36. The maximum amount of the monetary penalty that may be imposed under paragraph 49(1)(f) of the Act shall be \$10,000.

Professional misconduct defined

37. (1) The term unprofessional conduct or professional misconduct for the purpose of consideration of a complaint and the institution of disciplinary proceedings includes but is not limited to

- (a) failure to abide by the terms, conditions or limitations of a licence;
- (b) breach of the Code of Ethics governing the practice of pharmacy as outlined in section 16 of these regulations;
- (c) breach of the Code of Advertising as outlined in section 17 of these regulations;
- (d) failing to pay the appropriate fee to practise pharmacy;
- (e) entering into an agreement with a prescriber for the withholding of the composition of coded prescriptions;
- (f) falsifying a record in respect of a prescription or the sale of a drug;
- (g) providing a prescriber with prescription blanks, a professional diary, an appointment book or other gift which is imprinted with the name of a pharmacy;
- (h) sharing fees with a person who has referred a person to a pharmacist or to a pharmacy or receiving fees from a person to whom a member has referred a person;

- (i) participating in a lease of premises for a pharmacy that permits a person other than a member or the owner of the pharmacy to participate in the revenue of the pharmacy except by way of a rent normal for the area in which the premises are located;
- (j) entering into an agreement that restricts a person's choice of pharmacist;
- (k) knowingly submitting a false or misleading account or false or misleading charge for a drug or the compounding or dispensing of a prescription;
- (l) signing or issuing a certificate or similar document that contains a statement the signing or issuing member knows or ought to know is misleading;
- (m) announcing or holding out by a member that the member has special qualifications that are not in fact possessed by the member;
- (n) submitting an account or charging a fee for a service as a pharmacist that is excessive or unreasonable in relation to the service performed;
- (o) failing to fulfil the terms of an agreement with a person as to the charge for providing a service as a pharmacist to that person;
- (p) except as specifically permitted in these regulations, returning to stock or again selling or dispensing a drug previously sold or dispensed and delivered or a physician sample or outdated pharmaceutical products;
- (q) using improperly the authority to sell or dispense a drug or mixture of drugs;
- (r) acting as a pharmacist while the ability to perform an action as a pharmacist is impaired by alcohol or by a drug;
- (s) knowingly permitting the premises in which the pharmacy is located to be used for unlawful purposes;
- (t) a pharmacist permitting, consenting to or approving either expressly or by implication the commission of an offence under the Act or these regulations by another person associated with the pharmacy in which the pharmacist practises;
- (u) failing to maintain the records that are required to be kept respecting patients;
- (v) having a conflict of interest;
- (w) failing to maintain the standards of practice of the profession, including written standards;
- (x) refusing to allow an appointed person to enter at a reasonable time the pharmacy in which the member is engaged in the practice of pharmacy for the purpose of an inspection;
- (y) contravening, while engaged in the practice of pharmacy, a law, regulation or rule with respect to the practice of pharmacy or the distribution, sale or dispensing of alcoholic liquors;
- (z) conduct or an act relevant to the practice of pharmacy that, having regard to all the circumstances, would reasonably be regarded by members as disgraceful, dishonourable or unprofessional;
- (aa) disclosing of information relating to selling or dispensing of drugs to a person other than the person to whom the drugs are sold or dispensed, other than as required by law or with the consent of the person to whom the drugs are sold or dispensed;
- (bb) displaying of a lack of knowledge, skill or judgment or disregard for the welfare of the public he or she serves of a nature or to an extent that demonstrates a member is unfit to carry out the responsibilities of a pharmacist;
- (cc) selling or dispensing an excessive or unreasonable or improper amount of a drug or medicine; and
- (dd) purchasing a drug other than from another pharmacist, a recognized drug wholesaler, or the manufacturer of the drug.

(2) Notwithstanding paragraph (1)(aa), it is not professional misconduct for a pharmacist to disclose information relating to the selling or dispensing of drugs to a person other than the person to whom the drugs are sold or

dispensed, including providing the information in the form of copies of prescriptions, where the information is disclosed

- (a) to the person in the furtherance of
 - (i) a lawful drug monitoring program, or
 - (ii) a lawful investigation;
- (b) at the request of an official of the department engaged in an audit for the purpose of gathering information relative to a prescription drug plan administered by the department; or
- (c) to a professional involved in the active treatment or care of a person.

Meaning of expenses

38. (1) Where an investigated person is found guilty and is ordered to pay expenses related to an investigation and hearing the word expenses means the exact total reasonably spent by the association on the case in question.

(2) When the discipline committee or a panel of the committee orders as part of the committee's or panel's decision that the investigated person pay expenses of the investigation and hearing, the committee shall

- (a) itemize in reasonable detail the expenses to be paid by the investigated person; and
- (b) stipulate the time within which payment of the expenses is to be made to the association.

Rehearing

39. The discipline committee may, if evidence becomes available that was not available at the time of hearing, or for good reason, as determined at the sole discretion of the discipline committee, was not presented at the hearing, rehear a matter already heard by it and for that purpose has the same power and authority and is subject to the same duties as it had and was subject to in connection with the original hearing.

Cancelled or suspended licence

40. Upon receipt by the secretary-registrar of a licence or certificate that is cancelled or suspended, the secretary-registrar shall affix to or note on the licence or certificate the fact of the cancellation or suspension and shall retain the licence or certificate, in the case of suspension, for the period of the suspension and in the case of cancellation permanently.

Expiry of member's term

41. Where a discipline committee member's term of office expires while a complaint is under consideration or within an appeal period, that member shall continue to hold jurisdiction as a member of the discipline committee notwithstanding that a successor member may have been appointed.

Further inquiries

42. The discipline committee, after receiving the report of the preliminary investigation, may order the investigating person to conduct further inquiries and report back in writing to the discipline committee within a specified time.

Right to examine reports

43. The secretary-registrar shall make available to a member whose conduct is being investigated, before the hearing, the opportunity to examine written reports or other records in the possession of the secretary-registrar that is intended to be produced or form part of the evidence at the hearing.

Record of proceedings

44. The discipline committee shall compile a record of a proceeding in which a hearing has been held which shall include:

- (a) the complaint by which the proceeding was commenced;
- (b) the notice of a hearing;
- (c) all documentary evidence filed with the discipline committee;
- (d) the tapes and transcript, if one has been prepared, of the oral evidence given at the hearing; and
- (e) the findings of the discipline committee and the reasons for the findings.

PART VI.1 TAMPER RESISTANT PRESCRIPTION DRUG PADS

Rep. by 2006 cP-12.01 s56

44.1 [Rep. by 2006 cP-12.01 s56]

PART VII DRUG SCHEDULES

Drug schedules

45. (1) The minister approves drug schedules recommended by the council based on *Canada's Drug Scheduling System* and consisting of 3 schedules or 4 categories:

- (a) Schedule I drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner;
- (b) Schedule II drugs, while less strictly regulated, do require professional intervention from the pharmacist at the point of sale and possible referral to a practitioner and while a prescription is not required, the drugs are available only from the pharmacist and shall be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection;
- (c) Schedule III drugs may present risks to certain populations in self-selection and although available without a prescription, these drugs are to be sold from the self-selection area of the pharmacy which is operated under the direct supervision of the pharmacists; or
- (d) Unscheduled drugs can be sold without professional supervision if adequate information is available for the patient to make a safe and effective choice and labelling is considered sufficient to insure the appropriate use of the drug and drugs not included in Schedules I, II or III and may be sold from any retail outlet.

(2) A list of the drugs contained in each of Schedules I, II and III is on file with the minister and may be examined or obtained during regular business hours.

PART VIII DISPENSING OF SUBSTITUTE BRAND-NAME DRUGS

Lower-priced drug substitution

46. Where a person authorized by law to dispense prescriptions is given a prescription directing the dispensing of a brand of a drug ordinarily available without a prescription, the person may dispense a substitute brand of the drug where,

- (a) the substituted brand of the drug is less expensive than the brand of the drug prescribed; and
- (b) the substituted brand of the drug contains the same active ingredients as that of the prescribed brand; and
- (c) the specific generic drug category is approved for the purpose by the Newfoundland Pharmaceutical Association and the Newfoundland and Labrador Medical Association.

Substitution prohibited

47. Where a prescription contains a written direction in the handwriting of the person prescribing the drug that the prescribed brand of the drug is not to be substituted, the person dispensing the drug shall not make a substitution.

Duty of dispenser

48. Where a brand of the drug is substituted for the brand of the drug prescribed, the person dispensing the drug shall ensure that the brand of the drug that is substituted contains the same amount of the same active ingredients and in the same form as the brand prescribed.

PART IX REPEAL

Repeal

49. (1) The *Dispensing of Substitute Brand-name Drugs Regulations*, Newfoundland Regulation 2/98, are repealed.
- (2) The *Hospital Pharmacy Registration Regulations*, Newfoundland Regulations 73/96 and 74/96, are repealed.
- (3) The *Pharmaceutical Association Regulations*, Newfoundland Regulation 108/96, are repealed.