LEGISLATION AFFECTING THE PRACTICE OF PHARMACY IN NOVA SCOTIA

The day to day practice of pharmacy is governed by many laws. Laws exist that dictate the qualifications/requirements for licensure as a pharmacist and as a pharmacy technician, the requirements to maintain that license to practice pharmacy, the requirements for day to day practice as a pharmacist/pharmacy technician, and the requirements to open and operate a pharmacy. Because registrants must deal with the laws of pharmacy practice every day and since "ignorance of the law is no excuse", it is crucial that practicing pharmacists, pharmacy technicians and pharmacy students/interns know and understand the laws under which they practice.

The key legislation and regulations affecting the practice of pharmacy in Nova Scotia include:

- The Food and Drugs Act and Regulations
- The Controlled Drugs and Substances Act and Regulations
- The Pharmacy Act of Nova Scotia and Regulations
- The Prescription Monitoring Act and Regulations
- Personal Health Information Act (PHIA) and Regulations

The Food and Drugs Act is a federal act and provides legislation and regulations regarding food and drugs, including the process by which food, drugs, cosmetics and therapeutic devices are manufactured, marketed and sold in Canada.

The Controlled Drugs and Substances Act and the Regulations made under this legislation contain the federal rules relevant to the distribution of drugs and substances that have abuse potential. These rules, along with those found in the Food and Drugs Act and its regulations, ensure that the Canadian market has safe and effective drugs.

The Prescription Monitoring Act and its Regulations enable the provincial prescription monitoring program to promote the appropriate use of monitored drugs in Nova Scotia and to reduce the abuse or misuse of monitored drugs in the province.

The Pharmacy Act of Nova Scotia is a provincial statute, which governs the practice of pharmacy in Nova Scotia. Through the Pharmacy Act and its associated Regulations, the Nova Scotia College of Pharmacists was created to regulate the profession of pharmacy in Nova Scotia in the public interest.

The Personal Health Information Act and its Regulations governs the collection, use, disclosure, retention, disposal and destruction of personal health information. The Act recognizes both the right of individuals to protect their personal health information and the need of custodians to collect, use and disclose personal health information to provide, support and manage health care.
BRIEF OVERVIEW OF THE PHARMACY ACT; THE REGULATIONS; STANDARDS OF PRACTICE; CODE OF ETHICS; AND POLICIES, POSITIONS AND GUIDELINES

Pharmacy Act

The Pharmacy Act of Nova Scotia and its associated Regulations and related documents, unlike the federal legislation, do not focus on the manufacture, marketing and approval of drugs. They regulate pharmacists, pharmacy technicians, students, and interns, as well as pharmacies and the practice of pharmacy in Nova Scotia.

The Pharmacy Act (also called the legislation or statute) provides the foundation for the regulation of the practice of pharmacy. The provisions found in the Act are general in nature and often refer to the Regulations for more specific requirements. The Act can only be amended by the provincial legislature.

Pharmacy Regulations

The Regulations provide, in more detail, the rules enabled by the Act. The Regulations can be amended by an Order in Council in order to adapt to a dynamic profession. The Regulations include the provincial drug schedules which define the conditions/rules for selling specific groups of drugs, including nonprescription drugs. Currently in Nova Scotia the following Regulations are in place:

- Pharmacy Act and Regulations Definitions Regulations
- Registration, Licensing and Professional Accountability Regulations
- Pharmacy Practice Regulations
- Drug Schedules Regulations
- Pharmacist Drug Prescribing Regulations
- Pharmacist Extended Practice Regulations
Standards of Practice

In addition to the Act and its associated Regulations, Standards of Practice are in place to further define expected practice. The Standards of Practice in Nova Scotia include:

- Standards of Practice: General Pharmacy Practice
- Model Standards of Practice for Canadian Pharmacy Technicians
- Supplemental Standards of Practice for Schedule II and III Drugs
- Standards of Practice: Continuous Quality Assurance Programs in Community Pharmacies
- Model Standards of Practice for Pharmacy Compounding of Non-hazardous Sterile Preparations
- Model Standards of Practice for Pharmacy Compounding of Hazardous Sterile Preparations
- Standards of Practice: Non-Sterile Compounding
- Standards of Practice: Medical Assistance in Dying (MAiD)
- Standards of Practice: Prescribing of Drugs by Pharmacists
- Standards of Practice: Drug Administration
- Standards of Practice: Testing
- Standards of Practice: Opiate Agonist Maintenance Treatment Services
- Standards of Practice: Professional Library Requirements for Community Pharmacies
- Standards of Practice: Pharmacists Offering Pharmacy Services via the Internet

Code of Ethics

Code of Conduct: Conflict of Interest

- Identifies the ethical expectations and obligations of registrants and provides guidance to registrants in making ethical decisions.

Policies, Position Statements and Guidelines

- Further aid in the regulation of the practice of pharmacy in the public interest.
PHARMACY LEGISLATION

The Pharmacy Act

1. Title and Definitions
   • Defines relevant words found in the Act

2. The Nova Scotia College of Pharmacists
   • Roles and responsibilities of the NSCP

3. Registration and Licensing
   • High level requirements for registering and licensing with the NSCP

4. Pharmacies
   • High level rules for opening and operating a pharmacy

5. Professional Responsibility
   • High level legal responsibilities of registrants; includes information on supervision and delegation requirements; confidentiality requirements

6. Professional Accountability
   • Complaints, investigations, discipline hearings, settlement agreements, fitness to practice, reinstatement of licence to practise

7. Unauthorized Practice
   • Includes the activities that cannot be carried out without a pharmacist, pharmacy technician, or pharmacy licence; title protection

8. General
   • Includes clauses regarding application of Act to hospital pharmacies, exemption of pharmacies operated by armed forces
Pharmacy Regulations

Pharmacy Act and Regulations Definitions Regulations

These regulations contain the additional definitions for words or expressions found in the Pharmacy Act and the associated Regulations.

The Registration, Licensing and Professional Accountability Regulations

1. Interpretation / definitions

2. Registration and Licensing Classes and Requirements
   • registration requirements/qualifications for pharmacists, pharmacy technicians, students, and interns
   • practice experience requirements
   • limits on the authority of a pharmacy technician

3. License Renewals and Resumption of Practice
   • requirements for annual renewal of licence
   • requirements for resuming a direct patient care licence

4. License Conditions, Suspensions and Revocations

5. Pharmacy Accreditation and Licensing
   • general requirements for registering and licensing a pharmacy

6. Limited service pharmacies

7. Patient Records
   • storage/access/retention/disposing of patient records, the provincial Drug Information System (DIS)

8. Conditional Authority

9. Appointment of Public Representatives

10. Statutory Committees
    • Registration Appeals, Investigation, Fitness to Practice, Hearing, and Reinstatement Committees

11. Appeals to Registration Appeals Committee

12. Professional Accountability
    • Filing a complaint, Investigation Committee disposition of a complaint, referral to Fitness to Practice Committee, Hearing procedures

13. Reinstatement of Registrant’s Registration and Licence

14. Notice and Service
The Pharmacy Practice Regulations

1. General

2. Registration and Licensing
   - registrants of the NSCP are pharmacists, registered students, interns, pharmacy technicians and pharmacy technician candidates
   - pharmacist classifications: practicing direct patient care, practicing indirect patient care or non-practising
   - pharmacy technician classifications: practicing direct patient care or non-practising
   - preceptors
   - insurance requirements
   - classification of practice
   - continuing education requirements

3. Pharmacy Technicians

4. Pharmacy Practice
   - dispensing
   - assessment of drug therapy
   - counseling
   - monitoring
   - prescriptions
   - product integrity
   - pharmacist not present
   - delegation of drug therapy by injection
   - delegation of tests and services

5. Pharmacies
   - qualifications of a pharmacy manager
   - responsibilities of a pharmacy manager
   - quality assurance
   - dispensary/pharmacy
   - physical facilities
   - security
   - advertising
   - closing a pharmacy
Pharmacist Drug Prescribing Regulations

1. Citation and Definitions

2. When a pharmacist may prescribe drugs
   - Schedule II and III drugs
   - Schedule I drugs for conditions approved by Council (i.e., minor ailments)
   - under conditional authority
   - in an emergency
   - to renew an existing prescription
   - to adapt an existing Rx
   - for therapeutic substitution
   - in a practice setting approved by Council
   - in emergency circumstances identified by Council to be in the public interest

3. Knowledge and understanding

4. Information to be provided to the patient

5. Documenting, monitoring, communicating

Pharmacist Extended Practice Regulations

1. Citation and Definitions

2. Pharmacist’s responsibilities when carrying out the approved extended activities
   - administration of drugs (including some vaccines via injection) and ordering, receiving, conducting and interpreting tests needed to properly manage drug therapy
   - must be carried out in accordance with the standards of practice

3. Administering drug therapy

4. Administering drug therapy by injection

5. Permit issuance and renewal
   - only pharmacists with a NSCP injection permit may administer drugs via injection

6. Information and consent respecting testing
   - the pharmacist must obtain informed consent

7. Procedures and requirements for test results
   - must be carried out in accordance with the Standards of Practice
Drug Schedules Regulations

In addition to the federal drug schedules, there are three provincial drug schedules.

1. Schedule I
2. Schedule II
3. Schedule III

Standards of Practice

As noted earlier in this document, in addition to the Act and its associated Regulations, various Standards of Practice are in place to further define expected practice. The Regulations state that registrants are expected to practice in accordance with the Standards of Practice in Nova Scotia. A list of all Standards of Practice documents can be found on page 3.

The Code of Ethics

Code of Conduct: Conflict of Interest

The Regulations state that all registrants are expected to practice in accordance with the NSCP Code of Ethics.

Policies and Position Statements

These are issue-specific (e.g., Narcotic Reconciliation Policy, Sale of Exempted Codeine Position Statement)

Guidelines

These are issue-specific (e.g., Practice Guidance: Dispensing Mifegymiso)
“RULE HIERARCHY” IN NOVA SCOTIA

Pharmacy Act of Nova Scotia (“The Act”)

Regulations and Regulatory Agreements

Standards of Practice

Policies Positions Guidelines

Code of Ethics
Code of Conduct: Conflict of Interest