

Pharmacy Jurisprudence in Nova Scotia

The practice of pharmacy in Nova Scotia is governed by various federal and provincial laws and rules that set out:

- the qualifications and requirements to become licensed as a pharmacy practitioner,
- the requirements to maintain a license to practice pharmacy,
- the requirements for day-to-day pharmacy practice, and
- the requirements to open and operate a pharmacy.

All individuals who hold a license must adhere to these pharmacy practice laws and rules. As a result, it is crucial that pharmacists, pharmacy technicians, pharmacy students, interns, and pharmacy technician candidates know and understand the legislation under which they practice.

This document provides a basic overview of the Legislation, Standards, and policies that are relevant to the practice of pharmacy in Nova Scotia. Successful completion of the Nova Scotia Pharmacy Jurisprudence Examination requires an understanding of legislation, standards and policies that goes beyond the content of this document. Those taking the exam should ensure they are familiar with the referenced documents.

Federal Legislation

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

Food and Drugs Act and Regulations

 This federal act 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.

• Controlled Drugs and Substances Act (CDSA) and Regulations

This legislation contains 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 Personal Information Protection and Electronic Documentation Act (PIPEDA)

This is Canadian law relating to data privacy. It governs how private sector organizations manage personal information in the course of commercial business. Prior to NS passing its own provincial privacy legislation (PHIA – Personal Health Information Act), PIPEDA would have been the sole privacy

legislation guiding practice. Although PIPEDA is still relevant legislation, health care practitioners in NS are predominantly guided by PHIA.

• The Policy on Manufacturing and Compounding Drug Products in Canada

 This provides background information on compounding and manufacturing of drugs in Canada and provides a policy framework to assist in distinguishing between what is compounding and what would be considered manufacturing activities.

Provincial Pharmacy Legislation

The Regulated Health Professions Act (RHPA)

This is the provincial Act that governs the regulation of all health professions in Nova Scotia, including pharmacy. Through the RHPA, and the General and Pharmacy Regulations, the Nova Scotia Pharmacy Regulator is tasked with regulating the profession of pharmacy in Nova Scotia in the public interest.

The RHPA sets a common legislative foundation across all Nova Scotia healthcare regulators with respect to governance, registration, licensing, and professional accountability and contains sections describing:

- Title and Definitions
- Governance
- Joint Panels and Pools
- Registration and Licensing
- Practice
- Professional Conduct
- Reinstatement
- Fitness-to-Practise Process
- Practice Reviews
- Confidentiality
- Professional Incorporation
- Offences and Penalties
- General Information

Regulated Health Professions General Regulations

The Regulated Health Professions General Regulations to the RHPA provide further details with respect to matters including government reporting and consultation obligations, committees, professional conduct, and quality assurance practices and contains sections describing:

- Definitions
- Regulatory Body Requirements
- Committees, Joint Panels and Pools
- Professional Conduct

- Settlement Agreements
- Reinstatement
- Practice Reviews
- Quality Assurance Program
- Custodianship
- Information Disclosure and Confidentiality
- Practice
- Transition

Pharmacy Regulations

The Pharmacy Regulations provide more detailed pharmacy-specific regulations under the RHPA and includes sections on:

- Definitions
- Regulator
- Scope of Practice
- Registration and Licensing
- Inspections
- Evidence of Drug and Certificate of Analysis
- Fines
- Pharmacies

The RHPA, the General Regulations and the Pharmacy Regulations are pieces of legislation that can only be amended by the provincial government.

NSPR Bylaws

The RHPA enables certain areas to be regulated through a regulator's Bylaws, instead of government regulations. The Bylaws set out the Nova Scotia Pharmacy Regulator's governance structure, the criteria for registration and licensing of pharmacy professionals and pharmacies, and some rules for pharmacy practice. Bylaws can be amended through a defined process that does not require government approval. The Bylaws include the following sections:

- Definitions
- Part I: Governance
- Part II: Registration and Licensing
 - Licence categories
 - Practicing Licences
 - Conditional Licenses (pharmacy technician candidate, pharmacy student)
 - Practice Experience
 - License Renewal and Resumption of Practice
 - Pharmacy Accreditation and Licensing
 - Limited-Service Pharmacies

Part III: Pharmacy Practice

- Pharmacy Technician Scope of Practice,
- Pharmacist/Pharmacy Technician conditional
- Variation of conditions for practice during state of emergency or public health emergency
- Delegation: administering drug therapy/testing activities
- Drug Therapy Management
 - Dispensing
 - Assessment of drug therapy
 - Counselling
 - Monitoring, Prescriptions
 - Provision of pharmacy services outside licensed pharmacy
- Pharmacies
 - Qualifications of pharmacy manager
 - Responsibilities of the pharmacy manager
 - Changes
 - Reinspection

- Pharmacist Not Present
 - Supervision of Pharmacies
 - Persons permitted in dispensary and pharmacy
 - Security
- Part IV: Schedule of Drugs
 - o Schedule of Drugs: Schedule I, Schedule II, Schedule III

Standards of Practice

In addition to the RHPA, its associated Regulations, and the Bylaws, the Standards of Practice are in place to further define expected practice. The Standards of Practice 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
- Standards of Practice: Non-Sterile Compounding
- NAPRA Model Standards of Practice for Pharmacy Compounding of Non-hazardous Sterile Preparations
- NAPRA Model Standards of Practice for Pharmacy Compounding of Hazardous Sterile Preparations
- Standards of Practice: Centralized Prescription Processing
- Standards of Practice: Medical Assistance in Dying (MAiD)
- Standards of Practice: Sexual Misconduct
- Standards of Practice: Prescribing Drugs
- Standards of Practice: Drug Administration
- Standards of Practice: Testing
- Standards of Practice: Drug Therapy for the Treatment of Opioid Use Disorder
- Standards of Practice: Pharmacists Offering Pharmacy Services via the Internet

Policies, Position Statements and Guidelines

These are issue-specific documents that further define expectations for pharmacy practice and include policies on things such as:

- Inventory Management of CDSA and Z-Drugs
- Sale of Exempted Codeine
- Compliance Packaging,
- Patient Records, and
- Other various topics

Code of Ethics & Code of Conduct: Conflict of Interest

The Code of Ethics set out the ethical expectations and obligations of registrants, as required by the RHPA and provides guidance to registrants in making ethical decisions.

The Code of Conduct: Conflict of Interest is a companion document to the NSPR Code of Ethics. It expands on the basic concept of conflicts of interest as introduced in the Code of Ethics and was developed in response to a pharmacist's expanding scope of practice.

Other Provincial Legislation

Prescription Monitoring Act and Regulations

This Act enables the provincial prescription monitoring program (NS PMP) to promote the appropriate use of monitored drugs in Nova Scotia and to reduce the abuse or misuse of monitored drugs in the province.

Personal Health Information Act (PHIA) and its Regulations

This Act governs the collection, use, disclosure, retention, disposal and destruction of personal health information. It 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.

"Rule Hierarchy" in Nova Scotia

Regulated Health Professions Act



General & Pharmacy Regulations



Bylaws



Standards of Practice



Policies, Positions, & Guidelines

All underpinned by the

Code of Ethics