

Pharmacy Jurisprudence Requirements

Introduction

The second of six competencies in the "Professional Competencies for Canadian Pharmacists at Entry-to-Practice" relates to pharmacy jurisprudence. This Competency Unit states that:

"Pharmacists practise within legal requirements, demonstrate professional integrity and act to uphold professional standards of practice and codes of ethics."

NAPRA's "National Licensing Standards Committee" established the foundation for the jurisprudence sub-competencies and elements presented in this Report in early 1998. The NLSC was comprised of individuals appointed by pharmacy regulatory authorities, the Canadian Society of Hospital Pharmacists, the Association of Faculties of Pharmacy of Canada, the Pharmacy Examining Board of Canada, the Association of Deans of Pharmacy of Canada, the Canadian Council for Accreditation of Pharmacy Programs, and the Canadian Pharmacists Association. Building on this framework, representatives from all provincial pharmacy regulatory authorities and the Canadian Council for Accreditation of Pharmacy Programs further developed and refined the ten Sub-Competencies and 50 Competency Elements relating to this Competency Unit.

The primary intent of this Report is to provide definition to students and teachers of pharmacy jurisprudence across Canada. Provinces could use the Report to form the basis of a jurisprudence course outline, for education and assessment purposes. The project was funded in part by Human Resources Development Canada, because of its relevance to the development of a Mutual Recognition Agreement for the profession.

Jurisprudence Sub-Competency #1

Pharmacists apply legal requirements and ethical principles, together with professional policies and standards, concerning patient care.

Competency Elements

Pharmacists:

- 1.1 accept responsibility for personal actions and decisions with regard to patient care
- 1.2 delineate and demonstrate all parameters of confidentiality
- 1.3 comply with monitoring requirements with regard to patients
- 1.4 adhere to legal requirements and ethical principles in promotion and advertising
- 1.5 comply with legal requirements and ethical principles regarding counselling and in the provision of pharmacist services

1.6 uphold legal and policy requirements with regard to referral of patients to other health care providers and/or agencies

1.7 comply with regulations with regard to refusal to fill prescriptions or refusal to sell products

1.8 comply with storage and disposal requirements regarding prescription records

Jurisprudence Sub-Competency #2

Pharmacists apply legal requirements and ethical principles affecting the acquisition, storage, distribution, promotion and disposal of drugs and devices.

Competency Elements

2.1 Acquisition of drugs and devices

Pharmacists:

i. apply their knowledge of legal requirements in the acquisition of drugs and devices

ii. adhere to established drug schedules and conditions of sale

iii. determine the interchangeability of pharmaceutical products within provincial and territorial parameters

v. explain and comply with regulations and guidelines in the use of samples

2.2 Storage of drugs, devices and related information..

Pharmacists

i. determine and apply the necessary security systems

ii. document and securely store inventory

iii. adhere to established labeling procedures for drugs and devices

2.3 Distribution of drugs and devices

Pharmacists

i. follow ethical principles and legal and practice requirements, in the distribution of all products

ii. apply legal requirements and professional judgment in the processing of prescriptions

- iii. adhere to professional regulations regarding drug diversion
- iv. apply legal requirements and ethical principles in the use of pharmacy support personnel
- v. adhere to legal requirements and ethical principles in the transmission of prescriptions by electronic technologies
- vi. explain the national, and provincial or territorial processes for drug scheduling

2.4 Promotion of drugs and devices

Pharmacists

- i. adhere to the legal requirements and ethical principles when advertising products and services.

2.5 Disposal of drugs and devices

Pharmacists

- i. adhere to legal requirements and ethical principles in the disposal and/or reuse of returned or unused medications
- ii. adhere to legal requirements and ethical principles in the disposal and/or reuse (where appropriate) of devices

Jurisprudence Sub-Competency #3

Pharmacists can elucidate the complaints and discipline processes and consequences for pharmacists and non-pharmacists

Competency Elements

Pharmacists can

- 3.1 describe components of professional liability such as malpractice and negligence
- 3.2 explain the role and function of the complaints committee and complaints processes and procedures
- 3.3 explain the role and function of the discipline committee and the processes and procedures for disciplinary action
- 3.4 describe the concept of conflict of interest
- 3.5 describe what constitutes illegal sales and illegal signage respecting non-pharmacy outlets

3.6 explain the parameters of professional incompetence and incapacity, offenses and misconduct, including harassment and abuse issues, and the possible consequences for such behaviour

3.7 explain an individual's responsibilities in the reporting of suspected impairment and harassment cases, and professional misconduct.

Jurisprudence Sub-Competency #4

Pharmacists can specify the requirements for obtaining, maintaining and reactivating a licence to practise as a pharmacist

Competency Elements

Pharmacists can:

4.1 explain the registration process and the requirements for initial licensure

4.2 state the requirements for maintaining and reactivating a licence to practise pharmacy

4.3 differentiate between an internship and a clerkship

4.4 describe the requirements for the display of licence

Jurisprudence Sub-Competency #5

Pharmacists can explain the requirements for owning and managing a pharmacy

Competency Elements

Pharmacists can

5.1 state the accreditation requirements to allow for the operation of a pharmacy

5.2 explain what is involved in the acquisition, sale, renovation, relocation, and closure of a pharmacy and describe the necessary procedures for such events as bankruptcy and death of the owner

5.3 explain what is meant by a sub-divided pharmacy and/or operation

5.4 detail the requirements for the supervision of a pharmacy

5.5 describe the purpose and operations of pharmacy inspections

5.6 detail the responsibilities of an owner and/or a manager

5.7 detail the necessary security measures

Jurisprudence Sub-Competency #6

Pharmacists can explain the code of ethics

Competency Elements

Pharmacists can

6.1 outline the code of ethics

6.2 explain professional ethical principles

Jurisprudence Sub-Competency #7

Pharmacists can demonstrate basic knowledge of the legal requirements for manufacturers of drugs and devices

Competency Elements

Pharmacists can

7.1 explain the basic requirements regarding manufacturers' advertising

7.2 describe drug dosage limits, package size restrictions and labeling requirements

7.3 describe the basics of manufacturers' responsibility with regard to drug recalls

7.4 describe the basic requirements for the importation and exportation of drugs

7.5 describe "Notice of Compliance" and the "Drug Identification Number" (DIN)

7.6 describe the basics of Establishment Licensing and applications of the Good Manufacturing Practices (GMP) requirements

Jurisprudence Sub-Competency #8

Pharmacists exercise professional judgment in ethical and legal decision-making

Competency Elements

Pharmacists

8.1 explain the peer review process as it relates to exercising professional judgment

8.2 assess situations and apply profession judgment in a reasonable manner as judged by peers

8.3 use gained knowledge and experience in legal decision-making

Jurisprudence Sub-Competency #9

Pharmacists can explain the meaning of fundamental legal terms which are relevant to pharmacy

Competency Elements

Pharmacists can:

9.1 identify and define fundamental legal terms, for example

- drug
- hospital
- intern
- pharmacist
- pharmacy
- prescriber/practitioner
- prescription
- sell
- registered pharmacy student
- pharmacy technician or assistant

9.2 explain the relevance of the legal terms to the practice of pharmacy

Jurisprudence Sub-Competency #10

Pharmacists can describe the role, structure, function and mandate of the Provincial and Territorial Regulatory Authorities

Competency Elements

Pharmacists can

10.1 define regulatory authority

10.2 describe the role and function of the administration, management and governance of the Provincial or Territorial Regulatory Authority

10.3 distinguish among by-laws, policies, rules, guidelines and regulations

10.4 discuss other professional acts and how other health professions are regulated

10.5 discuss scope of practice, authorized acts and protected titles

10.6 compare the public interest role with that of advocacy