Alberta College of Pharmacy

Standards of Practice for Pharmacists and Pharmacy Technicians

Effective January 2022

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Introduction

These standards are made under the authority of Section 133 of the *Health Professions Act*. They are one component of the law that governs the practice of pharmacy in Alberta.

These standards are part of and must be read in the overall legislative scheme that regulates the practice of pharmacists, the practice of pharmacy technicians, the operation of pharmacies, and the sale of food and drug products, which includes

- the *Health Professions Act*,
- the Pharmacists and Pharmacy Technicians Profession Regulation,
- the Alberta College of Pharmacy Code of Ethics,
- the *Pharmacy and Drug Act*,
- the Pharmacy and Drug Regulation,
- the Standards for the Operation of Licensed Pharmacies,
- the *Food and Drug Act*,
- the Food and Drug Regulations, and
- the *Animal Health Act*.

Pharmacists and pharmacy technicians practising in Alberta must know, understand and comply with this overall legislative scheme.

These standards are mandatory. They set out the minimum acceptable standard of practice for pharmacists and pharmacy technicians.

For each standard, there is a basic statement of principle followed by detailed rules set out in the application of standard. Both the basic statement of principle and the detailed rules are mandatory.

Definitions

1. Throughout the standards:

a) **animal** means any animal other than a human being;

b) **authorization to administer drugs by injection** means authorization to administer anything by an invasive procedure on a body tissue below the dermis or the mucous membrane for the purpose of administering subcutaneous or intramuscular injections under Section 16(5) of the Pharmacists and Pharmacy Technicians Profession Regulation;

c) **additional prescribing authorization** means authorization to prescribe under Sections 16(3) and (4) of the Pharmacists and Pharmacy Technicians Profession Regulation;

d) **collaborative relationship** means a relationship between two or more regulated health professionals that is developed to:

i. facilitate communication,

ii. determine mutual goals of therapy that are acceptable to the patient,

iii. share relevant health information, and

iv. establish the expectations of each regulated health professional when working with a mutual patient;

e) **emergency** means a circumstance where a patient urgently requires a professional service that includes a restricted activity for the purposes of preventing imminent mortality or morbidity.

f) **employee** means an individual employed in a pharmacy who is not a regulated member and includes a volunteer who works in a pharmacy;

g) **health care facility** means:

i. a hospital as defined in the *Hospitals Act*,

ii. a nursing home as defined in the *Nursing Homes Act*,

iii. a correctional institution as defined in the *Corrections Act*, or

iv. a facility as defined in the *Mental Health Act*;

h) **health care products, aids or devices** means:

i. devices as defined in the *Food and Drugs Act* (Canada);

ii. natural health products as defined in the Natural Health Products Regulations (Canada); and

iii. products, aids and devices that promote health and treat diseases, dysfunctions and disorders;

i) **herd** means a group or population of animals that cohabitate and feed together in the same environment and includes flocks, schools, or hives;

j) **medically important antimicrobial** means an antimicrobial drug or class of drugs used in human medicine that can also be used in animals[1];

1 A comprehensive list of medically important antimicrobials appears on List A, the document entitled List of Certain Antimicrobial Active Pharmaceutical Ingredients, that is published by the Government of Canada on its website, as amended from time to time.

k) **patient** means any human or animal to whom a regulated member provides a service that is within the scope of the practice of pharmacists or the practice of pharmacy technicians;

l) **patient's agent** means

i. in the case of a human who is the patient, a family member, caregiver or another individual who has a close personal relationship with the patient; and

ii. in the case of an animal who is the patient, an owner, an agent or employee of an owner, or caregiver of the animal or herd;

m) **pharmacist** means a clinical pharmacist, a provisional pharmacist, a courtesy pharmacist or a student pharmacist, unless the context requires otherwise;

n) **pharmacist service** means any service that falls within the practice of pharmacists;

o) **pharmacy technician** means a pharmacy technician, courtesy pharmacy technician, or a provisional pharmacy technician unless the context requires otherwise;

p) **pharmacy technician service** means any service that falls within the practice of pharmacy technicians;

q) **practice of pharmacists** means the scope of practice described in Section 3(1) of Schedule 19 to the *Health Professions Act*;

r) **practice of pharmacy technicians** means the scope of practice described in Section 3(2) of Schedule 19 to the *Health Professions Act*;

s) **prescriber** means

i. in respect of a prescription for a human, a regulated health professional who is authorized to prescribe Schedule 1 drugs or blood products under the *Health Professions Act* or similar legislation that governs a regulated health professional in another province or territory; or

ii. in respect of a prescription for an animal,

A. a veterinarian who is authorized to prescribe drugs or blood products to animals under the *Veterinary Profession Act* or similar legislation that governs the veterinary profession in another province or territory; and

B. a pharmacist who adapts a prescription from a veterinarian under clause A for the purpose of providing continuity of care;

t) **prescribing at initial access** means prescribing a drug or blood product under Sections 16(3) and (4) of the Pharmacists and Pharmacy Technicians Profession Regulation when the patient does not have a current prescription or has not recently had a prescription;

u) **prescribing to manage ongoing therapy** means prescribing a drug or blood product under Sections 16(3) and (4) of the Pharmacists and Pharmacy Technicians Profession Regulation when the patient has a current prescription or has recently had a prescription;

v) **professional service** means any service that falls within the practice of pharmacists or the practice of pharmacy technicians;

w) **professional relationship** means

i. in respect of a patient who is a human, a relationship formed with a patient for the purpose of optimizing the patient's health or drug therapy; and

ii. in respect of a patient who is an animal, a relationship formed with the patient's agent for the purpose of optimizing the patient's health or drug therapy;

x) **regulated health professional** means

i. in the case of humans, a health professional who practises under the terms of the *Health Professions Act* or similar legislation that governs a health profession in Alberta; and

ii. in the case of animals, a veterinarian or veterinary technologist who practises under the terms of the *Veterinary Profession Act*.

y) **regulated member** means an individual registered on a register referred to in Section 2 of the Pharmacists and Pharmacy Technicians Professions Regulation;

z) **residue** has the same meaning as in the *Animal Health Act*[2];

aa) **restricted activity**[3] means an activity named as a restricted activity in Section 2 of Schedule 7.1 of the *Government Organization Act*;

ab) **withdrawal time** has the same meaning as in the *Animal Health Act*.

2. Unless these standards provide a more specific definition, terms used in these standards have the same meaning as in Schedule 19 to the *Health Professions Act*, the Pharmacists and Pharmacy Technicians Profession Regulation, the *Pharmacy and Drug Act*, or the Pharmacy and Drug Regulation[4].
3. All provisions in these standards that are applicable to Schedule 1 drugs also apply to blood products, with all necessary modifications.
4. Where a provisional pharmacist, courtesy pharmacist or student pharmacist engages in the practice of pharmacists, that provisional pharmacist, courtesy pharmacist or student pharmacist must comply with those standards applicable to the practice of a clinical pharmacist.
5. Where a provisional or courtesy pharmacy technician engages in the practice of pharmacy technicians, that provisional or courtesy pharmacy technician must comply with those standards applicable to a pharmacy technician.
6. Where a patient is an animal, all duties under these standards that contemplate communication from a patient or that require communication with a patient must be read as requiring communication from or with the patient's agent.
7. Where a patient is an animal, all duties under these standards that contemplate when an animal may enter the food chain should be read to include an animal or any animal products that may enter the food chain for human consumption.

2 "residue" means medicine, chemicals, or deleterious substances or their metabolized products remaining in animals, animal products, animal by-products, or animal tissues;

3 The concept of "restricted activities" only applies to human beings.

4 For example:
Section 1 of the *Pharmacy and Drug Act*, which defines compound (b.1), council (c), dispense (d) and drug (e); and
Section 1 of the Pharmacy and Drug Regulation, which defines dispensary (1)(e), patient services area (1)(h), prescription department (2)(a).

Standards

Act professionally

- Standard 1:

  Pharmacists and pharmacy technicians must act professionally.

Establish and maintain professional relationships with patients

- Standard 2:

  Pharmacists and pharmacy technicians must establish and maintain professional relationships with their patients.

Consider appropriate information

- Standard 3:

  Pharmacists must consider appropriate information for each patient.

Determine whether there is a drug therapy problem

- Standard 4:

  Pharmacists must determine whether a patient has or is likely to have a drug therapy problem.

Take appropriate action if there is a drug therapy problem

- Standard 5:

  If a pharmacist determines that a patient has or is likely to have a drug therapy problem, the pharmacist must take appropriate action.

  If a pharmacy technician determines that a patient has or is likely to have drug therapy problem, the pharmacy technician must refer the patient to a pharmacist so that the pharmacist can take appropriate action.

Determine the appropriateness of each prescription

- Standard 6:

  Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription:

  a) the pharmacist must determine that the prescription is appropriate; and

  b) the pharmacist or the pharmacy technician must determine that the prescription is current, authentic, and complete.

Follow proper procedures when dispensing

- Standard 7:

  Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, the pharmacist or the pharmacy technician must ensure that:

  a) the prescription is filled correctly,

  b) appropriate dispensing procedures are used,

c) the drug or blood product is packaged properly,

d) the container is labeled properly, and

e) a final check is performed.

Release of drugs and providing patients with sufficient information

- Standard 8:

  Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, or sells a Schedule 2 drug:

  a) the pharmacist or the pharmacy technician must confirm the patient's identity, and

  b) the pharmacist must provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy.

Offer assistance with Schedule 3 products

- Standard 9:

  A pharmacist or a pharmacy technician must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug or a health care product, aid or device.

Compound according to written formula and process

- Standard 10:

  Each time a pharmacist or a pharmacy technician compounds a drug or a blood product, the pharmacist or the pharmacy technician must ensure that the compounded drug or blood product is prepared according to:

  a) a written compounding formula, and

  b) a written preparation process.

Comply with regulatory framework if prescribing

- Standard 11:

  A pharmacist who prescribes a Schedule 1 drug or blood product must understand the regulatory framework in relation to pharmacist prescribing and must comply with it.

Follow proper procedures when adapting a prescription

- Standard 12:

  A pharmacist who adapts an existing prescription under Sections 16(1)(e) and (f) of the Pharmacists and Pharmacy Technicians Profession Regulation must:

  a) have the original prescription,

  b) determine whether adapting the prescription is appropriate in the circumstances,

  c) document the adaptation, and

  d) inform the original prescriber.

Adhere to restrictions when prescribing in an emergency

- Standard 13:

  A pharmacist who prescribes for emergency purposes under Sections 16(1)(g) and (h) of the Pharmacists and Pharmacy Technicians Profession Regulation must:

  a) be satisfied that it is not reasonably possible for the patient to see another health professional to obtain the prescription,

  b) be satisfied that there is an immediate need for drug therapy, and

  c) only prescribe the minimum amount of the drug or blood product necessary to give the patient sufficient time to see a prescriber.

Base prescribing at initial access or to manage ongoing therapy on appropriate information

- Standard 14:

  A pharmacist with additional prescribing authorization must prescribe based on:

  a) the pharmacist's own assessment of the patient,

  b) a recommendation from a prescriber that the patient receive a Schedule 1 drug or blood product, or

  c) a consultation with another regulated health professional.

Separate prescribing and dispensing

- Standard 15:

  A pharmacist who prescribes a drug or blood product at initial access based on the pharmacist's own assessment of the patient must not dispense the drug him or herself, unless:

  a) the pharmacist is satisfied that adhering to this standard will compromise the health of the patient, or

  b) the patient chooses to have the pharmacist dispense the drug.

Ensure proper procedures and environment when administering a drug, blood product or vaccine

- Standard 16:

  A pharmacist who administers a drug, blood product or vaccine must:

  a) have policies and procedures for handling emergencies; and

  b) ensure that the environment in which the drug, blood product or vaccine is to be administered is appropriate.

Ensure patient safety when administering a drug, blood product or vaccine

- Standard 17:

  A pharmacist who administers a drug, blood product or vaccine must have proper regard for the interests of the patient and take all steps necessary to ensure that the drug, blood product or vaccine is administered safely.

Create and maintain patient records

- Standard 18:

  A pharmacist must create and maintain patient records for the pharmacist services provided by that pharmacist.

  A pharmacy technician must create and maintain patient records for pharmacy technician services provided by that technician.

Do not accept drugs or health products for reuse

- Standard 19:

  Neither a pharmacist nor a pharmacy technician may accept the return of a drug or a health care product, aid or device for reuse.

Provide direction and supervise others responsibly

- Standard 20:

  A pharmacist who provides direction to a pharmacy technician must do so in accordance with Section 21(3) of the Pharmacists and Pharmacy Technicians Profession Regulation.

  A pharmacist who supervises others in the practice of pharmacists or the practice of pharmacy technicians, or a pharmacy technician who supervises others in the practice of pharmacy technicians must:

  a) do so in accordance with Section 23 of the Pharmacists and Pharmacy Technicians Profession Regulation,

  b) ensure that the person being supervised acts within the limits established by the Pharmacists and Pharmacy Technicians Profession Regulation, and

  c) remain responsible for the delivery of all components of any restricted activity that requires the professional skills and training of the pharmacist or the pharmacy technician.

Protect patient safety when repackaging

- Standard 21:

  A pharmacist or a pharmacy technician who repackages drugs must take appropriate steps to protect patient safety.

Limits on insertion or removal of instruments, devices, or fingers under section 16(1)(d)(i) and (ii) of the Pharmacists and Pharmacy Technicians Regulation.

- Standard 22:

  In the practice of a pharmacist, a pharmacist must not insert or remove instruments, devices or fingers beyond the anal verge or beyond the labia majora, except if

  a) it is for the purposes of administering a drug or medication;

  b) it is an emergency;

  c) the patient is not able to take the drug or medication orally or the drug or medication requires intra-anal or intra-vaginal administration to achieve the intended therapeutic effect; and

  d) another appropriately authorized regulated health professional is not readily available to insert or remove instruments, devices or fingers beyond the anal verge or beyond the labia major for the purpose of the administration of the drug or medication.

Act professionally

Standard 1: Pharmacists and pharmacy technicians must act professionally.

Application of Standard 1

Compliance with the law

1.1 Pharmacists and pharmacy technicians must practice in accordance with the law that governs each of their practices, including but not limited to:

a) the *Health Professions Act*, its regulations, these standards;

b) the *Pharmacy and Drug Act*, its regulations, and the Standards for the Operation of Licensed Pharmacies;

c) the Code of Ethics;

d) Section 7.1 of the *Government Organization Act*;

e) the *Food and Drugs Act* and its regulations;

f) the *Controlled Drugs and Substances Act*, and its regulations, including the Narcotic Control Regulations;

g) the *Health Information Act* and its regulations; and

h) the *Animal Health Act*.

1.2 In approaching the law that governs their practices, pharmacists and pharmacy technicians must comply with its letter and its spirit to ensure that the public and each patient receive the full protection of the law.

1.3 Pharmacists and pharmacy technicians have a duty to be aware of changes in the law that governs their practices and adjust their practices to ensure compliance with the changes.

Working collaboratively with colleagues

1.4 When required to serve the best interests of the patient, each pharmacist and pharmacy technician must work collaboratively with colleagues, including other regulated health professionals, in the provision of pharmacist and pharmacy technician services. This obligation includes but is not limited to:

a) treating colleagues with respect,

b) acting as a positive role model,

c) fulfilling obligations to colleagues in a timely manner,

d) making appropriate and efficient use of the expertise and availability of colleagues, and

e) developing and maintaining collaborative relationships.

1.5 A pharmacist must not provide pharmacist services to a patient who cannot be appropriately treated within the practice of pharmacists.

1.6 A pharmacy technician must not provide pharmacy technician services to a patient who cannot be appropriately treated within the practice of pharmacy technicians.

1.7 A pharmacist must:

a) only practice within the practice of pharmacists;

b) only engage in restricted activities;

that the pharmacist is authorized and competent to perform and that are applicable to the pharmacist's practice and the procedure being performed.

c) For animals, only engage in

i. the activities of compounding, dispensing and selling drugs for animals; and

ii. the prescribing of drugs for the purpose of renewing a prescription to dispense a Schedule 1 drug, schedule 2 drug, or blood product to ensure continuity of care

that the pharmacist is competent to perform and that are applicable to the pharmacist's practice;

d) be aware of the limits of the pharmacist's personal competence and only provide pharmacist services within these limitations; and

e) be aware of the circumstances in which the pharmacist should refer the patient to another appropriately qualified regulated health professional, including when:

i. the pharmacist does not have the training, experience or skills necessary to address the patient's needs;

ii. the condition of the patient cannot be effectively treated within the practice of pharmacists; or

iii. the patient's condition has not adequately or appropriately responded to drug therapy or other therapy within the practice of pharmacists.

1.8 A pharmacy technician must:

a) only practice within the practice of pharmacy technicians;

b) only engage in restricted activities that the pharmacy technician is authorized and competent to perform, and that are applicable to the pharmacy technician's practice and the procedure being performed;

c) For animals, only engage the activities of compounding, dispensing and selling drugs that the pharmacy technician is competent to perform and that are applicable to the pharmacy technician's practice;

d) be aware of the limits of the pharmacy technician's personal competence and only provide services within these limitations; and

e) be aware of circumstances in which the pharmacy technician should refer the patient to a pharmacist, including when:

i. the pharmacy technician identifies an actual or potential drug therapy problem;

ii. alerts are generated by the pharmacy software system during entry or processing of a prescription that require therapeutic knowledge, clinical analysis or assessment; or

iii. the patient asks questions or seeks information that requires therapeutic knowledge, clinical analysis or assessment.

1.9 A pharmacist must not:

a) sell a schedule 2 drug for use in an animal without a prescription, or

b) recommend a schedule 3 or non-scheduled drug for use in an animal without an assessment by a veterinarian.

Participation in quality assurance processes

1.10 Each pharmacist and pharmacy technician must participate in the quality assurance processes required by the Standards for the Operation of Licensed Pharmacies or another workplace quality assurance program applicable to the pharmacists' or the pharmacy technicians' practice.

1.11 A pharmacist who provides patient care in an environment where a quality assurance program does not exist or does not meet the minimum standards established under the Standards for the Operation of Licensed Pharmacies must implement a program that meets or exceeds the requirements outlined in the Standards for the Operation of Licensed Pharmacies.

Appearance, demeanour and identification as a regulated pharmacy professional

1.12 When engaged in their practices, each pharmacist and pharmacy technician must:

a) maintain a professional appearance and demeanour; and

b) be readily identifiable to the public, other regulated health professionals and other workers in the health care system as a pharmacist or pharmacy technician as the case may be.

Preservation of professional independence

1.13 A pharmacist must not practice under conditions that compromise the pharmacist's professional independence, judgment or integrity.

1.14 A pharmacy technician must not practice under conditions that compromise the pharmacy technician's professional independence, judgment or integrity.

1.15 No pharmacist or pharmacy technician may impose conditions on another pharmacist, pharmacy technician or other regulated health professional that compromises the other professional's independence, judgment or integrity.

1.16 Neither a pharmacist nor a pharmacy technician may:

a) accept gifts or other benefits from, or

b) enter into any association with,

a patient, regulated health professional or any other person that could have the effect of compromising his or her professional independence, judgment or integrity.

1.17 Nothing in Standard 1.14 to 1.16 limits the obligation of a pharmacy technician to practice under the direction of a clinical pharmacist or courtesy pharmacist in accordance with Schedule 19, Section 3(2) of the *Health Professions Act* and Section 21 of the Pharmacists and Pharmacy Technicians Profession Regulation.

1.18 In Standard 1.19 and 1.20:

a) "inducement" means

i. a reward,

ii. a gift, including a gift of cash,

iii. a prize,

iv. a coupon,

v. points or other mechanisms in incentive or loyalty programs that can be redeemed for rewards, gifts, cash, prizes or other goods or services; and

b) "drug product" means

i. a Schedule 1 drug,

ii. a Schedule 2 drug,

iii. a blood product, or

iv. a Schedule 3 drug that is provided under a prescription.

1.19 A regulated member must not offer or provide or be party to the offering or provision of an inducement to a patient where the inducement is offered or provided on the condition that the patient obtains:

a) a drug product, or

b) a professional service

from the regulated member or licensed pharmacy.

1.20 The following are not prohibited under Standard 1.19:

a) the provision of a drug product, professional service or health care product, aid or device to a patient by a regulated member or licensed pharmacy where, in the professional opinion of the regulated member, it

i. is required for compassionate reasons based on the circumstances of the patient, and

ii. will support the health care of the patient; and

b) the provision of a drug product, professional service or health care product, aid or device to augment drug therapy or augment a professional service provided by a regulated member.

1.21 Nothing in Standard 1.19 is intended to limit a regulated member from taking any steps required or necessary to comply with the law that governs the practice of pharmacy referred to in Standard 1.1.

1.22 A pharmacist must not prescribe a drug or blood product for:

a) the pharmacist,

b) a family member of the pharmacist, or

c) anyone else with whom the pharmacist has a close personal relationship;

except for minor conditions, in an emergency, or when another prescriber is not readily available to prescribe the drug or blood product.

Requirement to be trained in CPR and first aid

1.23 A pharmacist must maintain current certificates in cardiopulmonary resuscitation (CPR) and first aid, at a level determined by Council, if the pharmacist has been authorized to administer drugs by injection.

Facilitating compliance with the *Protection of Students with Life Threatening Allergies Act*

1.24 Subject to the directions of Council, a pharmacist or a pharmacy technician practising with the pharmacist may sell epinephrine auto-injectors to an individual authorized by a school board* to purchase epinephrine auto-injectors to be maintained in a school under the *Protection of Students with Life Threatening Allergies Act* despite the requirements in these standards respecting identification, assessment, communication, documentation and record keeping on a patient specific basis.

* As defined within the *Protection of Students with Life-Threatening Allergies Act* (2019)

Establish and maintain professional relationships with patients

Standard 2: Pharmacists and pharmacy technicians must establish and maintain professional relationships with their patients.

Application of Standard 2

2.1 A pharmacist must:

a) establish a professional relationship with each patient to whom the pharmacist provides services,

b) identify each patient's health needs and expectations,

c) collect the information required to provide pharmacist services to the patient,

d) take all information collected into consideration when providing the pharmacist services, and

e) make decisions in the best interest of the patient.

2.2 A pharmacy technician must:

a) establish a professional relationship with each patient to whom the pharmacy technician provides services,

b) assist the pharmacist in identifying the patient's health needs and expectations,

c) collect the information required to provide pharmacy related services to the patient,

d) take all information collected into consideration when:

i. providing dispensing, compounding or undertaking other pharmacy related services; and

ii. determining whether the patient must be referred to the pharmacist; and

e) make decisions in the best interest of the patient.

2.3 In the case of a patient who is a human, each pharmacist and pharmacy technician must deal directly with the patient unless:

a) it is in the best interest of the patient for the pharmacist or the pharmacy technician to deal with the patient's agent,

b) the pharmacist is satisfied that a regulated health professional acting within the scope of their profession is responsible for the administration of drugs to the patient.

2.4 In the case of a patient who is a human, the following factors may be taken into account in determining whether dealing with a patient's agent is in the best interests of the patient:

a) the express wishes of the patient,

b) the patient's health,

c) the patient's age,

d) the patient's mental state and capacity, and

e) the patient's absence from the area where the service is being provided.

2.5 All standards applicable to the relationship between the pharmacist or pharmacy technician and the patient apply to the pharmacist or pharmacy technician and the patient's agent with the necessary modifications to make them effective.

2.6 Nothing in this standard relieves a pharmacist or a pharmacy technician from the duty to see a patient personally where specifically required elsewhere in these standards.

Termination of patient relationship

Termination at the patient's request

2.7 A pharmacist and a pharmacy technician must honour a patient's request to transfer care to another health professional.

2.8 As soon as reasonably possible after receipt of a request from a patient to transfer care to another pharmacist, the pharmacist or the pharmacy technician must provide to the pharmacist of the patient's choice:

a) transfer of active prescriptions with remaining refills that can be legally transferred; and

b) other information that, in the opinion of the transferring pharmacist, may be required to ensure continuity of care, including but not limited to:

i. current prescriptions with no refills remaining,

ii. current prescriptions that cannot be legally transferred,

iii. inactive or discontinued prescriptions that may affect current care,

iv. drug therapy problems identified, and

v. monitoring and follow-up plans currently in place.

Termination by the pharmacist

2.9 A pharmacist who terminates a relationship with a patient must:

a) do so in accordance with Principle Five of the Alberta College of Pharmacy Code of Ethics,

b) have reasonable grounds for ceasing to provide care to the patient and document those reasons on the patient record, and

c) give advance notice of the intention to terminate care and provide a timeline that is commensurate with the continuing care needs of the patient.

2.10 Notwithstanding Standard 2.9, a pharmacist may terminate a relationship with a patient without providing advance notice if:

a) the patient poses a risk to the pharmacist, pharmacy staff or other patients;

b) the patient fails to respect professional boundaries;

c) the pharmacist is leaving the practice location and another pharmacist will assume the practice in the same location; or

d) the pharmacist is leaving practice because of personal illness or other urgent circumstances; and

the pharmacist provides for continuity of care by offering to provide information to another pharmacist.

Consider appropriate information

Standard 3: Pharmacists must consider appropriate information for each patient.

Application of Standard 3

Duty to consider appropriate information

3.1 A pharmacist must consider appropriate information to assess the patient and the patient's health history and history of drug therapy each time:

a) the pharmacist:

i. prescribes a Schedule 1 drug or blood product;

ii. conducts a review of a patient's drug utilization; or

iii. provides advice to a patient about a drug, a blood product or drug therapy.

b) the pharmacist or a pharmacy technician practising with the pharmacist:

i. dispenses a Schedule 1 drug or blood product under a new or a repeat prescription, or

ii. dispenses or sells a Schedule 2 drug.

3.2 Notwithstanding Standard 3.1(b), a pharmacist may delay the assessment of a patient if the pharmacist is satisfied that:

a) drugs are dispensed in frequent, limited quantities only to assist patient to self-administer or to comply with distribution processes in institutions; or

b) drugs will only be administered by another regulated health professional; and

c) the delay will not negatively impact the patient.

3.3 A pharmacist who delays an assessment under Standard 3.2 must ensure that appropriate information to assess the patient and the patient's health history and history of drug therapy is completed each time a new prescription or drug order is received, or every 90 days, whichever comes first.

Meaning of appropriate information

3.4 Appropriate information means the following information in relation to a patient:

a) health condition to be treated and history of the condition;

b) symptoms or signs to be treated;

c) treatment history for the condition including drug therapy and outcomes;

d) age;

e) pregnancy or lactation status, if applicable;

f) allergies or intolerances to drugs, excipients or other products that may affect drug therapy;

g) other drugs or blood products being used;

h) other health care products, aids and devices or other products being used that may affect the pharmacist's decision;

i) other health conditions that may affect the pharmacist's decision; and

j) any other information that a reasonable pharmacist would require to provide the pharmacist service.

Additional information that may be required

3.5 Information that may be required under Standard 3.4(j) includes:

a) patient demographic information;

b) patient's weight or other physical characteristics;

c) identity of other regulated health professionals or caregivers who are providing care to the patient;

d) diagnosis;

e) laboratory values;

f) relevant medical history;

g) lifestyle information and social history, including tobacco, alcohol or recreational drug use; and

h) if the patient is an animal,

i. animal species; and

ii. whether the animal may enter the food chain.

Determine whether there is a drug therapy problem

Standard 4: Pharmacists must determine whether a patient has or is likely to have a drug therapy problem.

Application of Standard 4

Pharmacists' duty in relation to drug therapy problems

4.1 A pharmacist must consider whether a patient has a drug therapy problem or is likely to have a drug therapy problem, each time:

a) the pharmacist:

i. prescribes a Schedule 1 drug or blood product;

ii. conducts a review of a patient's drug utilization; or

iii. provides advice to a patient about a drug, a blood product or drug therapy;

b) the pharmacist or a pharmacy technician:

i. dispenses a Schedule 1 drug or blood product pursuant to a new or a refill prescription, or

ii. dispenses or sells a Schedule 2 drug.

Meaning of a drug therapy problem

4.2 A drug therapy problem includes the following circumstances in relation to a patient:

Name of problem	**Description of problem**
a) Untreated condition	Requiring a drug or blood product but not receiving it
b) Drug selection	Taking or receiving the wrong drug or blood product
c) Sub-therapeutic dosage	Taking or receiving too little of the right drug or blood product
d) Over dosage	Taking or receiving too much of the right drug or blood product
e) Non-adherence	Failure to take or receive a drug or blood product or taking or receiving a drug or blood product inappropriately
f) Adverse reaction	Experiencing an adverse reaction to a drug or blood product
g) Drug interaction	Experiencing a drug interaction or blood product interaction including drug-drug, drug- food, drug-laboratory test, drug-disease, or drug-blood product
h) No indication	Taking or receiving a drug or blood product for no medically valid indication or substance abuse

Take appropriate action if there is a drug therapy problem

Standard 5: If a pharmacist determines that a patient has or is likely to have a drug therapy problem, the pharmacist must take appropriate action.

If a pharmacy technician determines that a patient has or is likely to have a drug therapy problem, the pharmacy technician must refer the patient to a pharmacist so that the pharmacist can take appropriate action.

Application of Standard 5

Pharmacist to use professional judgment in relation to drug therapy problem

5.1 If a patient has or is likely to have a drug therapy problem, the pharmacist must determine the appropriate response.

Pharmacy technician to use professional judgment in relation to drug therapy problem

5.2 A pharmacy technician who determines that a patient has or is likely to have a drug therapy problem must bring the problem or the potential problem, and any contributing factors identified, to the attention of the pharmacist for consideration as outlined in Standard 5.1.

Nature of the appropriate response to a drug therapy problem

5.3 The appropriate response to a drug therapy problem may include any one or more of the following:

a) gathering additional information from the patient, the patient's health record, the patient's agent or another regulated health professional;

b) implementing a plan to monitor the occurrence and impact of the drug therapy problem with mechanisms for intervention when required;

c) resolving or reducing the drug therapy problem to a clinically acceptable level by adapting a prescription under Section 16(1)(e) of the Pharmacists and Pharmacy Technicians Profession Regulation;

d) advising the patient or the prescriber or both about the drug therapy problem and suggesting an alternative;

e) entering into a collaborative relationship with another regulated health professional to manage the patient's drug therapy;

f) refusing to dispense or sell the drug or blood product to the patient;

g) in the case of a patient who is a human, reporting an adverse reaction to the original prescriber and to the Canadian Adverse Drug Reaction Monitoring Program; or

h) in the case of a patient who is an animal, reporting an adverse reaction to the prescribing veterinarian, and reporting an adverse reaction:

i. to a drug in an animal to Health Canada's Veterinary Drugs Directorate; or

ii. to a veterinary biologic to the Canadian Centre for Veterinary Biologics.

Changes to prescriptions to be documented

5.4 If a pharmacist or pharmacy technician changes a prescription as a result of an authorization received from the original prescriber, the pharmacist or pharmacy technician must document and initial or sign the change on the original prescription or drug order.

Determine the appropriateness of each prescription

Standard 6: Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription:

a) **the pharmacist must determine that the prescription is appropriate; and**

b) **the pharmacist or the pharmacy technician must determine that the prescription is current, authentic, and complete.**

Application of Standard 6

Factors to be considered in determining the appropriateness of a prescription

6.1 A pharmacist must determine the appropriateness of a prescription by considering relevant factors that a reasonable pharmacist would consider in the circumstances.

6.2 For the purposes of Standard 6.1,

a) for all prescriptions for all patients the relevant factors include, but are not limited to whether

i. the prescription is accurate;

ii. the prescription orders a drug or blood product for an indication that is:

A. approved by Health Canada,

B. considered a best practice or accepted clinical practice in peer-reviewed literature, or

C. part of an approved research protocol;

iii. the dose, frequency and route of administration are appropriate;

iv. there is therapeutic duplication;

v. there are actual or potential adverse reactions, allergies, or sensitivities;

vi. there are actual or potential drug interactions;

vii. the regimen for administration is practical, based on the patient's functional ability; and

viii. any information was brought to the pharmacist's attention by a pharmacy technician involved in the care of the patient;

b) for a refill prescription, in addition to the factors under subsection a), the relevant factors include, but are not limited to:

i. continued need for the drug,

ii. the date of the last fill,

iii. patient compliance with drug therapy, and

iv. the patient's response to the drug therapy;

c) for a patient that is a human, in addition to the factors under subsection a) and b), where applicable, the relevant factors include but are not limited to whether:

i. the patient's organ function, such as renal and hepatic function, will tolerate the drug or blood product;

ii. the results of laboratory or other tests, if applicable, affect the appropriateness of the drug or blood product; and

iii. other patient-specific characteristics such as age, pregnancy or lactation status, cognitive, mental and physical challenges, lifestyle, cultural beliefs or living environment may affect the appropriateness of the drug or blood product;

d) for a patient that is an animal, in addition to the factors under subsection a) and b), where applicable, the relevant factors include, but are not limited to, whether:

i. the dosage form provided is appropriate for use in the animal;

ii. if the prescription is for a drug containing a medically important antimicrobial; and

iii. there are any other barriers to care that are brought to the pharmacist's attention by the patient's agent;

e) for a patient that is an animal that may enter the food chain, in addition to the factors under subsection a), b), where applicable, and d), consideration of relevant factors include but are not limited to when the animal will enter the food chain for human consumption; and

f) for patients in a herd of animals, in addition to the factors under subsection a), b), where applicable, d) and e), consideration of relevant factors includes, but is not limited to how many animals in the herd will be treated.

Determining the currency of a prescription

6.3 Before dispensing a prescription, a pharmacist or a pharmacy technician must review the prescription to determine when it was written.

6.4 Neither a pharmacist nor a pharmacy technician may dispense a drug or blood product under a prescription that was issued more than one year before the date the drug or blood product is to be dispensed.

6.5 Neither a pharmacist nor a pharmacy technician may refill a prescription for:

a) a benzodiazepine or other targeted substance, as defined in the regulations to the *Controlled Drugs and Substances Act*, for a period of greater than 12 months after the prescription was first written; or

b) a Schedule 1 drug for a period greater than 18 months after the prescription was first filled.

Determining the authenticity of a prescription

6.6 Before dispensing a prescription, a pharmacist or a pharmacy technician must determine the authenticity of the prescription by taking reasonable steps to:

a) identify the prescriber;

b) determine whether the prescriber is legally authorized to prescribe the drug or blood product for which the prescription has been given; and

c) assess whether the prescription has been altered, forged, or stolen.

Determining the completeness of a prescription

6.7 Prior to dispensing a prescription, a pharmacist or a pharmacy technician must determine the completeness of a prescription by ensuring that the prescription includes the:

a) name and address of the patient, or in the case of a herd of animals, a unique identifier or the location of the herd;

b) drug or blood product name;

c) drug strength, if applicable;

d) dosage, if applicable;

e) route of administration, if applicable;

f) quantity of drug or blood product to be dispensed;

g) directions for use;

h) number of refills authorized and interval between each refill, if applicable;

i) prescriber's name and phone number;

j) prescriber's signature, in the case of a written prescription;

k) the date of the prescription;

l) the withdrawal time if the prescription is for an animal that may enter the food chain; and

m) the number of animals treated if the prescription is for a herd of animals.

6.8 In addition to the information required in Standard 6.7, when considering the completeness of a prescription for medicated feed for animals, a pharmacist or a pharmacy technician must ensure that the prescription includes:

a) the species, production type and age or weight of the animals to be treated with the medicated feed;

b) the number of animals treated if the prescription is for a herd of animals;

c) the type and amount of medicated feed to be mixed;

d) the proper name, or the common name if there is no proper name, of the drug or each of the drugs, as the case may be, to be used as medicating ingredients in the preparation of the medicated feed, and the dosage levels of those medicating ingredients;

e) any special mixing instructions;

f) labelling instructions including

i. feeding instructions,

ii. a warning statement respecting the withdrawal period to be observed following the use of the medicated feed, and

iii. where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.

Verbal order to be reduced to writing

6.9 If a pharmacist or a pharmacy technician receives a verbal order for a drug or blood product from a prescriber, the pharmacist or the pharmacy technician must reduce the prescription to writing and sign or initial the prescription.

Follow proper procedures when dispensing

Standard 7: Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, the pharmacist or the pharmacy technician must ensure that:

a) the prescription is filled correctly,
b) appropriate dispensing procedures are used,
c) the drug or blood product is packaged properly,
d) the container is labeled properly, and
e) a final check is performed.

Application of Standard 7

Filling the prescription correctly

7.1 A pharmacist or a pharmacy technician who dispenses a drug or blood product must ensure that:

a) the drug or blood product is correct and in accordance with the prescription; and

b) the dosage form, strength, manufacturer and quantity dispensed are correct and in accordance with the prescription.

Using appropriate dispensing procedures

7.2 A pharmacist or a pharmacy technician who dispenses a drug or blood product must ensure that his or her dispensing procedure:

a) is hygienic,

b) maintains the stability of the drug or blood product,

c) uses the proper diluents and mixing procedures where applicable,

d) prevents cross contamination, and

e) complies with any requirements applicable to the specific drug or blood product.

Proper packaging

7.3 A pharmacist or a pharmacy technician who dispenses a drug or blood product must ensure that the drug or blood product is dispensed:

a) in an appropriate package, having regard for the nature of the drug or blood product, including sensitivity to light and temperature; and

b) in a child-resistant package unless:

i. the prescriber or patient directs otherwise,

ii. the pharmacist or the pharmacy technician is satisfied that child-resistant packaging is not appropriate,

iii. child-resistant packaging is not suitable because of the form of the drug or blood product, or

iv. the pharmacist or the pharmacy technician is unable to obtain a child-resistant package for the drug or blood product because a supply of those packages is not reasonably available.

Duty to warn when child-resistant packaging not used

7.4 If a drug or blood product is not dispensed in a child-resistant package, the pharmacist or the pharmacy technician who dispenses the drug must be satisfied that:

a) the patient has been warned of the risks of not using a child-resistant package, or

b) the patient is aware of the associated risk.

Proper labeling

7.5 A pharmacist or a pharmacy technician who dispenses a drug or blood product must ensure that the container in which the drug or blood product is dispensed has a label that is clearly legible and includes the following:

a) the name of the patient for whom the drug or blood product is dispensed;

b) the name, address and telephone number of the pharmacy;

c) the name of the prescriber of the drug or blood product;

d) a description of the drug or blood product in English by:

i. generic name, strength and the identity of the manufacturer for single entity drugs;

ii. generic name, strength and the identity of the manufacturer for combination drugs, where possible, or the brand name and strength;

iii. name of compounded drugs or ingredients and strength; or

iv. in the case of a blood product, the name of the blood product;

e) instructions for the use of the drug or blood product;

f) a unique prescription number;

g) the date the drug or blood product was dispensed;

h) the quantity of the drug or blood product dispensed;

i) the number of refills remaining if applicable; and

j) the withdrawal time, if the prescription is for an animal that may enter the food chain.

Name of the pharmacy to be used

7.6 The name of the pharmacy under Standard 7.5(b) must be the name provided on the application for pharmacy licence or another name approved by the Registrar.

Special circumstances when a DIN may be used

7.7 Despite Standard 7.5(d), a pharmacist may use, or direct a pharmacy technician to use, only a Drug Identification Number (DIN) to identify the drug or blood product on the label in circumstances where:

a) it is in the best interests of the patient or required for the purpose of a medical or scientific investigation, and

b) the pharmacist has consulted with the prescriber.

Procedure if it is not practical to affix prescription label to drug package

7.8 When it is not practical to affix the prescription label to the drug package, a pharmacist or a pharmacy technician who dispenses the prescription must ensure that:

a) the prescription label is affixed to the outer container; and

b) another label is attached to the drug package containing, at a minimum, the patient's name, the name of the drug and the drug strength.

Procedure if it is not practical to affix prescription directions on the drug package

7.9 When it is not possible to place complete directions for use on the prescription label, the pharmacist or the pharmacy technician who dispenses the prescription must ensure that complete written directions are provided on an instruction sheet accompanying the drug.

Labeling for a scientific or medical investigation

7.10 Despite Standard 7.5, if a drug is dispensed as a part of an official scientific or medical investigation, the drug container may be labeled in a manner appropriate to the investigation as long as the information on the label ensures that the contents can be readily identified in an emergency.

Labeling to assist patients

7.11 Subject to meeting the requirements of Standard 7.5, a pharmacist or a pharmacy technician may use a form of label that provides additional information or forms of information to facilitate understanding by patients with special needs, including visually impaired or non-English speaking patients.

Labeling prescriptions for animals

7.12 In addition to the labeling requirements described in sections 7.5 to 7.11, when a pharmacist or pharmacy technician dispenses a drug or blood product for an animal or herd, the label must:

a) state "for veterinary use only",

b) include a means to identify the specific animal or herd for which the drug is dispensed;

c) include the species of the animal or herd;

d) include minimal withdrawal time, in the case of an animal or herd that may enter the food chain; and

e) in the case of a prescription for medicated feed[5]:

i. feeding instructions;

ii. a warning statement respecting the withdrawal period to be observed following the use of the medicated feed; and

iii. where applicable, cautions with respect to animal health or to the handling or storage of the medicated feed.

Exemption in institution pharmacy

7.13 Standards 7.5 to 7.11 inclusive do not apply if a drug is dispensed to a patient in a health care facility.

5 Labelling requirements for prescriptions for medicated feed are established by section C.08.012(1)(d)(vi) of the Food and Drug Regulations.

Completing the final check

7.14 A pharmacist or a pharmacy technician who dispenses a drug must perform a final check in order to be satisfied that each step in the dispensing process has been completed properly by verifying that:

a) the drug dosage form, strength, manufacturer and quantity dispensed are correct according to the prescription;

b) the prescription label is accurate according to the prescription and contains the information required under this standard and under federal and provincial legislation; and

c) appropriate auxiliary instruction labels are affixed.

7.15 Whenever possible, a final check must be performed by a pharmacist or a pharmacy technician who did not enter the prescription into the dispensing software system or select the drug from stock.

Requirement for an audit trail of the dispensing process

7.16 A pharmacist or a pharmacy technician who engages in dispensing must ensure that their dispensing activities are recorded in a clear audit trail that identifies:

a) all individuals who were involved in the processing of a prescription and dispensing of the drug, and

b) the role of each individual.

7.17 If more than one regulated member of the college is involved in dispensing a drug, they must work together to ensure that:

a) the role and responsibility of each regulated member is clear,

b) each step required to be performed is properly performed, and

c) the audit trail clearly identifies the regulated member that fulfilled each role and responsibility.

Release of drugs and providing patients with sufficient information

Standard 8: Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, or sells a Schedule 2 drug:

a) the pharmacist or the pharmacy technician must confirm the patient's identity, and

b) a pharmacist must provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy.

Application of Standard 8

Confirmation of patient's identity when a drug or blood product is dispensed or sold

8.1 Before the release of a drug or blood product provided under a prescription or the sale of a Schedule 2 drug, the pharmacist or the pharmacy technician who releases the drug or blood product must ensure communication occurs with the patient to confirm:

a) the identity of the patient, or in the case of animals who live in a herd, the herd;

b) the identity of the drug or blood product being dispensed or sold; and

c) refill information, if applicable.

Release of a drug by a pharmacy technician

8.2 In addition to the requirements outlined in Standard 8.1, a pharmacy technician who releases a drug or blood product provided under a prescription or sells a Schedule 2 drug must:

a) ensure that a pharmacist has:

i. assessed the patient, the patient's health history and medication record and has determined that the drug therapy is appropriate for the patient;

ii. evaluated the prescription when the drug is dispensed under a prescription; and

iii. provided information as required in Standard 8.3;

b) if the patient is a human being, inform the patient that a pharmacist is available to speak with them if desired and refer the patient to the pharmacist for a dialogue if:

i. the patient requests a dialogue with the pharmacist;

ii. the patient asks questions that require therapeutic knowledge, clinical analysis or assessment;

iii. in the pharmacy technician's professional opinion, a dialogue is required to:

A. provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy; or

B. avoid, resolve, or monitor a drug therapy problem; or

c) if the patient is an animal, refer the patient's agent to the pharmacist so that the pharmacist can ensure that there is a prescription for the drug as required under standard 1.9 (a) or that the pharmacist has prescribed the drug for the purpose of renewing a prescription in accordance with standard 1.7(c).

Circumstances in which a dialogue is required

8.3 A pharmacist must enter into a dialogue with a patient:

a) when a Schedule 1 drug or blood product is dispensed to the patient for the first time;

b) when a Schedule 2 drug is sold to the patient for the first time;

c) if the patient requests information;

d) if, in the pharmacist's professional opinion, a dialogue is required to:

i. provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy; or

ii. avoid, resolve, or monitor a drug therapy problem; and

e) if the sale of schedule 2 product is for an animal.

8.4 Despite Standards 8.1 to 8.3, a communication or dialogue with a patient may not be required if the drug being dispensed or sold will only be administered by or under the supervision of a regulated health professional acting within the scope of their profession.

Dialogue to be specific to the patient

8.5 The pharmacist must:

a) focus the dialogue on the particular patient's condition and needs,

b) assess the patient's level of understanding, and

c) endeavor to respond to the patient at the appropriate level.

Required elements of the dialogue when a drug or blood product is dispensed or sold to a patient for the first time

8.6 The dialogue under Standard 8.3(a) or (b) must include:

a) procedures to be followed for the proper administration or use of the drug;

b) instructions for proper drug storage, handling and disposal;

c) common or important adverse effects that may apply to the patient and recommendations to minimize the risk associated with them;

d) signs and symptoms that indicate a therapeutic response, a therapeutic failure or an adverse reaction;

e) cautions regarding activities, food or other drugs that:

i. may affect the therapeutic effect of the drug or blood product, or

ii. pose a risk to the patient in conjunction with the drug or blood product; and

f) when it is necessary to seek additional care or advice.

Professional judgment to guide pharmacist in other circumstances when a dialogue is required

8.7 In the case of a dialogue under Standards 8.3(c) or (d), the dialogue must include those components of Standard 8.6 that, in the professional opinion of the pharmacist, are applicable to the patient.

Use of written materials

8.8 A pharmacist may provide written information to a patient to enhance understanding about the patient's drug therapy, but the written materials cannot be used to replace the dialogue required under Standards 8.1 and 8.3.

Written materials must be specific to the patient

8.9 Subject to Standard 8.8, written materials provided to a patient must specifically address the patient and the patient's needs.

8.10 A pharmacist may provide written materials that are general in nature if the pharmacist identifies those portions of the information that are relevant to the patient.

8.11 If a patient has special needs, including a hearing impairment or inability to speak English, the pharmacist may use appropriate written materials to assist in counseling the patient.

Offer assistance with Schedule 3 products

Standard 9: A pharmacist or a pharmacy technician must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug or a health care product, aid or device.

Application of Standard 9

9.1 A pharmacist must be available and accessible to a person who wishes to purchase a Schedule 3 drug or a health care product, aid or device.

9.2 A pharmacist must take reasonable steps to enter into a dialogue with or provide information to a person who:

a) requests a Schedule 3 drug or a health care product, aid or device;

b) requests assistance in making a choice about a Schedule 3 drug or a health care product, aid or device;

c) appears to be having difficulty in making a choice about a Schedule 3 drug or a health care product, aid or device;

d) is observed to be making purchases of a Schedule 3 drug or a health care product, aid or device in a quantity or at a frequency that is therapeutically inappropriate;

e) the pharmacist recognizes as someone who may face a risk from the selection or use of a Schedule 3 drug or a health care product, aid or device;

f) the pharmacist recognizes as someone purchasing Schedule 3 products for use in an animal;

g) is identified by a pharmacy technician as someone who requires assistance or may face a risk from the selection of use of a Schedule 3 drug or health care product, aid or device; or

h) is identified by a pharmacy technician as purchasing Schedule 3 products for use in an animal.

9.3 A pharmacy technician must refer to the pharmacist:

a) anyone the pharmacy technician recognizes as someone who requires assistance with or may face a risk from the selection or use of a Schedule 3 drug;

b) any questions that require therapeutic knowledge, clinical analysis or assessment; and

c) anyone who indicates they are purchasing the Schedule 3 drug for an animal.

9.4 A pharmacy technician may enter into a dialogue with or provide information to a person who:

a) requests a health care product, aid or device;

b) requests assistance in making a choice about a health care product, aid or device;

c) appears to be having difficulty in making a choice about a health care product, aid or device; or

d) the pharmacy technician recognizes as someone who may face a risk from the selection or use of a health care product, aid or device.

Compound according to written formula and process

Standard 10: Each time a pharmacist or a pharmacy technician compounds a drug or a blood product, the pharmacist or the pharmacy technician must ensure that the compounded drug or blood product is prepared according to:

a) a written compounding formula, and

b) a written preparation process.

Application of Standard 10

Requirements in relation to the compounding formula and preparation process

10.1 The formula must include a calculation of the amount of each ingredient and a description of the process of compounding that is specific enough to allow the process to be replicated in formulation and production.

Reputable source required for the formula

10.2 Whenever possible, a pharmacist or a pharmacy technician who compounds a drug or blood product must do so according to a compounding formula from a reputable source such as a pharmacy text or peer-reviewed published journal.

Requirements if no formula is available

10.3 If no formula is available, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to create a formula and reduce it to writing.

Written preparation process to be followed

10.4 Whenever possible, a pharmacist or a pharmacy technician who compounds a drug or blood product must ensure that deviations from the written preparation process are avoided.

10.5 A pharmacy technician who determines that a deviation from the written formula, preparation process, or expiry date may be required, must consult with and obtain the approval of the pharmacist before preparing the compound.

10.6 If a deviation from the process is necessary, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to ensure the deviation is appropriate and will not negatively impact the stability or therapeutic effectiveness of the preparation.

Documenting deviations from the written preparation process

10.7 A pharmacist or a pharmacy technician who deviates from the written process while preparing a compound must ensure that the deviation and the rationale for it are documented.

Approved ingredients to be used in compounding

10.8 A pharmacist or a pharmacy technician who compounds a drug or blood product must ensure that all ingredients used in compounding have an approved designation of standard of quality such as:

a) BP (British Pharmacopeia),

b) USP (United States Pharmacopeia), or

c) NF (National Formulary)

unless such a designation does not exist for the ingredient.

Beyond-use date to be assigned to a compounded drug or blood product

10.9 A pharmacist or a pharmacy technician who compounds a drug or blood product must ensure that a beyond-use date based upon a reputable source of information such as a pharmacy text or a peer-reviewed published journal is assigned to each compounded drug or blood product.

10.10 If no reputable source of information for a beyond-use is available, a pharmacist must use the pharmacist's pharmaceutical knowledge, including but not limited to knowledge in pharmaceutics, pharmacology, medicinal chemistry and therapeutics to determine an appropriate beyond-use date.

Additional documentation requirements for compounded drugs

10.11 In addition to the documentation requirements for dispensing a drug or blood product in Standards 18.1 and 18.2, a pharmacist or a pharmacy technician who compounds a drug or blood product must ensure that a record is created that includes the:

a) name, lot number, expiry date and quantity of each ingredient used to prepare the compounded drug or blood product;

b) formula used to prepare the compounded drug or blood product;

c) beyond-use date assigned to the compounded drug or blood product; and

d) a clear audit trail that identifies all individuals who were involved in the preparation and verification of the compounded drug or blood product, and the role of each individual.

Requirements in relation to sterile products

10.12 A pharmacist or a pharmacy technician who engages in sterile compounding of drugs or mixing other products for parenteral or ophthalmic use, must do so in an environment and according to procedures that meet the requirements of a reputable source such as the Canadian Society of Hospital Pharmacists (CSHP), American Society of Health System Pharmacists, or the United States Pharmacopeia (USP).

10.13 Notwithstanding Standard 10.12, effective 180 days after Council approval of Guidelines for Preparing Sterile Compounds, a pharmacist or a pharmacy technician who engages in sterile compounding of drugs or mixing other products for parenteral or ophthalmic use, must do so in an environment and according to procedures that meet the requirements of United States Pharmacopeia (USP) chapter 797 as outlined in the Guidelines for Preparing Sterile Compounds.

Duty regarding final check

10.14 A pharmacist or a pharmacy technician must perform a final check of all compounded drugs or blood products to be satisfied that each step in the compounding process has been completed accurately by verifying that:

a) the drug, strength, manufacturer and quantity compounded are correct;

b) the compound was correctly prepared according to the written formula and process;

c) calculations and measures were completed accurately;

d) the label includes the information required in these standards; and

e) the package and packaging material are appropriate to protect the compounded product from light and moisture as necessary and to minimize the potential for interaction between a drug or health care product and the container.

10.15 Whenever possible, a final check of a compounded product must be performed by a pharmacist or a pharmacy technician who did not prepare the label, complete calculations, select the ingredients from stock or prepare the compound.

10.16 Before compounding drugs for use for an animal, the pharmacist must determine:

a) whether an appropriate equivalent product, intended either for human or animal use, is commercially available;

b) whether the formulation to be used is safe and appropriate for use in the animal species; and

c) whether the dosage form is appropriate for use in the animal.

Restriction on compounding for animals that may enter the food chain

10.17 A pharmacist or pharmacy technician must ensure:

a) a drug or substance banned by Health Canada must not be used in a compounded product for animals that may enter the food chain; and

b) any product that is an antimicrobial and is not a Health Canada approved product for use in animals that may enter the food chain must not be used in compounding.

10.18 A pharmacist who compounds drugs for use in animals that may enter the food chain must ensure:

a) all ingredients in the compounds are safe for use in the animals and for subsequent human consumption of the animals; and

b) an empirical drug withdrawal time is determined collaboratively with the prescribing veterinarian if the compound contains an active pharmaceutical ingredient that leaves a drug residue.

Comply with regulatory framework if prescribing

Standard 11: A pharmacist who prescribes a Schedule 1 drug or blood product must understand the regulatory framework in relation to pharmacist prescribing and must comply with it.

Application of Standard 11

11.1 A pharmacist must understand the restrictions and requirements applicable to prescribing by pharmacists set out in these standards and Section 16 of the Pharmacists and Pharmacy Technicians Profession Regulation including:

a) adapting a prescription (s16(1)(e), (f), and 16(2));

b) prescribing in an emergency (s16(1)(g) and (h)); and

c) prescribing at initial access or to manage ongoing therapy (s16(3) and (4)).

11.2 A pharmacist who chooses to engage in prescribing must prescribe in accordance with these standards.

Adapting a prescription

11.3 In accordance with Standard 12, but subject to section 11.4, a pharmacist may prescribe a Schedule 1 drug by adapting a prescription from another prescriber by:

a) altering the dosage, formulation or regimen;

b) substituting another drug that is expected to have a similar therapeutic effect; or

c) renewing a prescription to ensure continuity of care.

11.4 A pharmacist must not prescribe a:

a) Schedule 1 drug,

b) Schedule 2 drug, or

c) blood product

for an animal by adapting a prescription from another prescriber, except for the purposes of renewal for continuity of care.

11.5 In addition to Standard 11.4, a pharmacist must not prescribe a drug that is a medically important antimicrobial for an animal by adapting a prescription from another prescriber, for the purposes of renewal for continuity of care.

Prescribing in an emergency

11.6 In accordance with Standard 13, a pharmacist may prescribe a Schedule 1 drug or blood product in an emergency when:

a) there is an immediate need for drug therapy, and

b) it is not reasonably possible for the patient to see a prescriber to obtain a prescription.

11.7 Despite Standard 11.6, a pharmacist must not prescribe a Schedule 1 drug or blood product in an emergency for an animal.

Prescribing at initial access or to manage ongoing therapy

11.8 In accordance with Standard 14, a pharmacist who has received notification from the Registrar that the pharmacist has been granted additional prescribing authorization may prescribe a Schedule 1 drug or blood product at initial access or to manage ongoing therapy based on:

a) the pharmacist's own assessment of the patient,

b) a recommendation from a prescriber that the patient receive a Schedule 1 drug or blood product, or

c) a consultation with another regulated health professional.

11.9 Despite Standard 11.6 and notification from the Registrar, a pharmacist must not prescribe a Schedule 1 drug, Schedule 2 drug, or blood product at initial access or to manage ongoing therapy for an animal.

Prescribing only for approved uses of drugs

11.10 A pharmacist must not prescribe a drug or blood product unless the intended use:

a) is an indication approved by Health Canada,

b) is considered a best practice or accepted clinical practice in peer-reviewed clinical literature, or

c) is part of an approved research protocol.

Prohibition from prescribing narcotics and controlled drugs

11.11 A pharmacist must not prescribe any drugs listed in the schedules of the *Controlled Drugs and Substances Act* including but not limited to drugs listed in the Narcotic Control Regulations and the Benzodiazepines and Other Targeted Substances Regulations.

Fundamentals of prescribing

11.12 A pharmacist must only engage in prescribing a drug or blood product where the pharmacist:

a) has or develops a professional relationship with the patient,

b) has adequate knowledge and understanding of the condition being treated and the drug being prescribed,

c) has adequate information about the patient's health status and the disease or condition being treated,

d) takes reasonable steps to be satisfied that the patient has enough information to participate in the decision-making process and obtains the patient's informed consent to prescribe,

e) is satisfied that the patient is not inappropriately seeking drug therapy from the pharmacist in circumstances where that therapy has been refused by another prescriber, and

f) takes responsibility for the prescribing decision.

Duty to inform other health professionals

11.13 A pharmacist who prescribes a drug or blood product must communicate as soon as reasonably possible to any regulated health professionals whose care of the patient may be affected by their prescribing decision:

a) that they have prescribed for the patient,

b) the type and amount of the drug prescribed,

c) the rationale for prescribing the drug,

d) the date the drug was prescribed, and

e) instructions given to the patient, if applicable.

Obligation to document prescribing process and decisions

11.14 A pharmacist who prescribes a drug or blood product must reduce the prescription to writing in a clear, concise and easy-to- read format that includes all information required in a complete prescription as outlined in Standard 6.7.

11.15 A pharmacist who prescribes a drug or blood product must document in the patient's record:

a) the prescribing decision, the rationale for it and the information required in Standard 11.13;

b) a follow-up plan; and

c) a record of the notification of any other health professional.

Follow proper procedures when adapting a prescription

Standard 12: Pharmacists who adapt an existing prescription under Sections 16(1)(e) and (f) of the Pharmacists and Pharmacy Technicians Profession Regulation must:

a) have the original prescription,

b) determine whether adapting the prescription is appropriate in the circumstances,

c) document the adaptation, and

d) inform the original prescriber.

Application of Standard 12

12.1 Notwithstanding Standard 12(a), a pharmacist who does not have an original prescription, but is satisfied that:

a) the patient has presented evidence of current ongoing therapy based on a prescription (such as an empty prescription vial),

b) there is an immediate need for drug therapy, and

c) it is not reasonably possible:

i. for the patient to attend the pharmacy that dispensed the original prescription to obtain a refill, or

ii. to have the prescription transferred from the pharmacy that dispensed the original prescription,

may renew a prescription to ensure continuity of care.

12.2 A pharmacist who renews a prescription under Standard 12.1 must:

a) see the patient personally before renewing the prescription, and

b) only prescribe the minimum amount of the drug necessary to give the patient sufficient time to attend the pharmacy that dispensed the original prescription or see the prescriber of the original prescription.

12.3 In addition to the notification and documentation required in Standard 12.7, a pharmacist who renews a prescription under Standard 12.1 must:

a) notify a pharmacist at the pharmacy that dispensed the original prescription, and

b) document that notification.

12.4 A pharmacist who receives the notification required in Standard 12.3(a) must document the information on the patient's record.

Duty to determine whether it is appropriate to adapt a prescription

12.5 In determining whether it is appropriate to adapt a prescription, a pharmacist must:

a) obtain the patient's informed consent for the adaptation,

b) have sufficient knowledge about the patient's health status and the disease or condition being treated to make the decision to adapt the prescription,

c) consider the currency and appropriateness of the prescription being adapted,

d) consider appropriate information as described in Standard 3,

e) be satisfied that the adaptation will maintain or enhance the effectiveness of the therapy,

f) be satisfied that the adaptation cannot reasonably be expected to cause a drug therapy problem,

g) be satisfied that the adaptation will not place the patient at increased risk,

h) be satisfied that the intended use of any drug or blood product prescribed in the process of the adaptation is for an approved use as described in Standard 11.10, and

i) comply with any directions of Council in relation to the adaptation of prescriptions.

Restrictions on altering dosage

12.6 Unless a pharmacist has been granted additional prescribing authorization:

a) the pharmacist:

i. may only alter a dosage in relation to a new prescription, and

ii. must not alter a dosage in relation to a renewed prescription, and

b) before altering a dosage in relation to a new prescription the pharmacist must:

i. determine that the patient's age, weight, or organ function necessitates a dosage adjustment; or

ii. determine that the prescribed dosage is not commercially available.

Duty to document the adaptation

12.7 In addition to the requirements for documentation outlined in Standards 11.13 to 11.15, a pharmacist who adapts a prescription must:

a) provide a clear reference on the new prescription to the original prescription, and

b) retain both the new prescription and the original prescription where applicable.

Circumstances that do not require notification to the original prescriber

12.8 Despite Standard 11.13, notification of the original prescriber and other health professionals is not required:

a) for the substitution of a generic drug or blood product for a prescribed drug or blood product, unless the prescriber has directed that there be no substitutions on the original prescription; or

b) for the substitution of one dosage form for another dosage form, unless the dosage form change requires a change in regimen or dose.

Adhere to restrictions when prescribing in an emergency

Standard 13: Pharmacists who prescribe for emergency purposes under Sections 16(1)(g) and (h) of the Pharmacists and Pharmacy Technicians Profession Regulation must:

a) be satisfied that there is an immediate need for drug therapy,

b) be satisfied that it is not reasonably possible for the patient to see another health professional to obtain the prescription, and

c) only prescribe the minimum amount of the drug or blood product necessary to give the patient sufficient time to see a prescriber

Application of Standard 13

13.1 A pharmacist who has not been granted additional prescribing authorization who determines by gathering sufficient information from a patient and from independent inquiries that:

a) there is an immediate need for drug therapy;

b) it is not reasonably possible for the patient to see another prescriber;

c) the patient is not inappropriately seeking drug therapy from the pharmacist in circumstances where that therapy has been refused by another prescriber; and

d) the patient is not an animal;

may prescribe a Schedule 1 drug or blood product for emergency purposes.

Duty to determine whether it is appropriate to prescribe in an emergency

13.2 In determining whether it is appropriate to prescribe for emergency purposes, a pharmacist must:

a) personally see and assess the patient,

b) explain the basis on which they intend to prescribe and obtain the patient's informed consent,

c) obtain sufficient information about the patient's health status and disease or condition to make the decision to prescribe,

d) assess whether the prescription will cause a drug therapy problem,

e) be satisfied that the prescription will not place the patient at increased risk,

f) be satisfied that the intended use of any drug or blood product prescribed is for an approved use as described in Standard 11.10, and

g) comply with any directions of Council in relation to prescribing in an emergency.

Requirement for an assessment

13.3 To obtain adequate information for the purposes of Standard 11.12(c) a pharmacist who prescribes a Schedule 1 drug or blood product in an emergency must conduct a patient assessment that includes consideration of:

a) the information referred to in Standard 3;

b) physical qualities;

c) laboratory values, where applicable;

d) diagnostic and other relevant health information when available; and

e) the date and extent of the last assessment of the condition by another regulated health professional and the results of that assessment.

Restrictions on supply

13.4 In prescribing in an emergency, a pharmacist must only prescribe a limited and interim supply of a drug or blood product for the patient so that the patient's health or life is not at risk.

Obligation for follow-up and notification

13.5 A pharmacist who prescribes in an emergency must:

a) follow up and appropriately monitor the response to the drug prescribed,

b) refer the patient to another regulated health professional for additional care, or

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

13.6 A pharmacist who prescribes in an emergency must, as soon as reasonably possible, contact the patient's usual prescriber, where applicable, to communicate the information required in Standard 11.13.

Prescribing at initial access or to manage ongoing therapy

Standard 14: Pharmacists who have been granted additional prescribing authorization who prescribe under Sections 16(3) and (4) of the Pharmacists and Pharmacy Technicians Profession Regulation must prescribe based on:

a) their own assessment of the patient,

b) a recommendation from a prescriber that the patient receive a Schedule 1 drug or blood product, or

c) a consultation with another regulated health professional.

Application of Standard 14

Conditions to be met before prescribing with additional prescribing authorization occurs

14.1 A pharmacist must not prescribe at initial access or to manage ongoing therapy unless:

a) the prescribing decision is in the best interests of the patient, and

b) the pharmacist has taken the appropriate steps to maintain patient safety.

14.2 A pharmacist who prescribes a Schedule 1 drug or blood product for a patient at initial access or to manage ongoing therapy must:

a) see the patient personally at the time of prescribing,

b) have seen the patient personally in the past and have developed a professional relationship over a period of time, or

c) have a strong collaborative relationship with a regulated health professional acting within the scope of their profession who regularly sees the patient in person.

Requirement of an assessment

14.3 To obtain adequate information for the purposes of Standard 11.12(c), a pharmacist who prescribes a Schedule 1 drug or blood product at initial access or to manage ongoing therapy must conduct a patient assessment that includes consideration of:

a) the information referred to in Standard 3,

b) physical qualities,

c) laboratory values where applicable,

d) diagnostic and other relevant health information when available, and

e) the date and extent of the last assessment of the condition by another regulated health professional and the results of that assessment.

Duty to communicate with other regulated health professionals

14.4 A pharmacist who prescribes at initial access or to manage ongoing therapy must take reasonable steps to:

a) determine which other regulated health professionals the patient is consulting, and

b) communicate as soon as reasonably possible to any regulated health professionals whose care of the patient may be affected by their prescribing decision the information required in Standard 11.

Additional requirements applicable to prescribing under Section 14(a)

14.5 In addition to meeting the requirements under Standards 14.1 to 14.4 inclusive, a pharmacist who prescribes at initial access based on the pharmacist's own assessment of the patient must:

a) in the case of a previously diagnosed condition, endeavor to develop a collaborative relationship with other regulated health professionals identified under Standard 14.4; and

b) in the case of a condition that was not previously diagnosed, refer the patient to another regulated health professional if diagnosis or further treatment by another regulated health professional is necessary.

Additional requirements applicable to prescribing under Section 14(b)

14.6 In addition to meeting the requirements under Standards 14.1 to 14.4 inclusive, a pharmacist who prescribes based on the recommendation of another authorized prescriber must:

a) receive a written recommendation from the prescriber or reduce a verbal recommendation to writing,

b) confirm that the prescriber is authorized to prescribe in Alberta, and

c) develop a collaborative relationship with the prescriber to obtain diagnostic and other relevant health information and to determine mutual goals for therapy.

Additional requirements applicable to prescribing under Section 14(c)

14.7 In addition to meeting the requirements under Standards 14.1 to 14.4 inclusive, a pharmacist who prescribes based on collaboration with another regulated health professional must:

a) confirm that the health professional is a regulated member of a college with whom the Alberta College of Pharmacy has a memorandum of understanding in relation to collaborative prescribing, and

b) develop a collaborative relationship with that other regulated health professional to obtain diagnostic and other relevant health information and to determine mutual goals of therapy.

Obligation for follow-up and notification

14.8 When a pharmacist prescribes at initial access or to manage ongoing therapy, the pharmacist must:

a) develop a follow-up plan with the patient including parameters that will be monitored, expected outcomes and time frames; and

b) be satisfied that there is ongoing monitoring by a regulated health professional acting within the scope of their profession.

14.9 The follow-up plan and monitoring may involve professional services provided by other regulated health professionals involved in the patient's care.

14.10 A pharmacist who prescribes at initial access or to manage ongoing therapy must, as soon as reasonably possible, contact the patient's usual prescriber, where applicable, to communicate the information required in Standard 11.13.

Prohibition on prescribing for animals

14.11 A pharmacist must not prescribe a Schedule 1 or Schedule 2 drug at initial access or to manage ongoing therapy for a patient that is an animal.

Separate prescribing and dispensing

Standard 15: A pharmacist who prescribes a drug or blood product at initial access based on the pharmacist's own assessment of the patient must not dispense the drug him- or herself, unless:

a) the pharmacist is satisfied that adhering to this standard will compromise the health of the patient, or

b) the patient chooses to have the pharmacist dispense the drug.

Application of Standard 15

Same pharmacist should not prescribe and dispense

15.1 A pharmacist who dispenses a drug that the pharmacist prescribed at initial access based on the pharmacist's own assessment of the patient must:

a) have advised the patient that the patient may choose to have the prescription dispensed by another pharmacist,

b) take reasonable steps to be satisfied the patient has enough information to participate in the decision-making process,

c) obtain the patient's informed consent to dispense the drug, and

d) document compliance with each step of the dispensing process required under Standard 7.

Ensure proper procedures and environment when administering a drug, blood product or vaccine

Standard 16: A pharmacist who administers a drug, blood product or vaccine must:

a) have policies and procedures for handling emergencies, and

b) ensure that the environment in which the drug, blood product or vaccine is to be administered is appropriate.

Application of Standard 16

Policies and procedures to be developed and updated

16.1 A pharmacist who administers a drug, blood product or vaccine must have in place and be prepared to implement current policies and procedures for handling emergencies.

Obligation to review policies and procedures

16.2 A pharmacist who administers a drug, blood product or vaccine must, at a minimum, review the policies and procedures required under Standard 16.1 annually.

Environment within which drugs, blood products or vaccines will be administered

16.3 A pharmacist who administers a drug, blood product or vaccine must ensure that the environment within which the drug, blood product or vaccine will be administered is clean, safe, appropriately private and comfortable for the patient.

Ensure patient safety when administering a drug, blood product or vaccine

Standard 17: A pharmacist who administers a drug, blood product or vaccine must have proper regard for the interests of the patient and take all steps necessary to ensure that the drug, blood product or vaccine is administered safely.

Application of Standard 17

Steps required for the safe administration of a drug, blood product or vaccine

17.1 A pharmacist who administers a drug, blood product or vaccine to a patient must:

a) obtain informed consent from the patient;

b) be satisfied that there has been compliance with Standard 6 in relation to the appropriateness of the drug, blood product or vaccine that will be administered;

c) take appropriate steps to ensure the patient is given the right drug, blood product or vaccine, for the right reason, in the right dose, at the right time, using the right route.

17.2 In addition to the requirements in Standard 17.1, a pharmacist who is authorized to administer drugs by injection who administers an injection to a patient must:

a) ensure that:

i. there is ready access to drugs and health care products, aids and devices used to treat reactions to injectable drugs, blood products and vaccines; and

ii. the pharmacist is trained to administer the drugs and use the health care products, aids and devices used to treat reactions to injectable drugs, blood products and vaccines, and to manage reactions to injectable drugs, blood products, and vaccines;

b) be satisfied that the drug, blood product or vaccine to be administered:

i. has been prepared for administration using aseptic technique,

ii. is stable, and

iii. has been stored and labeled appropriately prior to and following reconstitution or mixing,

c) observe routine precautions for infection control; and

d) use aseptic technique.

Routine precautions for infection control defined

17.3 For the purpose of Standard 17(2)(c), routine precautions for infection control include precautions to help prevent the spread of infection, including but not limited to:

a) handling all body fluids and tissues as if they were infectious, regardless of the patient's diagnosis;

b) washing hands before and after caring for the patient, and after removing gloves; and

c) wearing gloves when required to prevent contact with body fluids, excretions or contaminated surfaces or objects.

Steps required after administration

17.4 Following the administration of a drug, blood product or vaccine, a pharmacist must:

a) ensure the patient is appropriately monitored;

b) respond appropriately to complications of therapy if they arise;

c) ensure devices, equipment and any remaining drug, blood product or vaccine is disposed of safely and appropriately;

d) document the administration in the patient record as required in Standard 18 and Appendix A; and

e) provide relevant information to other regulated health professionals and provincial health agencies as appropriate.

No injection for a child younger than five years

17.5 A pharmacist authorized to administer drugs by injection must not administer an injection to a child younger than five years old.

Prohibition for animals

17.6 A pharmacist authorized to administer drugs by injection must not administer a drug, blood product or vaccine to a patient that is an animal.

Create and maintain patient records

Standard 18: A pharmacist must create and maintain patient records for pharmacist services provided by that pharmacist.

A pharmacy technician must create and maintain patient records for pharmacy technician services provided by that technician.

Application of Standard 18

Transaction record

18.1 Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product, the pharmacist or the pharmacy technician must ensure that a written transaction record is created that includes:

a) the name of the patient for whom the drug was dispensed, or in the case of a herd of animals, a unique identifier or the location of the herd;

b) the name of the prescriber of the drug;

c) the date the drug was dispensed;

d) the name, strength, and dosage form of the drug dispensed;

e) the DIN of the drug dispensed;

f) the quantity of drug dispensed;

g) route of administration and directions for use; and

h) a unique prescription and transaction number.

Duty to enter information in a patient's record

18.2 A pharmacist or a pharmacy technician who:

a) dispenses a Schedule 1 drug or blood product;

b) sells a Schedule 2 drug; and

a pharmacist who:

c) prescribes a Schedule 1 drug or blood product;

d) administers a drug or blood product; or

e) establishes a follow-up plan or other patient care plan

must ensure that an appropriate entry is made in the patient's record.

Requirements of a patient record

18.3 A patient record must include:

a) patient demographics,

b) a profile of drugs provided, and

c) a record of care provided including but not limited to:

i. drug therapy problems identified and/or interventions, monitoring plans or actions related to drug therapy problems;

ii. prescriptions written;

iii. drugs, blood products, or vaccines administered;

iv. other information related to patient care practice.

18.4 In addition to the requirements set out in this standard, a patient record must meet the requirements of Appendix A.

Amending a patient record

18.5 When a record of patient care is amended after the fact to correct an error the following must be identifiable:

a) the original entry,

b) the identity of the pharmacist or the pharmacy technician who made the alteration, and

c) the date of the alteration.

Patient record to be current

18.6 A pharmacist or a pharmacy technician must keep the patient record accurate and current with regard to the pharmacist's or the pharmacy technician's activities.

Form of patient record

18.7 The patient record must be kept:

a) in a clear, concise and easy-to-read format; and

b) in a manner that facilitates sharing, ease of use and retrieval of patient information by authorized individuals.

18.8 A pharmacist or a pharmacy technician who provides professional services in an institution pharmacy, as defined in the *Pharmacy and Drug Act*, or in an environment with other regulated health professionals who have a shared medical or patient record may:

a) document the pharmacist's or pharmacy technician's activities in the institution's medical record or the shared medical or patient record for the patient; and

b) rely upon documentation within the drug distribution system and the institution's medical record or the shared medical or patient record if the pharmacist or pharmacy technician is satisfied that the information required in Standards 18.1, 18.3, and 18.4 is available to the pharmacist or the pharmacy technician.

18.9 A pharmacist or a pharmacy technician who provides professional services in an environment with other regulated health professionals who share a medical or patient record must:

a) determine ownership of the patient record, and

b) collaborate with other regulated health professionals to ensure the creation and maintenance of patient records meet the requirements outlined in these standards.

18.10 A pharmacist who provides professional services outside of a pharmacy, an institution pharmacy or an environment with other regulated health professionals who share a medical or patient record must:

a) create and maintain a patient record that meets the requirements for format and content outlined in these standards and all other applicable legislation;

b) ensure the records are created, stored and maintained in a manner that meets or exceeds the requirements outlined for record keeping in the Standards for the Operation of Licensed Pharmacies;

c) if the patient is a human, retain the record for a period of

   i. not less than 10 years after the last pharmacy service, or

   ii. two years past the age of majority of the patient whichever is greater;

d) retain the record for a period of not less than 10 years after the last pharmacy service if the patient is an animal; and

e) create a plan for transfer of the records when they cease the practice.

   i. The plan must include provision of notice to the college of the location of the patient records and how they may be accessed when the transfer occurs.

Do not accept drugs or health products for reuse

Standard 19: Neither a pharmacist nor a pharmacy technician may accept the return of a drug or a health care product, aid or device for reuse.

Application of Standard 19

19.1 After a drug, health care product, aid or device has been dispensed or sold, neither a pharmacist nor a pharmacy technician may:

a) accept that drug or health care product for reuse, or

b) reuse that drug or health care product.

19.2 Despite Standard 19.1, a pharmacist or a pharmacy technician may repackage a drug, health care product, aid or device for reuse if:

a) the drug, health care product, aid or device will be reused only for the patient for whom it was originally dispensed; or

b) the drug or health care product, aid or device is in a tamper-resistant package and was provided to a health care facility and maintained under the control of a regulated health professional at all times while in that facility; and

c) the pharmacist or pharmacy technician is confident that the drug or health care product:

i. has not been tampered with, and

ii. has been stored in a manner that would not adversely affect its stability.

19.3 Standard 19.1 does not apply to a drug that was dispensed for a patient by an institution pharmacy, as defined in the *Pharmacy and Drug Act*, if the pharmacist or pharmacy technician is satisfied that the drug distribution system is adequate to ensure the integrity of the drug and the safety of any patient who may receive the drug.

Provide direction and supervise others responsibly

Standard 20: A pharmacist who provides direction to a pharmacy technician must do so in accordance with Section 21(3) of the Pharmacists and Pharmacy Technicians Profession Regulation.

A pharmacist who supervises others in the practice of pharmacists or the practice of pharmacy technicians, or a pharmacy technician who supervises others in the practice of pharmacy technicians must:

- **a) do so in accordance with Section 23 of the Pharmacists and Pharmacy Technicians Profession Regulation,**
- **b) ensure that the person being supervised acts within the limits established by the Pharmacists and Pharmacy Technicians Profession Regulation, and**
- **c) remain responsible for the delivery of all components of any restricted activity that require the professional skills and training of the pharmacist or the pharmacy technician.**

Application of Standard 20

Providing direction

20.1 A pharmacist who provides direction to a pharmacy technician must:

a) be engaged in the practice of pharmacists in the same pharmacy as the pharmacy technician to whom the pharmacist is providing direction, unless otherwise authorized by the Registrar in writing;

b) be authorized to perform the restricted activities that the pharmacy technician will provide under the pharmacist's direction;

c) ensure the pharmacy technician's involvement in restricted activities is limited to those activities authorized in Section 21 of the Pharmacists and Pharmacy Technicians Profession Regulation;

d) ensure there is a system in place in the pharmacy to ensure compliance with these standards and the Standards for the Operation of Licensed Pharmacies including but not limited to:

i. ensuring that a clinical pharmacist or a courtesy pharmacist is available to:

A. evaluate each prescription;

B. assess each patient, the patient's health history, and medication record and determine that the drug therapy provided is appropriate for the patient;

C. counsel the patient and monitor the patient's drug therapy; and

D. consult with, provide guidance or provide assistance to the pharmacy technician if required.

20.2 A courtesy pharmacist must not provide direction to a pharmacy technician unless the courtesy pharmacist has been authorized in writing by the Registrar to do so.

Supervising pharmacy students and provisional pharmacists

20.3 A clinical pharmacist or a courtesy pharmacist who supervises a pharmacy student or a provisional pharmacist must ensure:

a) the pharmacist is registered on the student register or the provisional register, and

b) the duties being supervised and the method of supervision are in accordance with the rules of the Structured Practical Training Program established under Section 10 of the Pharmacists and Pharmacy Technicians Profession Regulation.

Supervising provisional pharmacy technicians and student pharmacy technicians

20.4 A clinical pharmacist, a courtesy pharmacist, or a pharmacy technician who supervises a provisional pharmacy technician must ensure:

a) the technician is registered on the provisional technician register, and

b) the duties being supervised and the method of supervision are in accordance with the rules of the Structured Practical Training Program established under Section 10.1 of the Pharmacists and Pharmacy Technicians Profession Regulation.

20.5 A clinical pharmacist, a courtesy pharmacist, or a pharmacy technician who supervises a student pharmacy technician must ensure:

a) the student pharmacy technician is registered in a training program approved by the Council, and

b) the duties being supervised and the method of supervision are in accordance with the rules of the Structured Practical Training Program established under Section 10.1 of the Pharmacists and Pharmacy Technicians Profession Regulation.

Supervising employees

20.6 A clinical pharmacist, courtesy pharmacist, or a pharmacy technician who supervises an employee must ensure that if the employee engages in compounding a drug, providing a drug for sale, or selling a drug under the pharmacist's or the pharmacy technician's supervision the employee does not engage in any component of the activity which requires the training and skills of a pharmacist or a pharmacy technician.

20.7 An employee engaged in selling a drug or providing a drug for sale must do so under the direct supervision of a clinical pharmacist, a courtesy pharmacist or a pharmacy technician and must not engage in any component of those restricted activities other than assisting the pharmacist or the pharmacy technician by:

a) placing a drug into stock,

b) entering information into the information management system about the sale of a drug,

c) gathering information for submission of an account to an insurance carrier,

d) selecting a drug from stock,

e) counting and packaging a drug,

f) entering information about the sale into the patient record, or

g) finalizing the commercial aspects of the sale.

20.8 An employee engaged in compounding a drug or blood product must do so under the direct supervision of a clinical pharmacist, a courtesy pharmacist or a pharmacy technician and must not engage in any component of those restricted activities other than by assisting the pharmacist or the pharmacy technician by:

a) selecting a drug from stock,

b) measuring the quantities of the drugs to be compounded,

c) physically mixing the drugs, or

d) entering information into the information management system about the act of compounding.

Transfer of prescriptions by pharmacy technicians

20.9 Pharmacy technicians who assist a pharmacist in the transfer of a prescription to another pharmacist must:

a) only transfer prescriptions when directed to do so by the pharmacist that they are assisting;

b) confirm that the prescription may be legally transferred;

c) provide to the receiving pharmacist:

i. a copy of the prescription as written by the prescriber or as reduced to writing in the case of verbal prescriptions;

ii. the number of authorized refills remaining;

iii. the date of the last refill;

iv. the name and address of the pharmacist that is transferring the prescription; and

v. any other information that the transferring pharmacist deemed necessary under Standard 2.9(b); and

d) render the prescription inactive to ensure that no further sales are made under the prescription and the prescription is not transferred to another pharmacist;

e) document that the prescription has been transferred in the patient record including:

i. the name and location of the pharmacist to whom the prescription was transferred;

ii. the name of the pharmacist transferring the prescription; and

iii. the name of the pharmacy technician assisting the pharmacist with the transfer.

Protect patient safety when repackaging

Standard 21: A pharmacist or a pharmacy technician who repackages drugs must take appropriate steps to protect patient safety.

Application of Standard 21

Duty regarding audit trail

21.1 A pharmacist or a pharmacy technician who repackages a drug or blood product must ensure that in respect of that drug or blood product there is sufficient documentation to provide a clear audit trail of the repackaging process.

21.2 The documentation required under Standard 21.1 must identify:

a) drug information from the original container including:

i. DIN, NPN or HN;

ii. lot number;

iii. expiry date; and

b) all individuals involved in the repackaging and verification process and the role of each individual.

Duty regarding labeling

21.3 A pharmacist or a pharmacy technician who dispenses or sells a repackaged drug or blood product must ensure that each repackaged drug or blood product has a label affixed to the package that meets the requirements of a prescription label required under Standard 7 or that explicitly identifies the following:

a) a description of the drug, in English, by:

i. generic name, strength and the identity of the manufacturer for a single-entity drug or blood product; or

ii. generic name, strength and the identity of the manufacturer for a combination drug or blood product, where possible, or the brand name and strength;

b) the size of the package or quantity;

c) a lot number that links to the audit trail described in Standard 21.1; and

d) an expiry date for the drug or blood product.

Duty regarding directions

21.4 A pharmacist or a pharmacy technician who engages in repackaging drugs or blood products for sale to patients must ensure that the label includes a direction statement which has on it the words:

"*Take or use [insert the manufacturer's suggested doses or use] or as directed by the prescriber.*"

Duty regarding final check

21.5 A pharmacist or a pharmacy technician must perform a final check of all repackaged drugs, blood products or health care products to be satisfied that each step in the repackaging process has been completed accurately by verifying that:

a) the drug or health care product, dosage form, strength, manufacturer and quantity packaged is correct;

b) the information on the label is accurate according to the original container, including the drug, dosage form, strength and manufacturer;

c) the label includes the information required in these standards; and

d) the package and packaging material are appropriate to protect the drug or health care product from light and moisture as necessary and to minimize the potential for interaction between a drug or health care product and the container.

21.6 Whenever possible, a final check of repackaged products must be performed by a pharmacist or pharmacy technician who did not create the label or select the drug from stock.

Special labeling requirements for individually packaged drugs

21.7 A pharmacist or a pharmacy technician must ensure that, when dispensed to a patient, individually packaged medications which include a drug (such as a lollipop) are:

a) individually labeled with the name of the drug or compound, lot number and expiry date; and

b) put in a larger container that bears a prescription label.

Limits on insertion or removal of instruments, devices, or fingers under section 16(1)(d)(i) and (ii) of the Pharmacists and Pharmacy Technicians Regulation

Standard 22: In the practice of a pharmacist, a pharmacist must not insert or remove instruments, devices or fingers beyond the anal verge or beyond the labia majora, except if

- **a) it is for the purposes of administering a drug or medication;**
- **b) it is an emergency;**
- **c) the patient is not able to take the drug or medication orally or the drug or medication requires intra-anal or intra-vaginal administration to achieve the intended therapeutic effect; and**
- **d) another appropriately authorized regulated health professional is not readily available to insert or remove instruments, devices or fingers beyond the anal verge or beyond the labia major for the purpose of the administration of the drug or medication.**

Application of Standard 22

22.1 A pharmacist who inserts or removes instruments, devices or fingers beyond the anal verge or beyond the labia majora to administer a drug or medication under this standard must

a) have the informed consent of the patient;

b) document the consent and describe the steps taken in sufficient detail to allow transfer of care to a physician or nurse practitioner; and

c) as soon as reasonably possible transfer care to a physician or nurse practitioner.

Prohibition for animals

22.2 A pharmacist must not insert or remove instruments, devices or fingers beyond the anal verge or beyond the labia majora under any circumstances for a patient that is an animal.

Appendix A

Patient record requirements

Element of record	Required information	Form of the record
Patient demographics	Patient demographics a) The patient's name, address and telephone number, if available b) The patient's date of birth c) The patient's personal health number (PHN) d) The patient's sex/gender e) Any known drug allergies, drug sensitivities and other contraindications and precautions f) Disease states and chronic conditions g) Weight and height, if applicable h) Pregnancy and lactation status, if applicable Additional required demographics for animal patients i) The name or identifier for the animal or herd j) The species of animal k) The name of the patient agent for the animal l) Whether the animal may enter the food chain m) The number of animals treated if the prescription is for a herd of animals.	Electronic
Drug profile	Schedule 1 drugs dispensed a) The name of the patient for whom the drug was dispensed or sold b) The name of the prescriber of the drug c) The date the drug was dispensed or sold d) The name, strength, and dosage form of the drug dispensed or sold e) The DIN of the drug dispensed or sold f) The quantity of drug dispensed or sold g) Route of administration and directions for use h) Unique prescription and transaction numbers i) The number of refills and interval between each refill, if applicable	Electronic
Drug profile	Schedule 2 drugs sold a) The name of the patient for whom the drug was dispensed or sold b) The date the drug was sold c) The name, strength, and dosage form of the drug sold d) The DIN of the drug sold e) The quantity of the drug sold f) A unique prescription or transaction number g) Identification of the selling pharmacist	Electronic

Element of record	Required information	Form of the record
Record of care	Drug therapy problem identified and/or interventions, monitoring plans or actions related to drug therapy problems a) Drug therapy problem identified including whether it is actual or potential b) A summary of information provided to the patient c) A summary of any consultations with other health professionals, if applicable d) A summary of any recommendations made, if applicable e) A follow-up plan that is sufficiently detailed to monitor the patient's progress and ensure continuity of care by other regulated health professionals or caregivers, if applicable f) Any additional information that is necessary for colleagues to provide care g) The date of the action h) Identification of the pharmacist who made the intervention or provided the care	Electronic or written
Record of care	Additional required information for animals a) If the prescription was for a medically important antimicrobial, what considerations or actions were undertaken b) The potential for the medication to leave a drug residue in an animal that may enter the food chain c) The established withdrawal times in an animal that may enter the food chain	Electronic or written
Record of care	Other information a) Information about prescriptions that were invalidated or not filled b) A summary of any consultations with other regulated health professionals about the patient c) Identification of the pharmacist or the pharmacy technician who made the entry onto the record of care	Electronic or written
Record of care	Prescription adapted by a pharmacist a) That the prescription has been adapted b) The nature of the adaptation c) The rationale for the adaptation d) The date of the adaptation e) Identification of the pharmacist who adapted the prescription f) The date and method of notification of the original prescriber as required under Standard 12.9	Electronic or written

Element of record	Required information	Form of the record
Record of care	Drug prescribed under Sections 16(1)(g), and 16(3) or 16(4) of the Pharmacists and Pharmacy Technicians Profession Regulation a) The circumstances under which the drug was prescribed b) The rationale for prescribing c) A summary of their assessment of the patient d) The complete prescription information as described in Standard 6 e) A follow-up plan that is sufficiently detailed to monitor the patient's progress and ensure the continuity of care by other regulated health professionals or caregivers, if applicable f) Any additional information that is necessary for colleagues to provide continuity of care g) The date of the prescription h) Identification of the pharmacist who prescribed i) The date and method of notification of other regulated health professionals	Electronic or written
Record of care	Drug, blood product or vaccine administered a) Drug, dose and route of injection b) Site of injection, if applicable c) Patient response d) Patient counseling provided e) Adverse reactions, if any, and management f) Plans for follow up g) Date of administration h) Identification of the pharmacist who administered the drug, blood product or vaccine	Electronic or written