Alberta College of Pharmacy

# Standards for the Operation of Licensed Pharmacies

Effective January 2022

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# Introduction

These standards are made under the authority of Section 29.1 of the *Pharmacy and Drug Act*. They are one component of the law that governs the practice of pharmacy in Alberta.

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

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

Licensees and proprietors must know, understand and comply with this overall legislative scheme.

These standards are mandatory. They set out the minimum acceptable standards applicable to operating a licensed pharmacy and provide direction for licensees and proprietors.

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)** **Act** means the *Pharmacy and Drug Act*;

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

**c)** **drug** means a drug under the Act;

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

**e)** **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*;

**f)** **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) SOR/2003-19; and

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

**g)** **herd** means a group or population of animals that cohabitate and feed together in the same environment and includes a flock, school, or hive;

**h)** **mail order pharmacy service** means a pharmacy service provided to or for a patient for which neither the patient nor the patient's agent attends at the community pharmacy to receive the service;

**i)** **patient** means any person 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;

**j)** **patient's agent** means

i. in the case of a human who is the patient, a family member, caregiver or another person 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;

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

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

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

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

**o)** **prescription department** means the dispensary and the patient services area;

**p)** **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;

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

**r)** **proprietor** means a person who owns, manages or directs the operation of a facility in which a licensed pharmacy is located and exercises a significant degree of control over:

i. the management and polices of the licensed pharmacy; or

ii. the conduct of the regulated individuals who are employed by the licensed pharmacy;

**s)** **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 profession in Alberta; and

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

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

**u)** **restricted activity**[1] means an activity named as a restricted activity in Section 2 of Schedule 7.1 of the *Government Organization Act*.

2. Unless these standards provide a more specific definition, terms used in these standards have the same meaning as in the *Pharmacy and Drug Act*, the Pharmacy and Drug Regulation, Schedule 19 to the *Health Professions Act*, or the Pharmacists and Pharmacy Technicians Profession Regulation[2].

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 pharmacist practice, the licensee shall consider these standards applicable to that provisional pharmacist, courtesy pharmacist or student pharmacist.

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

2 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).

5. Where a provisional pharmacy technician or courtesy pharmacist technician engages in pharmacy technician practice, the licensee shall consider these standards applicable to that provisional or courtesy 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.

# Standards

## Ensure compliance with laws governing pharmacies, drugs and professional practice

### *Standard 1:*

A licensee must ensure the licensed pharmacy operates in accordance with the law.

## Preserve independence of self and staff

### *Standard 2:*

A licensee must not practise under or impose any condition that compromises independence, judgment or integrity.

## Staff pharmacy adequately

### *Standard 3:*

A licensee must ensure that the licensed pharmacy has:

a) an adequate number of properly trained staff who are identifiable to the public; and

b) policies and procedures to ensure that restricted activities are only performed by, or under lawful supervision of, an authorized regulated health professional.

## Ensure suitable physical facility and equipment

### *Standard 4:*

A licensee must ensure that the physical facility and the equipment in the licensed pharmacy provides a suitable environment for practice in accordance with these standards and the Standards of Practice for Pharmacists and Pharmacy Technicians.

## Protect the integrity and safety of drugs, health care products and supplies

### *Standard 5:*

A licensee must ensure that the drug supply in the licensed pharmacy is managed so as to protect the integrity, quality and safety of drugs, health care products, aids and devices.

## Implement a quality assurance program

### *Standard 6:*

A licensee must implement a quality assurance program to monitor and improve processes to minimize risk.

## Ensure patients have access to compounding services

### *Standard 7:*

A licensee must ensure that patients of the licensed pharmacy have access to compounding services.

## Ensure comprehensive record keeping system

### *Standard 8:*

A licensee must ensure that there is an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records.

## If a compounding and repackaging pharmacy, maintain appropriate facilities and policies

### *Standard 9:*

A licensee of a compounding and repackaging pharmacy must ensure:

a) the pharmacy has adequate space and equipment to perform the activities of the pharmacy,

b) drugs are compounded or repackaged according to the Standards of Practice for Pharmacists and Pharmacy Technicians and all other applicable legislation,

c) a written agreement has been signed with each pharmacy to which a compounding and repackaging pharmacy service will be provided, and

d) all drugs are compounded or repackaged:

   i. in accordance with these standards, and

   ii. have a unique identifier that allows identification of the compounding and repackaging pharmacy.

## If a mail order pharmacy, maintain appropriate policies and records

### *Standard 10:*

A licensee of a mail order pharmacy must establish and monitor compliance with policies and procedures and keep appropriate records of activities related to the provision of mail order pharmacy services.

## If a satellite pharmacy, maintain appropriate facilities and policies

### *Standard 11:*

A licensee of a community pharmacy that holds a satellite pharmacy licence must:

a) ensure the satellite pharmacy has adequate space and equipment to perform the activities of the pharmacy,

b) maintain an adequate drug inventory in the satellite pharmacy,

c) establish and monitor compliance with policies and procedures and keep appropriate records of activities specific to the operation of the satellite pharmacy, and

d) comply with any conditions imposed by the Registrar.

## Remote dispensing

### *Standard 12:*

This standard has been left intentionally blank to accommodate a standard for remote dispensing from satellite pharmacies if necessary legislative amendments are made.

## Notify the college when closing a pharmacy

### *Standard 13:*

A licensee must provide the college with information when a licensed pharmacy closes permanently.

## Proprietor: Support the licensee

### *Standard 14:*

A proprietor must ensure the capability of and support the licensee.

# Ensure compliance with laws governing pharmacies, drugs and professional practice

## Standard 1: A licensee must ensure the licensed pharmacy operates in accordance with the law.

### *Application of Standard 1*

**Compliance with the law**

1.1 A licensee must ensure that the licensed pharmacy operates in accordance with the law that governs pharmacy operations, drug distribution, the practice of pharmacists and the practice of pharmacy technicians, including, but not limited to:

a) the *Pharmacy and Drug Act*, its regulations and these standards;

b) the *Health Professions Act*, its regulations, and the Standards of Practice for Pharmacists and Pharmacy Technicians;

c) the Alberta College of Pharmacy Code of Ethics;

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

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

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

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

h) the *Animal Health Act*.

1.2 A licensee must:

a) comply with the letter and the spirit of the law referred to in Standard 1.1 to ensure that the public and each patient receives the full protection of the law;

b) ensure that the licensed pharmacy has the facilities, equipment, staff, policies and procedures required to ensure that each regulated member practising in the licensed pharmacy can comply with the law referred to in Standard 1.1; and

c) be aware of changes in the law referred to in Standard 1.1 and adjust practice to ensure compliance with changes.

1.3 A licensee must not require a regulated member to engage in any activity or be party to any arrangement that will result in a contravention of Standard 1.19 of the Standards of Practice for Pharmacists and Pharmacy Technicians.

# Preserve independence of licensee and staff

## Standard 2: A licensee must not practise under or impose any condition that compromises independence, judgment or integrity.

### *Application of Standard 2*

2.1 A licensee must not practise under any condition that compromises the licensee's professional independence, judgment or integrity.

2.2 A licensee must not impose any condition on another regulated member or other regulated health professional working within a licensed pharmacy that compromises the other regulated member's or health professional's professional independence, judgment or integrity.

2.3 A proprietor must not impose any condition on a licensee, regulated member or other regulated health professional working in a licensed pharmacy, that compromises the licensee's or other regulated health professional's professional independence, judgment or integrity.

# Staff pharmacy adequately

## Standard 3: A licensee must ensure that the licensed pharmacy has:

a) an adequate number of properly trained staff who are identifiable to the public; and

b) policies and procedures to ensure that restricted activities are only performed by, or under the lawful supervision of an authorized regulated health professional.

### *Application of Standard 3*

**Adequate number of staff in a licensed pharmacy**

3.1 A licensee must ensure that a licensed pharmacy has an adequate number of staff to provide professional services:

a) safely,

b) effectively, and

c) in accordance with the laws referred to in Standard 1.1.

3.2 In assessing the need for staff for the purposes of Standard 3.1, a licensee must exercise professional judgment, including but not limited to having regard for the past and anticipated workloads in the pharmacy.

**Staff to be identified**

3.3 A licensee must ensure that each regulated member who works in the prescription department wears a name tag identifying the regulated member to the public, using one of the titles listed in the next column.

| Category of membership | Titles to be used on identification |
|---|---|
| a) Clinical pharmacist register | pharmacist, clinical pharmacist, pharmaceutical chemist, druggist, apothecary, registered pharmacist, Ph.C. or R.Ph. |
| b) Courtesy pharmacist register | pharmacist, pharmaceutical chemist, druggist, apothecary, registered pharmacist, Ph.C. or R.Ph. |
| c) Provisional pharmacist register | pharmacy intern or pharmacist intern |
| d) Student pharmacist register | pharmacy student or pharmacist student |
| e) Pharmacy technician register | pharmacy technician, dispensary technician, regulated pharmacy technician, registered pharmacy technician, Pharm. Tech, Ph.T., R.Ph.T. |
| f) Courtesy technician register | pharmacy technician, dispensary technician, regulated pharmacy technician, registered pharmacy technician, Pharm.Tech., Ph.T, R.Ph.T. |
| g) Provisional pharmacy technician register | provisional pharmacy technician |

3.4 A licensee must ensure that any employee who works in a licensed pharmacy and who is not a regulated member wears a name tag that clearly differentiates them from regulated members working in the pharmacy to avoid any potential perception that the employee is a regulated member.

**Duty to ensure that staff are properly trained**

3.5 A licensee must ensure that each employee and each regulated member who works in a licensed pharmacy has the appropriate education, experience, training and registration required to perform the duties and responsibilities assigned to that employee or regulated member.

**Period of initial assessment for staff engaged in restricted activities**

3.6 A licensee must ensure that each regulated member who will practise in a licensed pharmacy undergoes:

a) a suitable orientation to the pharmacy's operational policies and procedures with respect to the provision of restricted activities; and

b) a suitable period of supervision, training, observation, and evaluation of skills and knowledge.

**Duty to ensure that proper supervision is in place for restricted activities**

3.7 A licensee must ensure that any:

a) pharmacy technician or courtesy pharmacy technician who engages in a restricted activity under Section 21 or 21.2 of the Pharmacists and Pharmacy Technicians Profession Regulation does so under the direction of a clinical pharmacist or a courtesy pharmacist;

b) provisional pharmacist or student pharmacist who engages in a restricted activity under Section 17 or 19 of the Pharmacists and Pharmacy Technicians Profession Regulation does so under the appropriate form of supervision by a clinical pharmacist or a courtesy pharmacist;

c) provisional pharmacy technician who engages in a restricted activity under Section 21.1 of the Pharmacists and Pharmacy Technicians Profession Regulation does so under the appropriate form of supervision by a clinical pharmacist, courtesy pharmacist or pharmacy technician; and

d) employee who engages in a restricted activity under Section 22 of the Pharmacists and Pharmacy Technicians Profession Regulation does so under the direct supervision of a clinical pharmacist, a courtesy pharmacist or a pharmacy technician

in accordance with, and subject to, any restrictions in the applicable sections of the Pharmacists and Pharmacy Technicians Profession Regulation.

**Duty to ensure that unauthorized individuals do not engage in restricted activities**

3.8 A licensee must ensure that unauthorized individuals do not engage in or supervise restricted activities in the licensed pharmacy.

**Duty to establish limits**

3.9 A licensee must ensure that staff members who are not regulated members are given clear direction regarding the scope of their actions and the limitations on their actions within the pharmacy.

**Duty in relation to pharmacy technicians**

3.10 A licensee must ensure that any pharmacy technician who is employed in a licensed pharmacy and who will engage in a restricted activity, or who will supervise a restricted activity in the licensed pharmacy, is authorized under the Pharmacists and Pharmacy Technicians Profession Regulation to engage in that restricted activity.

3.11 If a pharmacy technician will engage in the restricted activities of dispensing or compounding in a licensed pharmacy, the licensee must:

a) have policies and procedures in place that ensure the safety and integrity of the process of dispensing or compounding drugs,

b) have a system in place to regularly monitor for compliance with the policies and procedures described in (a),

c) ensure that a clinical pharmacist or courtesy pharmacist provides direction to the pharmacy technician, and

d) ensure that the clinical pharmacist or courtesy pharmacist referred to in (c) is practising in the same pharmacy as the pharmacy technician.

**Duty in relation to courtesy pharmacists and courtesy pharmacy technicians**

3.12 A licensee must ensure that any courtesy pharmacist or courtesy pharmacy technician who works in the licensed pharmacy and who will engage in a restricted activity, or who will supervise a restricted activity in the licensed pharmacy, is authorized by the Registrar to engage in that restricted activity.

**Duty in relation to provisional pharmacists and provisional pharmacy technicians**

3.13 A licensee must ensure that any provisional pharmacist, provisional pharmacy technician or student pharmacist who works in a licensed pharmacy and who will engage in a restricted activity in the licensed pharmacy:

a) acts within the rules of the Structured Practical Training Program, and

b) is appropriately supervised.

**Duty to comply with rules of Structured Practical Training Program**

3.14 If a provisional pharmacist, provisional pharmacy technician or student pharmacist works in a licensed pharmacy, the licensee must:

a) comply with the rules of the Structured Practical Training Program, and

b) ensure that all regulated members in the licensed pharmacy comply with the rules of the Structured Practical Training Program.

**Duty to refer health-related matters to pharmacist**

3.15 A licensee must ensure that any regulated member or employee who works in the prescription department of a licensed pharmacy who is not a clinical or courtesy pharmacist, is trained and instructed to refer any drug or health related request or issue that requires therapeutic knowledge, clinical analysis or assessment, to a clinical or courtesy pharmacist.

3.16 Nothing in Standard 3.15 prevents a licensee from authorizing a regulated member or employee who is not a clinical or courtesy pharmacist from referring any health-related request or issue from a patient to another regulated health professional who:

a) has expertise in the area,

b) is employed in the pharmacy, and

is practising in accordance with the statues, regulations, standards and ethics applicable to that other regulated health profession.

# Ensure suitable physical facility and equipment

## Standard 4: A licensee must ensure that the physical facility and the equipment in the licensed pharmacy provides a suitable environment for practice in accordance with these standards and the Standards of Practice for Pharmacists and Pharmacy Technicians.

### *Application of Standard 4*

**Duty regarding prescription department**

4.1 The licensee must ensure that the prescription department:

a) has adequate lighting, ventilation and humidity and temperature control;

b) is equipped with a security system that will provide suitable protection against theft, diversion and tampering with drugs and health care products, aids and devices; and

c) the dispensary is accessible only to personnel approved by the licensee.

**Duty to maintain orderliness and cleanliness**

4.2 The licensee must ensure that the licensed pharmacy is maintained in a clean and orderly condition.

**Signs must not mislead**

4.3 The licensee must ensure that signage used in the licensed pharmacy is clear and not misleading.

**Signage for prescription department**

4.4 The prescription department must be differentiated from the public area by a sign that reads:

a) Pharmacist,

b) Prescriptions,

c) Prescription Department,

d) Pharmacy, or

e) Professional Services.

4.5 Standard 4.4 does not apply if the public area comprises 15 percent or less of the premises of the pharmacy.

**Patient services area**

4.6 The area located outside and adjacent to the dispensary where professional services are provided to patients and where Schedule 3 drugs are provided for sale, otherwise known as the patient services area, must be physically delineated from the public area by the use of:

a) variations in décor, flooring or fixtures; or

b) physical separation.

**Requirements for a dispensary**

4.7 A dispensary must have:

a) adequate shelf and storage space,

b) a refrigerator or appropriate temperature-controlled area,

c) a sink with hot and cold running water,

d) a lockable drug locker or cupboard,

e) a heat source for extemporaneous compounding,

f) a mechanism to send and receive faxes,

g) a computer,

h) an operating internet connection, and

i) equipment to allow the pharmacy to make and receive telephone calls.

4.8 The fixtures, equipment and services required in Standard 4.7 must be dedicated for the use of the licensed pharmacy for the provision of professional services and, if the licensed pharmacy is part of a larger business enterprise, must not be used to support that larger business enterprise.

4.9 The internet connection, computer and software must:

a) provide unrestricted access to relevant health and pharmacist and pharmacy technician practice information required to practice according to these standards, and the Standards of Practice for Pharmacists and Pharmacy Technicians;

b) facilitate submission of patient record information to the Alberta Netcare electronic health record system operated by Alberta Health and Wellness as required by Council; and

c) provide access to the Alberta Netcare electronic health record system operated by Alberta Health and Wellness.

**Equipment in a dispensary**

4.10 A dispensary must have the following compounding and dispensing equipment:

a) a prescription balance with a sensitivity to a minimum of 10 mg or an electronic balance with a sensitivity to a minimum of 10 mg,

b) a set of metric weights or a calibration weight, and

c) any other equipment required to support the professional services that are provided in that dispensary.

4.11 The equipment referred to in Standard 4.10 must be:

a) used only in relation to the provision of professional services; and

b) cleaned, inspected and maintained to ensure proper functioning and the safety of the public.

**Area for confidential communication**

4.12 A licensed pharmacy must have an area within the patient services area that ensures patient confidentiality.

4.13 The area referred to in Standard 4.12 must include:

a) suitable sound barriers that prevent conversations from being overheard by unauthorized individuals; and

b) suitable visual barriers to prevent others from seeing what drug, health care products, aids or devices are being provided to or for the patient.

4.14 The area referred to in Standard 4.12 must be kept free for use for communicating with patients or patients' agents and must not be used to store or display anything other than health care products, aids or devices or patient information materials.

**Library**

4.15 A licensed pharmacy must have an adequate library to which a regulated member in the dispensary can have immediate access.

4.16 The library must include the following:

a) applicable federal and provincial enactments governing pharmacy practice in Alberta,

b) Canadian compendium of pharmaceuticals,

c) a drug interaction reference,

d) a dispensatory/foreign drug reference,

e) a medical dictionary,

f) an over-the-counter (OTC) drug reference,

g) a therapeutics reference,

h) a natural health products and alternative therapies reference, and

i) if the licensed pharmacy provides pharmacy services for animals, a veterinary medicine reference.

4.17 For the purposes of Standard 4.16, a licensee shall rely on the list of required reference sources set out on the College's website.

4.18 A licensee must ensure that all materials required to be included in the library are kept current.

4.19 The library may be kept in an electronic format or may be provided through an electronic comprehensive pharmacy information system database.

# Protect the integrity and safety of drugs, health care products and supplies

## Standard 5: A licensee must ensure the drug supply in the licensed pharmacy is managed so as to protect the integrity, quality and safety of drugs, health care products, aids and devices.

### *Application of Standard 5*

**Duty to examine drugs**

5.1 A licensee must ensure that all incoming and outgoing shipments of drugs, and health care products, aids and devices are visually examined:

a) to verify the identity of the drugs or the health care products, aids and devices; and

b) to verify that there has been no contamination of or damage to the drugs or the health care products, aids and devices.

**Duty in relation to storing drugs**

5.2 A licensee must ensure that drugs are stored in the licensed pharmacy:

a) at appropriate temperatures,

b) under appropriate conditions, and

c) in accordance with any manufacturer's requirements to ensure stability.

5.3 To ensure drugs that require refrigeration or freezing are stored at appropriate temperatures, a licensee must:

a) track and document storage temperatures regularly using a device that indicates the minimum and maximum temperatures reached since the last reading, and

b) take appropriate action if the temperatures fall outside acceptable limits.

**Labeling drugs in storage**

5.4 A licensee must ensure that drugs stored in the pharmacy are labeled using names from an official compendium.

**Duty when drugs are packaged or transported**

5.5 A licensee must ensure that appropriate conditions are maintained to ensure the integrity and security of the drugs when drugs are packaged in or transported from a licensed pharmacy.

**Duty to store drugs in a manner that minimizes error**

5.6 A licensee must ensure that the storage procedure for drugs minimizes the possibility of dispensing errors.

5.7 The duty under Standard 5.6 includes ensuring that drugs

a) for external use are stored separately from drugs for internal use and injectable drugs; and

b) for veterinary use are stored in a manner that clearly identifies them as such and eliminates the possibility of them being dispensed for human use.

**Storage of flammable and hazardous chemicals**

5.8 A licensee must ensure that flammable and hazardous chemicals, including diluents, are stored safely.

**Location of drugs in prescription department**

5.9 A licensee must ensure that drugs are kept in the appropriate locations within the prescription department, having regard for their scheduling under Part 4 of the *Pharmacy and Drug Act*.

**Return of drugs to storage**

5.10 A licensee must ensure that there are proper procedures for returning stock drugs to storage to reduce the risk of an error.

**Security for drugs**

5.11 A licensee must ensure that all drugs in a licensed pharmacy are secured against theft, loss or diversion.

5.12 A licensee must ensure adequate procedures are in place to identify theft, loss or diversion of narcotic and controlled drugs, including but not limited to:

a) maintaining a perpetual inventory of each narcotic and controlled drug in stock,

b) routinely auditing perpetual inventories to verify accuracy,

c) investigating any discrepancies identified,

d) evaluating whether procedure changes or preventative measures are required to prevent future discrepancies, and

e) reporting any loss or theft of narcotic or controlled drugs to Health Canada within 10 days of discovery.

**Disposal of drugs**

5.13 A licensee must ensure that:

a) outdated, recalled, damaged, deteriorated, misbranded or adulterated drugs are kept separately from other drugs until they are destroyed or returned to their supplier;

b) the licensed pharmacy has procedures for the safe and proper disposal of drugs that are outdated, recalled, damaged, deteriorated, misbranded or adulterated; and

c) the procedures are followed in the operation of the pharmacy.

5.14 A licensed pharmacy must accept the following items from patients for proper disposal unless accepting the drug or item would pose a health risk or hazard to pharmacy staff:

a) unused drugs,

b) expired drugs,

c) needles or other sharps used in the administration of drugs.

**Restriction on return for reuse**

5.15 A licensee must ensure that:

a) no drug or portion of a drug that has been dispensed or sold to a person; and

b) no health care product, aid or device that has been provided to a person, is returned to the licensed pharmacy for use or reuse.

5.16 Despite Standard 5.15, a licensee may permit a regulated member to repackage a drug or health care product, aid or device if:

a) that drug or 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 regulated member 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.

# Implement a quality assurance program

## Standard 6: A licensee must implement a quality assurance program to monitor and improve processes to minimize risk.

### *Application of Standard 6*

In this standard:

a) drug incident means any preventable event that may cause or lead to inappropriate drug use or patient harm. Drug incidents may be related to the practice of pharmacists or the practice of pharmacy technicians, drugs, health care products, aids and devices, procedures or systems, and include:

i. prescribing;

ii. order communications;

iii. product labeling, packaging, nomenclature;

iv. compounding;

v. dispensing;

vi. distribution;

vii. administration;

viii. education;

ix. monitoring; and

x. use.

b) adverse drug event means an unexpected and undesired incident related to drug therapy that results in patient injury or death or an adverse outcome for a patient, including injury or complication.

c) drug error means an adverse drug event or a drug incident where the drug has been released to the patient.

**Duty to minimize risk of drug errors**

6.1 A licensee must ensure that:

a) the licensed pharmacy has appropriate systems, policies and procedures in place to minimize the risk of a drug incident or an adverse drug event; and

b) regulated members and employees of the licensed pharmacy:

i. are trained; and

ii. are required as a term of their employment to comply with those systems, policies and procedures.

6.2 The licensee must monitor and enforce compliance with the systems, policies and procedures referred to in Standard 6.1.

**Quality assurance process**

6.3 A licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy. The quality assurance process should:

a) provide for reporting, investigating, documenting and evaluating drug incidents that occur in the pharmacy;

b) include regular review and feedback mechanisms to prevent drug incidents; and

c) include a process or procedure for responding to complaints or concerns.

6.4 The quality assurance process must provide for reporting, investigating, and evaluating drug errors, and must comply with the following:

a) within 24 hours of initial discovery, the licensee must ensure that any suspected drug error is investigated and, if verified, is documented;

b) the regulated member(s) involved in the drug error must document an account of the error as soon as possible after the discovery. If the regulated member involved is not on duty at the time of discovery, the regulated member or employee who discovers the drug error must initiate the documentation;

c) drug error documentation must:

i. be in a format that can be easily audited and reviewed, and

ii. be retained for at least 10 years after the error is discovered,

d) the documentation must include a description of factors contributing to the drug error and actions taken to prevent recurrence; and

e) the report must clearly identify whether it relates to a drug incident or an adverse drug event.

**Response to a drug error**

6.5 If a drug error is discovered, or if there is a reasonable suspicion that a drug error has occurred or will occur, the licensee must ensure that the following steps are taken:

a) initiate immediately any emergency measures required to protect the health and safety of the patient;

b) contact the patient immediately and disclose the drug error and its implications;

c) immediately advise all other regulated health professionals and caregivers whose care for the patient may be affected by the drug error and notify them of the drug error and its implications;

d) take appropriate steps to promptly remedy the error by ensuring that the patient receives the correct drug;

e) take reasonable steps when necessary to ensure that the incorrect drug is returned to the licensed pharmacy for safekeeping to avoid risk of harm or further harm; and

f) implement changes in practices, procedures or staffing in the licensed pharmacy to prevent a recurrence of the drug error, if required.

**Follow-up process**

6.6 The licensee must, at least quarterly:

a) review the drug error reports for the licensed pharmacy to evaluate whether practice changes or preventative measures are required to prevent future drug errors, and

b) assess whether any changes implemented as a result of a drug error were successful in advancing patient safety.

6.7 Nothing in Standard 6.6 relieves a licensee from the duty to make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it.

6.8 The licensee must communicate the results of the licensee's drug error review to all regulated members and employees who work in the prescription department, along with any other information required to assist in ensuring that the risk of a drug error is reduced.

# Ensure patients have access to compounding services

## Standard 7: A licensee must ensure that patients of the licensed pharmacy have access to compounding services.

### *Application of Standard 7*

**Licensed pharmacy to be prepared to provide compounded products**

7.1 A licensee must ensure that the licensed pharmacy is willing and able to provide compounding services normally available in pharmacy practice by:

a) employing regulated members with the skills necessary to undertake such compounding;

b) having the requisite equipment;

c) having formulas, systems, procedures and references that facilitate compounding; and

d) providing the regulated members working in the pharmacy with the time necessary to undertake compounding.

7.2 If the licensed pharmacy does not have regulated members with the skills or the equipment to compound a prescription, the licensee must ensure that a regulated member working in the pharmacy refers a patient to another licensed pharmacy that has regulated members with additional expertise or equipment to compound it.

7.3 A licensee may meet the obligation under Standard 7.1 by entering into an agreement with a compounding and repackaging pharmacy under which the compounding and repackaging pharmacy will compound drugs for the licensed pharmacy.

7.4 If a pharmacist or pharmacy technician employed in a licensed pharmacy will engage in sterile compounding of drugs or mixing other products for parenteral or ophthalmic use, the licensee must ensure that the compounded sterile products are prepared in an environment and according to procedures that meet United States Pharmacopeia (USP) Chapter 797 or another reputable source such as the Canadian Society of Hospital Pharmacists (CSHP), or the American Society of Health System Pharmacists (AHSP).

7.5 Despite the reference in Standard 7.4 to the Canadian Society of Hospital Pharmacists (CSHP), or the American Society of Health System Pharmacists (AHSP), 180 days after council approval of Guidelines for Preparing Sterile Compounds, the licensee must ensure that clinical and courtesy pharmacists and pharmacy technicians who engage in sterile compounding of drugs or mixing other products for parenteral or ophthalmic use in the licensed pharmacy, 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.

**Drug compounded or dispensed for an animal**

7.6 A drug compounded or dispensed for an animal must be recorded on a patient record created for the animal or herd and must not be entered on the patient record of the patient's agent.

# Ensure comprehensive record keeping system

## Standard 8: A licensee must ensure that there is an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records.

### *Application of Standard 8*

**Keeping records**

8.1 The licensee must ensure that there is an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records, including but not limited to:

a) records required by federal and provincial legislation and Standards of Practice for Pharmacists and Pharmacy Technicians;

b) records of all prescriptions received by the pharmacy;

c) records of the services provided by the pharmacy and the regulated members or others who are associated with the pharmacy, including records identifying all individuals involved in the processing of prescriptions and dispensing a drug and the role of each individual;

d) records of all Schedule 1 and Schedule 2 drugs received by the pharmacy, dispensed from the pharmacy, or sold by the pharmacy other than pursuant to a prescription; and

e) records of the mode of delivery of a drug to a patient for all drugs that are not picked up at the pharmacy by the patient or the patient's agent.

8.2 The licensee must ensure that the records referred to in Standard 8.1 are:

a) stored securely to ensure that only persons authorized by the licensee have access to the records, and

b) maintained in the pharmacy unless the licensee has applied for and received permission from the Registrar to store the records at a location other than the pharmacy.

8.3 A licensee must ensure that written prescriptions, transaction records, compounding records and repackaging records for all drugs that have been dispensed, compounded or repackaged are:

a) filed systematically; and

b) retained for at least two years past the completion of drug therapy with regard to the prescription or for 42 months (3.5 years), from the date of first fill, whichever is the longest period.

8.4 Despite Standard 8.3, written prescriptions and transaction records for drugs in specialized delivery systems such as implants must be stored separately and must be retained for two years past the date on which drug therapy was calculated to be completed.

**Equipment and systems requirements**

8.5 A licensee must ensure that a licensed pharmacy has:

a) the equipment and systems necessary for the storage and retrieval of all documents required to be kept under the Standards of Practice for Pharmacists and Pharmacy Technicians and any other legislation referred to in Standard 1.1; and

b) the computer system, peripheral equipment and software necessary for the input, storage, use, protection and retrieval of the patient record required to be kept electronically under the Standards of Practice for Pharmacists and Pharmacy Technicians.

8.6 The system, equipment and software referred to in Standard 8.5(b) must:

a) be capable of storing and reporting the information required in a patient record;

b) be capable of storing and reporting the information required in a transaction record describing the dispensing of a drug;

c) be capable of storing and reporting the information required in a) and b) for the time required by the appropriate legislation and standards;

d) incorporate sufficient security to ensure that only persons authorized by the licensee have access to the system;

e) have the ability to uniquely identify each regulated member and employee who is granted access to the system;

f) have the ability to control which functions may be accessed by each regulated member and employee;

g) create an accurate audit trail of persons using the system;

h) be capable of collating and generating reports of prescription information chronologically and by drug name and strength, patient name and prescriber name;

i) have sufficient speed and capacity to enable the regulated members to fulfill their professional responsibilities efficiently and effectively;

j) have adequate backup and recovery systems; and

k) require a deliberate and auditable procedure to be carried out by the licensee or a person under the direction of the licensee before any information can be purged from the system.

**Patient record**

8.7 The licensee must ensure that the equipment and systems required under Standard 8.5 facilitate sharing, ease of use and retrieval of necessary data in the patient record to facilitate continuity of patient care.

8.8 The patient record must provide a history of all interactions required to be documented for a patient under the Standards of Practice for Pharmacists and Pharmacy Technicians and must be maintained for a period of

a) not less than 10 years after the last pharmacy service provided to the patient or two years past the age of majority, whichever is greater for a patient that is a human; or

b) not less than 10 years after the last pharmacy service provided to the patient for a patient that is an animal.

**Backup of information stored electronically**

8.9 A licensee must ensure that:

a) all data required under this standard or the Standards of Practice for Pharmacists and Pharmacy Technicians is backed up at least once daily;

b) a copy of the backup is stored off-site or in a fire and theft-resistant safe;

c) the backup is stored so that it is retrievable in the event the system malfunctions or is destroyed; and

d) the backup is kept securely to avoid theft or unauthorized access, use or disclosure.

# If a compounding and repackaging pharmacy, maintain appropriate facilities and policies

## Standard 9: A licensee of a compounding and repackaging pharmacy must ensure:

a) the pharmacy has adequate space and equipment to perform the activities of the pharmacy,

b) drugs are compounded or repackaged according to the Standards of Practice for Pharmacists and Pharmacy Technicians and all other applicable legislation,

c) a written agreement has been signed with each pharmacy to which a compounding and repackaging pharmacy service will be provided, and

d) all drugs compounded or repackaged:

   i. have been done so in accordance with these standards, and

   ii. have a unique identifier that allows identification of the compounding and repackaging pharmacy.

### *Application of Standard 9*

**Space and equipment requirements**

9.1 The licensee of a compounding and repackaging pharmacy must ensure that there is adequate space and equipment to perform the activities of the pharmacy.

9.2 If the compounding and repackaging pharmacy is not a community pharmacy, the pharmacy must, at a minimum, meet the size and equipment requirements of a dispensary in a community pharmacy as outlined in the regulations to the *Pharmacy and Drug Act* and these standards.

**Role of compounding and repackaging pharmacies**

9.3 Only pharmacies with a compounding and repackaging licence may perform compounding or repackaging for other licensed pharmacies.

9.4 The licensee of a compounding and repackaging pharmacy that will compound drugs must ensure that drugs are prepared in an environment and according to procedures that meet standards established by the United States Pharmacopeia (USP).

**Requirement for an agreement**

9.5 The compounding and repackaging pharmacy and the licensed pharmacy that is acquiring compounded or repackaged drugs must have a written agreement in the form required by Council outlining the services to be provided and the responsibilities and accountabilities of each party.

**Standards applicable**

9.6 The licensee of the compounding and repackaging pharmacy must ensure compliance with the standards regarding compounding and repackaging drugs including, but not limited to, record keeping and labeling requirements for compounded or repackaged drugs.

**Unique identifier required**

9.7 In addition to the prescription labeling requirements dictated under the Standards of Practice for Pharmacists and Pharmacy Technicians, the prescription label for all drugs processed by a compounding and repackaging pharmacy must include a unique identifier that identifies the compounding and repackaging pharmacy.

# If a mail order pharmacy, maintain appropriate policies and records

## Standard 10: A licensee of a mail order pharmacy must establish and monitor compliance with policies and procedures and keep appropriate records of activities related to the provision of mail order pharmacy services.

### *Application of Standard 10*

10.1 The licensee of a mail order pharmacy must:

a) establish policies and procedures regarding how information is collected to assess individual patients and obtain all the information necessary to allow the regulated members to meet the requirements of the Standards of Practice for Pharmacists and Pharmacy Technicians, and

b) ensure compliance with these policies and procedures via regular monitoring.

**Record keeping requirements in a mail order pharmacy**

10.2 In addition to the records that must be kept in a community pharmacy, a mail order pharmacy must keep records that identify any arrangement or agreement under which patients are referred to the mail order pharmacy.

# If a satellite pharmacy, maintain appropriate facilities and policies

## Standard 11: A licensee of a community pharmacy that holds a satellite pharmacy licence must:

a) ensure the satellite pharmacy has adequate space and equipment to perform the activities of the pharmacy,

b) maintain an adequate drug inventory in the satellite pharmacy,

c) establish and monitor compliance with policies and procedures and keep appropriate records of activities specific to the operation of the satellite pharmacy, and

d) comply with any restrictions imposed by the Registrar.

**NOTE: A licensee of a community pharmacy who makes an application to operate a satellite pharmacy must provide a written rationale for the operation of a satellite pharmacy. The rationale must include the reasons why the patients who are expected to attend the satellite pharmacy require a pharmacy service that cannot be effectively provided in a community pharmacy, or reasons that make it necessary for those patients to receive a pharmacy service at a satellite pharmacy.**

### *Application of Standard 11*

11.1 A licensee of a community pharmacy that operates a satellite pharmacy must:

a) establish policies and procedures specific to the operation of the satellite pharmacy, including but not limited to:

i. the management of prescription transfers, both into the satellite pharmacy and out to the community pharmacy or another pharmacy;

ii. the procedures for providing compounded prescriptions; and

iii. the procedures for providing compliance packaging.

**Standards applicable**

11.2 In addition to all other requirements set out in these standards, the licensee of a community pharmacy who has been granted a licence to operate a satellite pharmacy must:

a) maintain a drug inventory in the satellite pharmacy that is:

i. separate from the community pharmacy's drug inventory, and

ii. sufficient to meet the usual prescription volume at the satellite pharmacy,

b) not operate the satellite pharmacy as a lock and leave pharmacy, and

c) use unique prescription labels that display the address and telephone number of the satellite pharmacy and the parent pharmacy for drugs filled at the satellite pharmacy.

**Space and equipment requirements**

11.3 The dispensary of a satellite pharmacy must meet the size and equipment requirements of a dispensary in a community pharmacy as outlined in the regulations to the *Pharmacy and Drug Act* and these standards.

11.4 Despite Standard 11.3, the Registrar may license a satellite pharmacy that does not comply with all the standards set out in Standard 4 and, in such a case, may impose conditions to ensure the integrity of the drug distribution system, the safety of the public, and the integrity of the profession.

11.5 In the event the Registrar licenses a satellite pharmacy under Standard 11.4, the licensee must ensure compliance with all conditions imposed by the Registrar.

# Remote dispensing

**Standard 12: This standard has been left intentionally blank to accommodate a standard for remote dispensing from satellite pharmacies if necessary legislative amendments are made.**

# Notify the college when closing a pharmacy

## Standard 13: A licensee must provide the college with information when a licensed pharmacy closes permanently.

### *Application of Standard 13*

13.1 When a pharmacy closes permanently, the licensee must:

a) notify the college immediately of the exact date of closure, and

b) provide the following information to the college within five working days of the closure:

i. details of the disposition of drugs from the pharmacy,

ii. details of the disposition of records from the pharmacy,

iii. details of the manner in which patients may access their records, and

iv. a written record of all narcotic and controlled drugs transferred from the pharmacy.

# Proprietor: Support the licensee

## Standard 14: A proprietor must ensure the capability of and support the licensee.

### *Application of Standard 14*

**Reasonable steps to ensure competence of licensee**

14.1 A proprietor must take reasonable steps to ensure that the licensee of the proprietor's pharmacy is capable of:

a) managing the practice of pharmacists and pharmacy technicians in that licensed pharmacy, and

b) ensuring compliance with these standards.

**Support and resources**

14.2 A proprietor must provide the licensee of the proprietor's pharmacy with the support and resources necessary for the licensee to comply with the licensee's obligations under these standards and the legislation referred to in Standard 1.1.

**Failure of proprietor not an excuse for licensee**

14.3 Nothing in Standard 14.2 relieves a licensee from complying with these standards and the legislation referred to in Standard 1.1.

14.4 A pharmacist must not assume the position of a licensee or continue as a licensee if the proprietor places the pharmacist in a position where the pharmacist cannot comply with these standards and the legislation referred to in Standard 1.1.