Alberta College of Pharmacy

Standards for the Operation of Licensed Pharmacies

Effective February 1, 2025

Table of contents

Table of contents

Table of contents

Information

These standards were originally approved by the Council of the Alberta College of Pharmacy on June 12, 2024, and are effective as of February 1, 2025.

Always use the latest version of this document found on the college website.

Acknowledgements

The Alberta College of Pharmacy acknowledges that these standards govern the operation of licensed pharmacies and the conduct of licensees and proprietors on Treaty 6, Treaty 7, and Treaty 8 territory—the traditional lands of First Nations people—and six Métis regions. The roots of many modern medications come from the Indigenous peoples' traditional use of plants from these lands.

Introduction

The Alberta College of Pharmacy governs pharmacists, pharmacy technicians, and licensed pharmacies in Alberta to serve, support, and protect the public's health and well-being. As part of fulfilling this responsibility, the college establishes standards that set expectations for the operation of licensed pharmacies and the performance, professionalism, and ethical conduct of pharmacy licensees and proprietors in Alberta.

These standards set out the acceptable standard for the operation of licensed pharmacies. Licensees and proprietors are expected to comply with the letter and the intent of the legislative framework.

Legislative framework

The legislative framework that governs licensed pharmacies is comprised of several distinct pieces that work together to support and outline the related practices of pharmacists and pharmacy technicians and the environments in which they practise. The legislative framework regulates the operation of licensed pharmacies by establishing expectations for pharmacy licensees and proprietors.

The *Pharmacy and Drug Act* and its regulations enable the licensing and regulation of pharmacies and the provision of pharmacy services in Alberta. The *Pharmacy and Drug Act* and its regulations authorize the development of bylaws, standards, and a code of ethics that set out the responsibilities and accountabilities of licensees and proprietors in the operation of licensed pharmacies.

In every circumstance, the authority and responsibilities of the licensee and the proprietor must be interpreted and applied in the context of the roles established by the *Pharmacy and Drug Act*, the *Health Professions Act*, the *Health Information Act*, the *Personal Information Protection Act*, and the directions provided through federal and provincial legislation, standards, the college's Code of Ethics, relevant guidelines, and acceptable conduct.[1]

Roles of licensees and proprietors

Licensees and proprietors each have a unique set of responsibilities in a licensed pharmacy. Licensees provide leadership and oversight for the pharmacy team. They are responsible to ensure that patient needs are being met and that the operations of the licensed pharmacy, the practice of regulated members, and the work of unregulated employees occurs in accordance with these standards and the legislative framework. To this end, licensees must read and apply these standards in context with the Licensee Competencies Framework approved by Council.[2]

Proprietors and their representatives are responsible for ensuring that the licensee and pharmacy team are provided the necessary infrastructure, technology, information, environment, equipment, supplies, and human resources to provide patient care and practise pharmacy safely and effectively in compliance with the legislative framework.

1 Licensees and proprietors must be aware of and comply with all standards and guidelines approved by Council.
2 Refer to the Licensee Competencies Framework for additional information.

Introduction

Person-centred care

These standards ensure that licensed pharmacies operate in a way that enables and empowers regulated members to provide safe and effective person-centred care. Licensees and proprietors prioritize high-quality health care as the primary goal of all professional and pharmacy services provided from licensed pharmacies. When interpreting and implementing each standard, licensees and proprietors must always consider the impact of their actions on person-centred care and meaningfully involve patients in the decision-making processes related to their care.

Licensees and proprietors value equity, diversity, and inclusion in the collaborative environment of their pharmacy. Through their actions, they provide a culturally safe workplace where patients and pharmacy team members are supported, valued, and respected. They ensure the dignity and rights of every individual without prejudice and expect the same from pharmacy team members. In their pharmacy, they ensure person-centred care is provided in a manner that is equitable, inclusive, and accessible to patients.

Structure of the standards

There are six separate domains that represent facets of licensed pharmacy operations (see Figure 1 below). Each domain has a statement that summarizes and contextualizes the standards within the domain. Each domain is divided into topics. Each topic has an outcome standard that describes the expected outcome that must be achieved for the standard to be met. The achievement of each outcome standard is detailed further through the inclusion of descriptive standards that provide regulated members specific details of the activities needed to achieve the required outcome.

Person-centred care is foundational to every aspect of pharmacy practice. Within these standards, the person-centred care domain describes the importance of person-centred care within the context of a licensed pharmacy. Similarly, the domain of professionalism and leadership is fundamental to all other domains as it is an intrinsic part of activities performed by proprietors, licensees, and regulated members practising at a licensed pharmacy.

Descriptive standards use the language of "must" and "may." To achieve outcome standards, it is mandatory for licensees and proprietors to comply with each descriptive standard that uses the word "must." Descriptive standards that use "may" indicate standards that are not required but that can be used to meet an outcome standard if relevant and appropriate.

Figure 1: The six domains of licensed pharmacy operations

Interpretation and application of the standards

Throughout the standards

1. Unless a more specific definition is provided, the terms used in these standards have the same meaning as in the *Health Professions Act*, the Health Professions Restricted Activity Regulation, the Pharmacists and Pharmacy Technicians Profession Regulation, the *Pharmacy and Drug Act*, or the Pharmacy and Drug Regulation.
2. Unless mentioned specifically, all provisions in these standards that apply to Schedule 1 drugs also apply to blood products.
3. Where a provisional pharmacist, courtesy pharmacist, or student pharmacist engages in the practice of pharmacists, the licensee shall consider these standards applicable to that provisional, courtesy, or student pharmacist.
4. Where a provisional pharmacy technician or courtesy pharmacy technician engages in the practice of pharmacy technicians, the licensee shall consider these standards applicable to that provisional or courtesy pharmacy technician.
5. All standards applicable to the relationship between a pharmacist or pharmacy technician and a patient apply to the pharmacist or pharmacy technician and the patient's agent.
6. Unless specified otherwise within a standard, "proprietor" must be read as including proprietors and proprietor's representatives.
7. All standards relate to requirements for each licensed pharmacy. This means that each licensed pharmacy must autonomously fulfill all standards.
8. When 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.

Definitions

Throughout the standards

1. **Accessibility** means the ease with which a patient can obtain needed care (including advice and support) from a regulated member within a time frame appropriate to the urgency of the problem.[3]
2. **Animal** means any animal other than a human being.
3. **Blood product** means a product, commercially available or provided from an accredited laboratory, that is derived from blood.
4. **Circle of care** means the group of regulated health professionals, patient caregivers, and other individuals identified by a patient who work in collaboration with the patient and who are responsible for elements of providing or supporting the patient's care.
5. **Close call** means an event that could have resulted in unwanted consequences but did not because, either by chance or through timely intervention, the event did not reach a patient.
6. **Continuous quality improvement** means a structured process used within a pharmacy, which allows for the ongoing review and improvement of all aspects of the delivery of care, in order to ensure patient safety and satisfaction. It is reactive when quality concerns arise, but also proactive in assessing risk and taking action before harm can occur.
7. **Critical step** means a step in a process that must be reviewed during the process as it cannot be confirmed during a final check. These steps vary by task but may include performing calculations, verifying the selection of drugs or ingredients, verifying quantities of ingredients, or verifying technique.
8. **Cultural sensitivity** means the continual recognition that culture plays a significant role in determining a person's view of their care.[4]
9. **Culturally safe** means a physically, socially, emotionally, and spiritually safe environment, without challenge, ignorance, or denial of an individual's identity where patients feel secure, supported, and free to draw strength from their identity, culture, and community.[5]
10. **Dispensary** means the area of a licensed pharmacy that is not accessible to the public and in which regulated members dispense, compound, repackage, provide for sale, and sell drugs.
11. **Diversity** means the variety of unique dimensions, qualities, and characteristics we all possess including race, ethnicity, age, gender, sexual orientation, religious beliefs, economic status, physical abilities, life experiences, and other perspectives.[6]

3 Definition adapted from Christine Beaulieu, Marie-Dominique Beaulieu, Fatima Bouharaoui, Frederick Burge, David Gass, Jeannie L. Haggerty, Jean-Frédéric Lévesque, Raynald Pineault, and Darcy A. Santor. "Accessibility from the Patient Perspective: Comparison of Primary Healthcare Evaluation Instruments." Healthcare Policy, 7 (Special issue) (2011): 94–107.
4 Definition adapted from Alberta Health Services. What is Cultural Sensitivity? June 2020.
5 Definition adapted from Government of British Columbia. In Plain Sight. Addressing Indigenous-specific racism and Discrimination in BC Health Care Summary Report. November 2020.
6 Definition adapted from Canadian Centre for Diversity and Inclusion. Glossary of IDEA terms: A reference tool for inclusion, diversity, and accessibility terminology. May 2023.

12. **Drug product** means
    a) a Schedule 1 drug,
    b) a Schedule 2 drug,
    c) a blood product, or
    d) a Schedule 3 drug that is provided under a prescription.
13. **Equity** means the practice of ensuring fair, inclusive, and respectful treatment of all people, with consideration of individual and group diversities.[7]
14. **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.
15. **Healthcare facility** means
    a) a hospital as defined in the *Hospitals Act*,
    b) a type A continuing care home, as defined in the Continuing Care Regulation,
    c) a correctional institution as defined in the *Corrections Act*, or
    d) a facility as defined in the *Mental Health Act*.
16. **Healthcare products, aids, or devices** means
    a) devices as defined in the *Food and Drugs Act*;
    b) natural health products as defined in the Natural Health Products Regulations; or
    c) products, aids, and devices that promote health and treat diseases, dysfunctions, or disorders.
17. **Herd** means a group or population of animals that cohabitate and feed together in the same environment and includes flocks, schools, and hives.
18. **Inclusion** means the creation of an environment that embraces, respects, accepts, and values diversity.[8]
19. **Independent double check** means a regulated member double checks the critical steps completed by another individual at the practice site. In the case of an unregulated employee, a double check is mandatory at each critical step.
20. **In-person care** means a regulated member provides professional services to a patient from a licensed pharmacy, institution pharmacy, or other practice site located within Alberta.[9]
21. **Institution pharmacy** has the same meaning as in the *Pharmacy and Drug Act*.
22. **Just culture** means an atmosphere of trust in which healthcare workers are supported and treated fairly when something goes wrong with patient care. Just culture is important to patient safety as it creates an environment in which people (healthcare workers and patients) feel safe to report errors and concerns about things that could lead to patient adverse events.[10]

7 Definition adapted from Health Science Information Consortium of Toronto. Equity, Diversity & Inclusion.
8 Definition adapted from Canadian Centre for Diversity and Inclusion. Glossary of IDEA terms: A reference tool for inclusion, diversity, and accessibility terminology. May 2023.
9 Refer to the Standards of Practice for Virtual Care for additional information.
10 Definition adapted from Health Quality Council of Alberta. About Just Culture.

23. **Patient** means any human or animal to whom a regulated member provides a professional service.
24. **Patient's agent** means a person who acts for or on behalf of a patient and
    a) in the case of a human who is the patient, a family member, caregiver, public guardian, or another individual whom the regulated member is reasonably satisfied has the authorization of the patient to engage with the pharmacy team; or
    b) in the case of an animal who is the patient, an owner, an agent or an employee of an owner, or caregiver of the animal or herd.[11]
25. **Patient services area** means the area of a licensed pharmacy located outside and adjacent to the dispensary where
    a) patients receive professional services from regulated members or other regulated health professionals who are part of the pharmacy team,
    b) a pharmacy consultation room is located, and
    c) Schedule 3 drugs are provided for sale.
26. **Person centred** means care approaches and practices that see a patient as a whole with many levels of needs and goals, with these needs coming from their own personal social determinants of health.
27. **Pharmacist** means a clinical pharmacist, a provisional pharmacist, a courtesy pharmacist, or a student pharmacist, unless the context states otherwise.
28. **Pharmacy service** means the storing, compounding, dispensing, or selling of drugs.
29. **Pharmacy team** means the regulated members practising in the licensed pharmacy, other regulated health professionals practising collaboratively with the regulated members, and unregulated employees who provide support. Pharmacy team members work cohesively within the licensed pharmacy under the oversight of the pharmacy licensee.
30. **Pharmacy technician** means a pharmacy technician, provisional pharmacy technician, or courtesy pharmacy technician, unless the context states otherwise.
31. **Practice incident** means an event that may lead to inappropriate drug use or patient harm that has reached a patient. Practice incidents may be related to professional practice, drugs, procedures, and systems, and include assessment, prescribing, order communication, product labelling/packaging/nomenclature, compounding, repackaging, dispensing, distribution, administration, education, monitoring, and use.
32. **Practice of pharmacists** means the practice defined by section 3(1) of Schedule 19 to the *Health Professions Act* and carried out in accordance with the direction of Council, including any standards, guidelines, policies, and the Code of Ethics.
33. **Practice of pharmacy technicians** means the practice defined by section 3(2) of Schedule 19 to the *Health Professions Act* and carried out in accordance with the direction of Council, including any standards, guidelines, policies, and the Code of Ethics.
34. **Prescription department** means the dispensary and the patient services area.

11 A patient's agent is not otherwise an authorized decision maker under other legislation unless clearly specified.

35. **Prescriber** means
    a) with respect to a prescription for a human, a regulated health professional who is authorized to prescribe Schedule 1 drugs under the *Health Professions Act* or similar legislation that governs a regulated health professional in another province or territory; or
    b) with respect to a prescription for an animal,
        i. a veterinarian who is authorized to prescribe drugs to animals under the *Veterinary Profession Act* or similar legislation that governs the veterinary profession in another province or territory, and
        ii. a pharmacist who adapts a prescription from a veterinarian under part a) of this definition for the purpose of providing continuity of care.
36. **Professional service** means a service that is within the practice of pharmacists or the practice of pharmacy technicians.
37. **Professional relationship** means a relationship formed before providing a professional service to a patient between the regulated member and the patient that
    a) is collaborative;
    b) facilitates trust;
    c) is intended to optimize the patient's health or drug therapy;
    d) is formed in accordance with principle 2 of the Code of Ethics;
    e) with respect to a patient who is a human, is formed with the patient; and
    f) with respect to a patient that is an animal, is formed with the patient's agent.
38. **Public area** means the area of a licensed pharmacy located outside of the prescription department.
39. **Quota** means a requirement or expectation to achieve any measurement of professional services or revenue obtained from professional services provided to patients.
40. **Regulated health professional** means
    a) in the case of humans, a member of a profession practising under
        i. the *Health Professions Act*, or
        ii. similar legislation that governs a health profession in another province or territory; or
    b) in the case of animals, a member of a profession practising under
        i. the *Veterinary Profession Act*,
        ii. the *Health Professions Act*, or
        iii. similar legislation that governs a profession in another province or territory.
41. **Regulated member** means a pharmacist or pharmacy technician.
42. **Repackaging** means subdividing or breaking up a manufacturer's original package of a drug for the purpose of dividing and assembling the drug in larger or smaller quantities for redistribution or sale.

43. **Restricted activity** means an activity named as a restricted activity in the *Health Professions Act*.[12]
44. **Safety culture** means the underlying beliefs and values of an organization as they relate to safety as a priority.[13]
45. **Temporary pharmacist in charge** means a pharmacist employed at the pharmacy who is approved by the registrar to temporarily assume all responsibilities of a licensee and who agrees to personally manage, control, and supervise the practice of pharmacy and comply with the legislative framework, any condition imposed on the permission for the pharmacy to continue to operate temporarily, and any order made under the *Pharmacy and Drug Act* or its regulations.
46. **Unregulated employee** means an individual engaged to provide services as a paid or unpaid employee, consultant, contractor, or volunteer who assists regulated members, and is not themselves a regulated member.
47. **Virtual care** means any interaction between patients and regulated members that includes the provision of a professional service and occurs remotely using an enabling technology.[14,15]

12 The concept of "restricted activities" only applies to human beings.
13 Definition adapted from Institute for Safe Medication Practices Canada. Definitions of Terms.
14 Virtual care does not include patient contact using an enabling technology for non-care purposes.
15 Refer to the Standards of Practice for Virtual Care for the definition and application of "enabling technology."

Domain 1 – Person-centred care

Person-centred care recognizes that each patient is an individual with their own values, needs, and health concerns. It optimizes the delivery of health care by having regulated members collaborate with patients to understand what is important to them.

Proprietors and licensees design and operate licensed pharmacies in a manner that enables regulated members to provide person-centred care. This includes the use of policies, procedures, monitoring, and staff training to facilitate patient accessibility, respect for patient autonomy, and recognition of how patient diversity and systemic inequities can impact patient health needs, expectations, goals, and ability to access quality care.

Pharmacy licensees demonstrate person-centred care by always considering the potential impacts of pharmacy operations and environment, and by enabling and requiring regulated members to provide care in an equitable, inclusive, and culturally sensitive manner.

Equity, diversity, inclusion, accessibility, and cultural sensitivity

1.1 A licensee and a proprietor create a pharmacy environment that enables and requires equity, diversity, inclusion, accessibility, and cultural sensitivity.

1.1.1 A licensee and a proprietor must ensure the pharmacy team is supported by policies, procedures, staff training, and monitoring practices that enable and require every team member to

a) demonstrate equity, diversity, inclusivity, and cultural sensitivity in patient care within the context required by the Standards of Practice for Pharmacists and Pharmacy Technicians; and

b) provide professional services in a manner that ensures a patient has access to pharmacy care, by considering and accommodating the patient's

i. physical, cognitive, and sensory abilities;

ii. level of health literacy; and

iii. level of digital literacy.

Indigenous patients and culture

1.2 A licensee and a proprietor create a culturally safe environment for Indigenous patients.

1.2.1 A licensee and a proprietor must ensure that the pharmacy team is supported by policies, procedures, staff training, and monitoring practices that enable and require every team member to create and maintain a culturally safe environment for Indigenous patients within the context required by the Standards of Practice for Pharmacists and Pharmacy Technicians.

Domain 2 – Professionalism and leadership

Licensees and proprietors understand their distinct roles and responsibilities and the roles and responsibilities of regulated members. This empowers regulated members to exercise professionalism in fulfilling their professional responsibilities.

Licensees and proprietors foster a safe and inclusive work environment that encourages collaboration, openness, honesty, and continuous learning, and provides regulated members the opportunity to raise concerns and provide feedback without fear of reprisal.

Licensees enable the professional learning and development of their pharmacy team members, ensuring the care provided by the pharmacy team evolves with their communities and the healthcare system.

Licensees make operational decisions for the pharmacy and take responsibility for the outcomes of their decisions. They lead by example and provide leadership to pharmacy teams by mentoring and enabling team members to practise to their full abilities.

Licensees structure the operations of their licensed pharmacies to benefit their patients' health and to ensure pharmacy teams practise within the legislative framework.

Proprietors provide licensees and regulated members adequate resources to meet the requirements of these standards and the legislative framework.

Independence of licensees and regulated members

2.1 A licensee and a proprietor empower regulated members to use their professional judgement when providing patient care.

2.1.1 A licensee must ensure

a) they operate the licensed pharmacy in accordance with the legislative framework in the best interests of patient care;

b) regulated members and other regulated health professionals who are part of the pharmacy team are not constrained by any condition imposed by the proprietor or licensee that compromises the regulated members' or other regulated health professionals' professional independence, judgement, or integrity; and

c) there are provisions in place to meet patient needs if a regulated member exercises a conscientious objection.

2.1.2 A proprietor must not impose any condition or quota on a licensee, regulated member, or other regulated health professional who is part of the pharmacy team, which may compromise the licensee's, regulated member's, or other regulated health professional's professional independence, judgement, integrity, or ability to comply with the legislative framework that governs their practice.

Proprietor support for the licensee

2.2 A proprietor provides the pharmacy licensee the resources they require to comply with the legislative framework.

2.2.1 A proprietor must

a) ensure that the licensee of a licensed pharmacy is provided the resources required to fulfill the licensee's responsibilities, including

i. managing the practices of pharmacists and pharmacy technicians in that licensed pharmacy, and

ii. ensuring compliance with the legislative framework;

b) provide the licensee with the support and resources necessary for the licensee to comply with the expectations of the licensee under these standards and the legislative framework;

c) provide the licensee any records from the licensed pharmacy referred to in these standards that are in the possession or under the control of the proprietor or any person associated with the proprietor if those records are requested by the licensee;

d) ensure that the pharmacy is always under the personal management, control, and supervision of an approved licensee or temporary pharmacist in charge; and

e) upon pharmacy closure, support the licensee or retain a pharmacist to close the pharmacy in accordance with the Pharmacy and Drug Regulation.[16]

2.2.2 Regardless of the actions of the proprietor, nothing in Standard 2.1 or 2.2 relieves a licensee from complying with these standards and the legislative framework.

Pharmacy licensee changes

2.3 A licensee and a proprietor maintain continuity of access to prescriptions and patient records during licensee transitional periods.

2.3.1 A licensee who resigns or is away for an extended period must work with the proprietor and the Alberta College of Pharmacy to ensure the pharmacy

a) has a replacement licensee in place,

b) has a temporary pharmacist in charge in place, or

c) is closed in accordance with the Pharmacy and Drug Regulation.[17]

2.3.2 Standard 2.3.1 does not apply when a licensee

a) is terminated, or

b) no longer has access to the pharmacy.

2.3.3 Further to Standard 2.3.2, in the event that a licensee is terminated by the proprietor, the proprietor must retain a pharmacist to carry out the expectations required by Standard 2.3.1.

16 s 27 of the Pharmacy and Drug Regulation describes the responsibilities of the proprietor and licensee when a licensed pharmacy closes.
17 s 27 of the Pharmacy and Drug Regulation describes the responsibilities of the proprietor and licensee when a licensed pharmacy closes.

Professionalism

2.4 A licensee builds patient trust by maintaining professionalism in the licensed pharmacy.

2.4.1 A licensee must

a) ensure all regulated members conduct themselves in a manner consistent with the tenets of professionalism;[18] and

b) ensure each member of the pharmacy team is clearly identifiable to patients, the public, and other regulated health professionals of the licensed pharmacy, by wearing a nametag that

i. identifies their name;

ii. for licensees, identifies them as the pharmacy licensee or pharmacy manager;

iii. for regulated members, identifies their role using a title authorized in the Pharmacists and Pharmacy Technicians Profession Regulation that they are entitled to use;

iv. for other regulated health professionals who are part of the pharmacy team, identifies their role using a title authorized by their respective regulatory body that they are entitled to use; and

v. for unregulated employees, clearly differentiates them from regulated members.

Collaborative work environments

2.5 A licensee facilitates effective communication and collaboration among pharmacy team members, the patient, and the patient's circle of care.

2.5.1 A licensee must

a) ensure the licensed pharmacy has the required infrastructure, patient information management systems, policies, and procedures to effectively communicate patient information with a patient's circle of care to ensure continuity of patient care; and

b) manage concerns and issues that arise among the pharmacy team, a patient, and the patient's circle of care.

Culture of accountable leadership

2.6 A licensee creates an environment where authority, responsibility, and accountability are demonstrated by the licensee and the pharmacy team.

2.6.1 A licensee must

a) ensure each pharmacy team member at the licensed pharmacy understands their role and the expectations of them;

b) lead by example and support colleagues in their practice;

c) enable the abilities and scope of practice of team members as appropriate;

18 Refer to Understanding professionalism for information about the professionalism framework.

d) hold themselves and pharmacy team members accountable to their professional responsibilities; and

e) create opportunities for pharmacy team members to provide input about the operations of the licensed pharmacy, including safety concerns.

Staff training and orientation

2.7 A licensee facilitates access to the support and training required to enable regulated members to provide person-centred care.

2.7.1 A licensee must

a) ensure that they have the appropriate education, skills, and training required to perform the duties and responsibilities of a licensee;

b) ensure that each regulated member in a licensed pharmacy has the appropriate education, skills, training, and legislated authority required to perform the duties and responsibilities assigned to that regulated member;

c) ensure that each unregulated employee in a licensed pharmacy has the appropriate training to perform the duties and responsibilities assigned to that unregulated employee; and

d) ensure each regulated member who will practise in a licensed pharmacy and each unregulated employee who will work in a licensed pharmacy receives

i. an orientation that includes a review of

A. the pharmacy's operational policies and procedures,

B. the plan required by Standard 3.10, and

C. all professional services provided from the pharmacy; and

ii. a suitable period of supervision, training, observation, and assessment of skills and knowledge.

Structured Practical Training program

2.8 A licensee provides provisional pharmacists, provisional pharmacy technicians, and student pharmacists the support needed to successfully complete structured practical training requirements at the pharmacy.

2.8.1 A licensee must ensure that they and all regulated members in the licensed pharmacy comply with the requirements of the Structured Practical Training program if a provisional pharmacist, provisional pharmacy technician, or student pharmacist practises in that pharmacy.

Oversight of regulated members

2.9 A licensee protects patients by overseeing the practice of regulated members to ensure that restricted activities are only performed by authorized individuals.

2.9.1 A licensee must

a) ensure that any regulated member 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 to engage in that restricted activity;

b) ensure that no restricted activities occur in the licensed pharmacy at any time unless a regulated member who is authorized to perform the restricted activity is present to conduct or supervise the restricted activity;

c) be aware of any authorizations and facilitate compliance with any conditions or restrictions on a regulated member's practice permit; and

d) implement procedures in the licensed pharmacy to ensure that a clinical or courtesy pharmacist who provides direction to a pharmacy technician in the licensed pharmacy

i. is practising from the same licensed pharmacy as the pharmacy technician,

ii. consults with and provides guidance or assistance to the pharmacy technician if requested or required, and

iii. provides an opportunity for collaboration with the pharmacy technician.

Practising at a location offsite from a licensed pharmacy

2.10 A licensee ensures that regulated members provide patient care appropriately when practising at a location other than the licensed pharmacy.

2.10.1 A licensee must ensure that regulated members who practise at their licensed pharmacy only perform professional services while in the pharmacy except

a) if the regulated member is providing professional services to a patient in person in a healthcare facility serviced by the licensed pharmacy;

b) if the regulated member is providing professional services in person at an offsite location or a patient's residence; or

c) if the regulated member has determined it is in the best interests of a patient to provide the professional service from a location other than the licensed pharmacy, either virtually or in person

i. if the pharmacy is closed, or

ii. in the event of an emergency.

2.10.2 In addition to Standard 2.10.1, a licensee must ensure that regulated members performing professional services in a location other than the licensed pharmacy must

a) have access to all pharmacy resources required to provide professional services at that location,

b) practise in accordance with the Standards of Practice for Pharmacists and Pharmacy Technicians and the Standards of Practice for Virtual Care,

c) only access records and pharmacy resources using a secure means that has been included in the privacy impact assessment submitted to the Office of the Information and Privacy Commissioner of Alberta, and

d) return and maintain all drugs and records in the licensed pharmacy upon completion of the professional services being provided remotely.

2.10.3 A licensee must ensure that regulated members do not provide virtual care to a patient of the pharmacy from a location other than the licensed pharmacy, except in accordance with Standards 2.10.1 and 2.10.2.

Oversight of other regulated health professionals

2.11 A licensee protects patients by overseeing the practice of other regulated health professionals practising in the licensed pharmacy as part of the pharmacy team.

2.11.1 A licensee must

a) ensure any other regulated health professional practising in the licensed pharmacy as part of the pharmacy team practise

i. under the oversight of the pharmacy licensee,

ii. as collaborative members of the pharmacy team, and

iii. in compliance with the policies and procedures of the licensed pharmacy;

b) ensure that any other regulated health professional who is part of the pharmacy team in a licensed pharmacy and who engages in a restricted activity, or who will supervise a restricted activity in the licensed pharmacy, is authorized to engage in that restricted activity; and

c) ensure that patient records created by any other regulated health professional are

i. created and retained in accordance with Standard 5.4, and

ii. accessible by the regulated members of the pharmacy team.

2.11.2 Nothing in this standard permits any other regulated health professional to practise independently from the pharmacy team in or from a licensed pharmacy premises except in accordance with Standard 3.4.

Operations supervisor

2.12 A licensee supports effective administration and management of pharmacy operations.

2.12.1 A licensee may appoint a regulated member to occupy the role of operations supervisor in the pharmacy.

2.12.2 An operations supervisor may, under the direction of the licensee, oversee the management of the operations of a licensed pharmacy including

a) compliance with the policies and procedures in the licensed pharmacy,

b) human resource duties such as hiring and scheduling of pharmacy staff, and

c) training and orientation of pharmacy staff.

2.12.3 An operations supervisor must not perform or supervise restricted activities that they are not authorized to perform.

2.12.4 Nothing in Standard 2.12.2 relieves a licensee of the requirements of these standards or the legislative framework.

Supervision of unregulated employees

2.13 A licensee ensures appropriate supervision of unregulated employees.

2.13.1 A licensee must ensure that an unregulated employee

a) is not assigned or delegated the task of forming a professional relationship with a patient;

b) does not provide a professional service that requires the training and skills of a regulated member;

c) is given clear direction about the scope and limitations of their role within the pharmacy;

d) is trained and instructed to refer any drug- or health-related request or issue that requires therapeutic knowledge, clinical analysis, or assessment, to a regulated member;

e) is not assigned any component of the preparation of sterile compounds;

f) does not perform any component of a restricted activity other than assisting a regulated member by

i. collecting demographic information;

ii. selecting a drug from stock;

iii. counting a drug;

iv. packaging a drug;

v. entering information into the patient record for review by a regulated member;

vi. measuring the quantities of drugs for non-sterile compounds;

vii. physically mixing one or more ingredients identified by the regulated member together, using a process specified by the supervising regulated member for non-sterile compounding; or

viii. entering information into the information management system about the act of compounding; and

g) only performs the components of a restricted activity noted in Standard 2.13.1(f) under the supervision of a regulated member who

i. communicates critical steps, as identified by the regulated member and from the pharmacy policies and procedures, in a process that requires independent double checks by the regulated member;

ii. performs an independent double check of the work of the unregulated employee at each identified critical step within the assigned activity before the unregulated employee is permitted to proceed further; and

iii. is present and engaged in the practice of pharmacists at the same practice site as the unregulated employee.

Compliance with the law

2.14 A licensee ensures regulated members practise in compliance with the legislative framework for pharmacy practice in Alberta.

2.14.1 A licensee must

a) ensure that the licensed pharmacy operates in accordance with the letter and spirit of the laws that govern licensed pharmacy operations, drug distribution, the practice of pharmacists, and the practice of pharmacy technicians, including any standards, guidelines, policies of Council, and the Code of Ethics;

b) be aware of changes in the laws referred to in Standard 2.14.1(a) and adjust practice to ensure compliance with the changes;

c) 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 laws referred to in Standard 2.14.1(a);

d) ensure that regulated members and unregulated employees at the licensed pharmacy comply with the legislative framework and the policies and procedures of the licensed pharmacy;

e) comply with all federal and provincial legislation, Alberta Health policies, Alberta Health Services policies, and all applicable standards if the licensed pharmacy provides medications for Medical Assistance in Dying;

f) comply with all public health orders;

g) comply with the rules and requirements of any federal or provincial programs the licensed pharmacy participates in, as long as the rules and requirements of these programs do not conflict with these standards or the legislative framework; and

h) notify the college or another applicable regulatory college if they have reasonable grounds to believe a regulated member or another regulated health professional who is part of the pharmacy team practising within a licensed pharmacy

   i. presently is demonstrating incapacity that may impact patient safety or impair their ability to provide professional services due to a physical, cognitive, or mental health condition;

   ii. is charged with or convicted of a criminal offence;

   iii. has participated in drug diversion, theft, or fraud;

   iv. is demonstrating a repeated inability to provide patients with what is reasonably considered competent care; or

   v. is behaving in a manner that could reasonably be considered unprofessional conduct under the *Health Professions Act*.

Domain 3 – Practice environment

Licensed pharmacies provide a professional environment for the delivery of professional services to patients.

The professional design and appearance of a licensed pharmacy enable a practice environment that is inclusive, culturally safe, and conducive to patient wellness; maintains patient privacy; and supports regulated members in providing effective professional services.

Proprietors ensure the safety of pharmacy team members, patients, and the public by providing pharmacy teams the necessary infrastructure, equipment, information technology, and resources.

Safe and professional work environment

3.1 A licensee and a proprietor create a professional work environment that enables regulated members to meet expectations under the legislative framework and provide quality patient care.

3.1.1 A licensee must assess

a) the patient population and health needs of the community served by the licensed pharmacy,

b) the services offered by the pharmacy, and

c) the experience and skills of the pharmacy staff.

3.1.2 Based on the assessment required by Standard 3.1.1, the licensee must

a) schedule an appropriate number and type of pharmacy team members to

i. meet the actual and anticipated workload in the licensed pharmacy whereby each regulated member can comply with the legislative framework, and

ii. ensure the pharmacy environment protects the safety and security of staff on duty;

b) ensure that pharmacy workflow enables regulated members to

i. practise collaboratively to the full authorized ability of each regulated member with consideration of each individual's capacity, competence, and willingness;

ii. supervise unregulated employees as required by the Standards of Practice for Pharmacists and Pharmacy Technicians and these standards; and

iii. meet their responsibilities to the legislative framework; and

c) ensure access to adequate resources that enable regulated members to meet their responsibilities.

3.1.3 A proprietor must

a) meet all provincial occupational health and safety requirements for the licensed pharmacy;

b) provide any required personal protective equipment for the pharmacy team; and

c) provide an environment that supports the wellness of pharmacy team members and prevents undue pharmacy team member fatigue and burnout by

i. providing pharmacy team members adequate opportunities for rest; and

ii. in accordance with Standard 3.1.2(a), ensure the licensee is able to schedule an adequate number and type of pharmacy team members to meet practice requirements.

Physical specifications of a pharmacy

3.2 A licensee and a proprietor design a licensed pharmacy that is professional and facilitates safe and effective patient care.

3.2.1 A licensee and a proprietor must ensure a licensed pharmacy

a) has an overall design that is professional in appearance and function, including any consultation rooms, fixtures, equipment, and signage;

b) has a prescription department at least 33 m^2 in area;

c) has adequate lighting, ventilation, and humidity and temperature control to protect the quality and integrity of drugs; and

d) ensures the safety and supports the comfort of staff, patients, and the public.

Physical specifications of a dispensary

3.3 A licensee ensures a suitable environment for providing professional services to patients.

3.3.1 A licensee must ensure a licensed pharmacy has a dispensary that

a) is at least 18 m^2 in area of contiguous space that does not consist of or include any approved

i. areas separated by publicly accessible space, or

ii. separate adjoining rooms dedicated to compounding or repackaging;

b) has all aisles and entranceways at least 90 cm wide;

c) has a dedicated area for preparing drugs for dispensing, including a work area with at least 1.5 m^2 of uninterrupted counter space;

d) has drop-off and pick-up areas

i. that are located a suitable distance from patient waiting and high-traffic areas, and

ii. that have suitable sound and visual barriers to maintain patient confidentiality when communicating with a patient;

e) has sufficient space and equipment to allow the practice of pharmacy to be conducted effectively and safely;

f) is separated from the patient services area of the licensed pharmacy by a physical barrier that prevents access by individuals not authorized by the licensee; and

g) is equipped with a security system.

3.3.2 A licensee must ensure the dispensary described in Standard 3.3.1 has

a) adequate shelf and storage space for all equipment required by this standard and the pharmacy's inventory of drugs, healthcare products, aids, and devices;

b) a laboratory-grade or full-size domestic refrigerator or appropriate temperature-controlled area with a digital temperature monitoring device supplied by an uninterrupted power source;

c) a sink with hot and cold running water that is readily accessible for hand hygiene at all times, located outside of segregated compounding rooms;

d) a metal safe that is secured in place and equipped with a time-delay lock, unless

i. the licensee has made a declaration that the pharmacy

A. does not stock inventory of the drugs described in Standard 4.4.1(a),

B. is an institution pharmacy, or

C. is a pharmacy with a compounding and repackaging licence that is not accessible to the public and has alternative security measures in place, and

ii. the registrar has placed a condition on the licence of the licensed pharmacy permitting the pharmacy to operate without a metal safe with a time-delay lock;

e) Council-approved signage, posted in the dispensary and at all external entrances to the pharmacy, which communicates the requirements of Standard 3.3.2(d);

f) equipment that enables the electronic receipt and transmission of health information through means that are secure and acceptable to the college;

g) a computer or electronic device with an operating internet connection that allows regulated members to

i. access Alberta College of Pharmacy communications and clinical resources, and

ii. meet the operational requirements of the standards; and

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

3.3.3 A licensee must ensure the time-delay lock referenced in Standard 3.3.2(d)

a) is set for a length of time that

i. takes into consideration factors including location of the licensed pharmacy and police response times, and

ii. is at least five minutes, and

b) cannot be opened or overridden by any means before the time delay has expired.

3.3.4 A licensee must ensure the refrigerator required in Standard 3.3.2(b) is only used for drug products and devices used in the provision of professional services and not for any other purpose.

Shared premises

3.4 A licensee protects the public by ensuring that when it shares a premises with another business or regulated health professional who is not part of the pharmacy team, the licensed pharmacy is secure when it is not open, and the prescription department is differentiated from the other business or the practice area of the regulated health professional.

3.4.1 A licensee must

a) ensure that a pharmacy that shares premises with another business or regulated health professional who are not part of the pharmacy team

i. operates a lock and leave prescription department to prevent unauthorized access, even if the other business or regulated health professional operates during the same business hours;[19] and

ii. operates independently of the other business or regulated health professional who is not part of the pharmacy team;

b) ensure that the other business or regulated health professional who is not part of the pharmacy team that the licensed pharmacy shares a premises with is compatible with the integrity of the profession of pharmacy;

c) ensure that a prescription department that operates as part of a larger business enterprise operates as a lock and leave pharmacy if it operates for fewer hours than the hours that the premises are open to the public; and

d) ensure a prescription department is

i. physically delineated from the public area by the use of

A. variations in décor, flooring, or fixtures; or

B. physical separation; and

ii. differentiated from the public area by signage that reads

A. Pharmacist,

B. Prescriptions,

C. Prescription Department, or

D. Pharmacy.

19 Requirements of a lock and leave pharmacy are described in Foundational requirements: Guidance document for opening a licensed pharmacy.

3.4.2 If the pharmacy operates as part of a larger business, or shares a premises with another separate business or another regulated health professional who is not part of the pharmacy team, a licensee must not

a) use the fixtures, services, and equipment required by Standard 3.3.2 to support the larger business, separate business, or the practice of another regulated health professional who is not part of the pharmacy team;

b) permit the separate business or other regulated health professional who is not part of the pharmacy team to operate from the dispensary or the patient services area of the licensed pharmacy; or

c) permit the separate business or other regulated health professional who is not part of the pharmacy team to advertise or operate in a manner that could reasonably mislead the public to conclude the other business or regulated health professional is part of the licensed pharmacy.

Maintenance of the licensed pharmacy

3.5 A licensee ensures patient safety and confidence by operating the licensed pharmacy in a clean and orderly condition that maintains the professional image and integrity of the licensed pharmacy.

3.5.1 A licensee must

a) ensure the regular cleaning of the pharmacy including all premises, furniture, equipment, appliances, devices, and automated pharmacy systems; and

b) ensure all equipment, appliances, automated pharmacy systems, and devices used in the licensed pharmacy are

i. inspected regularly to ensure they are in working order and repaired or replaced as required;

ii. certified at the intervals specified by the standards or the manufacturer, if required; and

iii. if calibration is required, calibrated

A. at manufacturer recommended intervals, or

B. at least annually if no manufacturer recommendation is provided.

Private consultation area

3.6 A licensee protects patient confidentiality and privacy by ensuring an appropriate space exists within the patient services area for regulated members and other regulated health professionals who are part of the pharmacy team to interact with patients.

3.6.1 A licensee must ensure the licensed pharmacy has a private consultation area that

a) is attached to the dispensary or is adjacent to the dispensary within the patient services area;

b) is publicly accessible, but not located within the dispensary or require public access to or through the dispensary;

c) is not the only access point to the dispensary for pharmacy staff;

d) is clean, safe, and well lit;

e) is an adequate size to facilitate quality patient care;

f) is dedicated to providing confidential communication with a patient and must not be used to store or display anything other than healthcare products, aids, or devices; or patient information materials;

g) accommodates barrier-free access for patients with mobility limitations;

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

i) has suitable visual barriers

i. to prevent others from seeing what drugs; healthcare products, aids, or devices; or professional services are being provided to or for a patient; and

ii. to maintain patient comfort and privacy.

Library and resources

3.7 A licensee provides regulated members access to appropriate clinical resources to ensure quality patient care.

3.7.1 A licensee must

a) provide access to relevant electronic health and practice information required to practise according to these standards and the Standards of Practice for Pharmacists and Pharmacy Technicians; and

b) ensure regulated members have access to a library that

i. is immediately accessible to regulated members working in the dispensary,

ii. includes all resources required by the list of required reference sources set out by the college,[20] and

iii. is kept current.[21]

Signage

3.8 A licensee provides clarity for patients by posting clear pharmacy signage.

3.8.1 The licensee must ensure that signage used inside and on the exterior of the licensed pharmacy

a) is clear, accurate, and not misleading;

b) is clearly visible to patients and the public;

c) does not indicate or imply that a pharmacy is affiliated with another independent business; and

d) does not make inappropriate, unsubstantiated, or unprofessional claims about professional services.

20 Refer to the list of required references on the college website.
21 References must be the latest published edition unless otherwise specified by the required references list.

Licensed pharmacy closures

3.9 A licensee ensures continuity of patient care and appropriate disposition of drugs and records when a licensed pharmacy closes permanently.

3.9.1 A licensee of a licensed pharmacy that closes permanently must

a) ensure patients of the pharmacy are

i. notified of the pharmacy closure,

ii. given the opportunity to obtain their prepared prescriptions prior to pharmacy closure, and

iii. notified how to access their records after the pharmacy has closed;

b) transfer patient records to

i. another licensed pharmacy, or

ii. a custodian under the *Health Information Act* and a location, both approved by the registrar;

c) complete an inventory of all scheduled drugs in the pharmacy;

d) dispose of the drugs in a manner that complies with the *Controlled Drugs and Substances Act* and the *Food and Drugs Act*;[22]

e) notify the Alberta College of Pharmacy immediately about the exact date of closure; and

f) provide the following information to the Alberta College of Pharmacy 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;

iv. a copy of the inventory required by Standard 3.9.1(c); and

v. a written record of all controlled substances transferred from the pharmacy including drugs, quantities, and the receiving licensed pharmacy information.[23]

3.9.2 If a licensed pharmacy is closing permanently and does not have a licensee, the proprietor must retain a pharmacist to meet the requirements of Standard 3.9.1.

22 Refer to the Health Canada webpage Controlled substances guidance for community pharmacists: security, inventory reconciliation and record-keeping for an interpretation of the *Controlled Drugs and Substances Act* and the *Food and Drugs Act* with respect to a permanent pharmacy closure. Additional information can be found in the Permanent closure section on the college website.
23 Refer to the Permanent closure section on the college website for required information and forms.

Preparing for continuity of care

3.10 A licensee develops a plan to ensure continuity of patient care.

3.10.1 A licensee must

a) have a documented plan to ensure continuity of patient care that includes direction in the event of

i. planned pharmacy closures,

ii. unplanned pharmacy closures, or

iii. loss of pharmacy records or loss of access to pharmacy records; and

b) ensure all members of the pharmacy are aware of how to access and implement the plan.

Registrar authority

3.11 The registrar may approve a pharmacy that does not meet these standards when it serves the public interest.

3.11.1 Upon considering requirements for patient safety and care, the integrity of the drug distribution system, public health needs, and the overall public interest, the registrar may

a) approve a pharmacy that does not meet the requirements in Standards 3.2, 3.3, 3.4, 3.6, or 3.8; and

b) impose conditions on any approval granted under this standard.

Domain 4 – Drug management and licensure

The licensee ensures safe and effective patient care through storing, handling, delivering, and disposing of chemicals, hazardous materials, and sharps in a manner that is secure, maintains product integrity, and ensures the safety of the pharmacy team and the public.

The licensee ensures the professional services provided at the licensed pharmacy are appropriate for the category of pharmacy licence issued by the Alberta College of Pharmacy, and that all respective licence requirements are met. The licensee is responsible to ensure the licensed pharmacy has the policies, resources, and supports required for the provision of professional services.

Duty to examine drugs

4.1 A licensee protects patients by ensuring all incoming and outgoing drugs and healthcare products, aids, and devices, are monitored to ensure their quality and integrity.

4.1.1 A licensee must ensure that all incoming and outgoing drugs and healthcare products, aids, and devices are

a) visually examined to verify

i. the identity of the drugs or the healthcare products, aids, or devices; and

ii. that there has been no contamination of or damage to the drugs or the healthcare products, aids, or devices.

Location of stored drugs

4.2 A licensee stores drugs in a location that is compliant with the legislative framework.

4.2.1 A licensee must

a) ensure that the following are only stored and offered for sale in the dispensary of a licensed pharmacy:

i. Schedule 1 and Schedule 2 drugs;

ii. parenteral nutrition products;

iii. products the licensee believes, on reasonable grounds, pose a risk to the public if stored elsewhere in the pharmacy; and

iv. other products as required by Council;

b) ensure that the following are only offered for sale in the dispensary or patient services area of a licensed pharmacy:

i. healthcare products, aids, and devices;

ii. Schedule 3 drugs; and

iii. other products as required by Council;

c) ensure Schedule 3 drugs are offered for sale within the patient services area within view of regulated members working in the dispensary; and

d) ensure drugs are displayed and advertised independently of homeopathic products approved by Health Canada by means of

i. physical separation; or

ii. identification with appropriate signage.

such that a member of the public can easily distinguish drugs in the pharmacy from any homeopathic products.

Drugs stored safely and appropriately

4.3 A licensee stores drugs in a manner that maintains their integrity and minimizes the possibility of practice incidents.

4.3.1 A licensee must

a) ensure that drugs stored in the licensed pharmacy are labelled using names from the Canada Drug Product Database;

b) ensure that drugs for external use are stored separately from drugs for internal use and injectable drugs;

c) ensure that drugs for animal use only are stored in a manner that clearly identifies them as such and minimizes the possibility of them being dispensed for human use;

d) ensure flammable and hazardous chemicals, including diluents, are stored in a separate area in a manner that ensures staff and public safety;

e) ensure that damaged or outdated drugs are stored in an area that is separated from regular inventory;

f) ensure there are proper procedures for returning stock drugs to storage to minimize the chance of a practice incident;

g) ensure that drugs are stored in the licensed pharmacy

i. at appropriate temperatures,

ii. under appropriate conditions,

iii. in a manner that protects them from contamination, and

iv. in accordance with any manufacturer's requirements to ensure stability; and

h) track and document temperature conditions of drugs that require refrigerated or frozen temperature storage conditions at least twice daily when the licensed pharmacy is open, using a device that indicates the minimum and maximum temperatures reached since the last reading and take appropriate action if the temperatures fall outside of acceptable limits.

Security for drugs in the dispensary

4.4 A licensee protects the public by securing all drugs in a licensed pharmacy against theft, loss, or diversion.

4.4.1 A licensee must

a) maintain all Schedule 1 narcotics, all drugs designated as Type 1 medications by the Tracked Prescription Program Alberta, and any drugs required by Council, in the manner described in Standard 3.3.2(d);[24]

b) ensure adequate procedures are in place to identify theft, loss, or diversion of controlled substances, including

i. maintaining a perpetual inventory of each controlled substance in stock;

ii. a documented audit of the perpetual inventories to verify accuracy

A. at least every three months, and

B. each time there is a change in proprietor or licensee;

iii. investigating, resolving, and documenting any discrepancies identified;

iv. evaluating whether procedure changes or preventative measures are required to prevent future discrepancies; and

v. reporting any loss or theft of controlled substances to Health Canada within 10 days of discovery;[25]

c) ensure the licensed pharmacy has an electronic security system and procedures to

i. protect against theft, diversion, and tampering with drugs and healthcare products; and

ii. ensure that unauthorized individuals do not have access to Schedule 1 and Schedule 2 drugs; and

24 Refer to the list of TPP Alberta Type 1 medications, on the Tracked Prescription Program (TPP) website.
25 The guidance Reporting loss or theft of controlled substances or precursors can be found on the Health Canada website.

d) ensure the security of drugs that are

i. dispensed and awaiting pickup within the dispensary,

ii. delivered to a patient, or

iii. being actively administered to a patient.

Delivery of drugs to patients or caregivers

4.5 A licensee supports patient safety by ensuring that appropriate conditions are maintained to protect the integrity and security of the drugs when drugs are packaged in or transported from a licensed pharmacy.

4.5.1 A licensee must

a) ensure drugs are delivered directly to

i. a patient,

ii. an individual authorized within a healthcare facility to receive drug deliveries, or

iii. a regulated health professional who will administer or oversee the administration of the drug;

b) ensure that drugs are packaged and delivered in a manner that

i. maintains the stability and integrity of the drugs;

ii. does not expose the drugs to temperatures or other conditions that fall outside of manufacturer specifications; and

iii. protects the privacy, confidentiality, and safety of a patient;

c) ensure there is documentation for each delivered drug that includes

i. the shipping date, date received, shipping address, name of recipient, name of carrier, and environmental controls undertaken; and

ii. an audit trail that identifies

A. the prescription number of each drug delivered,

B. all individuals who were involved in the delivery of the drug,

C. the role of each individual involved in the delivery of the drug, and

D. confirmation of receipt by the patient or authorized receiver.

Disposal of drugs

4.6 A licensee protects patients, the public, and the environment by ensuring drugs, biomedical waste, and needles or other sharps are disposed of safely and appropriately.

4.6.1 A licensee must

a) ensure the licensed pharmacy accepts items from a patient for proper disposal, unless accepting the drug or item would pose a health risk or hazard to pharmacy staff, including

i. unused drugs,

ii. expired drugs,

iii. biomedical waste, and

iv. needles or other sharps;

b) ensure the licensed pharmacy has procedures for the safe and proper disposal of

i. drugs that are outdated, recalled, damaged, deteriorated, misbranded, or adulterated;

ii. biomedical waste; and

iii. needles or other sharps; and

c) ensure that the drugs, biomedical waste, needles, and sharps described in Standard 4.6.1(a) that are awaiting disposal are stored in a manner that

i. protects the safety of pharmacy staff, patients, and the public;

ii. secures the drugs from diversion; and

iii. clearly identifies them as marked for disposal and eliminates the possibility of them being administered, dispensed, or sold.

Reuse of returned drugs

4.7 A licensee protects patients from harm by ensuring drugs that have been stored outside of the control of regulated members are not dispensed to patients.

4.7.1 A licensee must ensure

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

b) no healthcare product, aid, or device that has been provided to a person

is returned to the licensed pharmacy for use or reuse.

4.7.2 Despite Standard 4.7.1, a licensee may permit a regulated member to repackage a drug or healthcare product, aid, or device

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

b) when both of the following circumstances apply:

i. the drug or healthcare product, aid, or device is in a tamper-evident package and was dispensed or provided for a patient to a regulated health professional and maintained under the control of a regulated health professional at all times; and

ii. the regulated member is confident that the drug or healthcare product, aid, or device

A. has not been tampered with, and

B. has been stored in a manner that would not adversely affect its integrity and stability.

Compounding services

4.8 A licensee provides patients access to compounding services that are appropriate, safe, and of high quality.

4.8.1 A licensee must provide a patient access to compounding services

a) by directly compounding preparations in the licensed pharmacy in accordance with standards approved by the college respecting the compounding of sterile and non-sterile preparations; or

b) through an agreement with a pharmacy issued a compounding and repackaging licence that is in a form that meets the requirements of the Pharmacy and Drug Regulation.

4.8.2 Nothing in Standard 4.8.1(b) relieves a licensee of the responsibility to ensure that the compounds prepared by a pharmacy the licensee has entered into an agreement with are prepared in accordance with the standards approved by the college respecting the compounding of sterile and non-sterile preparations.

Pharmacies with a compounding and repackaging licence

4.9 A licensee protects patients by ensuring a pharmacy issued a compounding and repackaging licence operates safely and in accordance with these standards and the legislative framework.

4.9.1 A licensee who has been issued a compounding and repackaging licence must ensure the pharmacy

a) has appropriate infrastructure, including adequate space and equipment to perform the activities of the licensed pharmacy;

b) meets the size and equipment requirements of a dispensary in a licensed community or satellite pharmacy as outlined in the legislative framework or is of the appropriate size and has the appropriate equipment as determined necessary by the registrar to safely and effectively perform the services undertaken at the pharmacy;

c) only provides drug products compounded or repackaged in accordance with the legislative framework and for other licensed pharmacies or institution pharmacies with which it has a compounding and repackaging agreement; and

d) in addition to the prescription labelling requirements required by the Standards of Practice for Pharmacists and Pharmacy Technicians, includes a unique identifier on each prescription label for all drugs processed by the compounding and repackaging pharmacy that identifies the compounding and repackaging pharmacy.

4.9.2 Despite Standard 3.3.1(d) and Standard 3.6.1, a pharmacy with a compounding and repackaging licence that does not have a community pharmacy licence does not require

a) drop-off and pickup areas, or

b) a private consultation area.

Obtaining compounded and repackaged drug products

4.10 A licensee of a community or satellite pharmacy protects patients by obtaining compounded and repackaged drug products only in accordance with the legislative framework.

4.10.1 A licensee must ensure drug products obtained from a pharmacy with a compounding and repackaging licence are

a) compounded or repackaged in accordance with the legislative framework including under any agreements required by Council;[26] and

b) prepared and distributed to the licensed pharmacy under conditions that ensure the products' security and integrity, the privacy of the receiving patient, and delivery within a timeline that meets the patient's needs.

4.10.2 Nothing in Standard 4.10.1 relieves a licensee of the responsibility to ensure that a patient receiving compounded or repackaged drug products is assessed in accordance with the Standards of Practice for Pharmacists and Pharmacy Technicians.

Pharmacies with mail order licences

4.11 A licensee holds a mail order licence to protect patients who do not regularly receive in-person care for restricted activities provided from the licensed pharmacy.

4.11.1 A licensee of a mail order pharmacy must

a) establish policies and procedures that enable regulated members to provide pharmacy services in accordance with the standards;[27] and

b) in addition to the records that must be kept in a community pharmacy, keep records that demonstrate that a patient who receives mail order services meets criteria outlined in the Standards of Practice for Virtual Care.

26 Refer to the Council-approved compounding and repackaging agreements on the college website.
27 Neither a mail order licence nor these standards enable a regulated member to provide virtual care when in-person care is required by the Standards of Practice for Virtual Care or the Standards of Practice for Pharmacists and Pharmacy Technicians.

Satellite pharmacies

4.12 A licensee supports safe and effective patient care provided from a satellite pharmacy that is equivalent to the services provided in a community pharmacy.

4.12.1 A licensee of a community pharmacy who operates a satellite pharmacy must

a) establish policies and procedures specific to the operation of the satellite pharmacy;

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

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

ii. consistent with the health needs of patients being provided professional services; and

c) use unique prescription labels that display the address and telephone number of the satellite pharmacy.

4.12.2 A licensee of a community pharmacy who operates a satellite pharmacy must not operate the satellite pharmacy as a lock and leave pharmacy.

4.12.3 A proprietor and a licensee of a satellite pharmacy must ensure the satellite pharmacy meets 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.

4.12.4 Despite Standard 4.12.3 and in accordance with Standard 3.11.1, the registrar may license a satellite pharmacy that does not comply with the standards, and in such a case, may impose conditions to support practices that result in the integrity of the drug distribution system, the safety of the public, and the integrity of the profession.

Prohibition on personal services

4.13 A licensee or proprietor does not permit services that fall under the Personal Services Regulation to be provided from a licensed pharmacy.

Domain 5 – Information management

Patient care is supported by regulated members having the appropriate equipment and technical systems they need to deliver professional services in the pharmacy. Information management systems allow regulated members to access required electronic resources and securely collect, create, use, store, protect, and disclose required records.

Licensees ensure that equipment and software that support the pharmacy team in meeting the requirements of these standards and of the Standards of Practice for Pharmacists and Pharmacy Technicians are provided by the proprietor.

Licensees protect the confidentiality and privacy of patients by developing and implementing administrative, technical, and physical safeguards for information management.

Proprietors provide licensees and regulated members the equipment and technical systems required to meet the standards and provide patient care.

Policy and training

5.1 A licensee supports patient care by ensuring that pharmacy team members are competent to collect, create, use, store, protect, and disclose personal health information.

5.1.1 A licensee must

a) develop and implement clear and comprehensive written policies and procedures that describe how pharmacy team members, acting in accordance with provincial and federal requirements,

i. document patient records in a manner that allows other pharmacy team members to access them and ensures continuity of patient care, and

ii. manage pharmacy information and records in the licensed pharmacy throughout their lifecycle; and

b) monitor, facilitate access to training for, and support regulated members and unregulated employees of the licensed pharmacy to ensure they comply with the policies and procedures referred to in Standard 5.1.1(a).

System requirements

5.2 A licensee and a proprietor support patient care by ensuring the licensed pharmacy has equipment and electronic systems to facilitate regulated members' practice.

5.2.1 A licensee and a proprietor must ensure that a licensed pharmacy has the computer system, peripheral equipment, and software necessary

a) to meet the pharmacy practice documentation requirements for patient care required by the Standards of Practice for Pharmacists and Pharmacy Technicians; and

b) for the input, storage, use, disclosure, protection, and retrieval of all relevant records required to be kept under the Standards of Practice for Pharmacists and Pharmacy Technicians and any other requirements of the legislative framework.

5.2.2 A licensee must ensure the system, equipment, and software referred to in Standard 5.2.1 meet the requirements outlined in Appendix A.

Transmission of data to the Alberta Netcare Electronic Health Record

5.3 A licensee supports patient care by ensuring that regulated members upload and access health information from the Alberta Netcare Electronic Health Record.

5.3.1 A licensee must

a) provide regulated members access to the Alberta Netcare Electronic Health Record system,

b) ensure the pharmacy system is submitting patient record information to and receiving patient record information from the Alberta Netcare Electronic Health Record system using real-time integration between the pharmacy system described in Standards 5.2.1 and 5.2.2 and the Alberta Netcare Electronic Health Record system,

c) ensure data transmitted to the Alberta Netcare Electronic Health Record system is accurate and complete, and

d) identify and correct any incomplete or inaccurate data transmitted by the licensed pharmacy to the Alberta Netcare Electronic Health Record system as soon as possible after such errors are discovered.

5.3.2 Despite Standard 5.3.1, a licensee does not need to comply with the requirements of Standard 5.3.1 if the pharmacy has a compounding and repackaging licence without a community pharmacy licence.

Management of licensed pharmacy records

5.4 A licensee supports patient care by ensuring that all required records are created, maintained, secured, stored, made available for retrieval, and appropriately destroyed.

5.4.1 A licensee must ensure that

a) there is an effective system for the creation, maintenance, secure storage, and retrieval of all records, including the records outlined in Appendix B;

b) all required records are stored securely to ensure that only persons authorized by the licensee have access to the records;

c) all required records that exist in physical form are maintained in the dispensary of the licensed pharmacy unless the licensee has applied for and received permission from the registrar to store the physical records at another location;[28]

d) prescriptions, transaction records, compounding records, and repackaging records for all drugs that have been dispensed, compounded, or repackaged are

i. filed using a defined process that ensures records are organized and easily retrievable and auditable; and

ii. 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;

e) the patient record contains a history of all patient interactions required to be documented under the Standards of Practice for Pharmacists and Pharmacy Technicians and is maintained and accessible for a period of

i. not less than 10 years after the last professional service provided to a patient or two years past the age of majority, whichever is greater for a patient who is a human; or

ii. not less than 10 years after the last professional service provided to a patient for a patient that is an animal; and

f) destruction of any records occurs

i. in a secure manner that maintains patient confidentiality during the destruction process,

ii. only after the appropriate retention time has been observed, and

iii. in accordance with established policies and procedures.

5.4.2 Despite Standard 5.4.1(c), a licensee does not require permission from the registrar to store records referred to in Standard 5.4.1(a) and Appendix B electronically if they are stored

a) offsite using a secure physical data centre or cloud-based service provider, and

b) the means of storage is documented in a privacy impact assessment that has been submitted to the Office of the Information and Privacy Commissioner of Alberta.

28 Physical records include paper-based records and physical electronic media such as hard drives, USB flash drives, and optical storage media.

Backup of information

5.5 A licensee supports continuity of patient care by ensuring a backup of all data required by these standards is regularly created.

5.5.1 A licensee must

a) ensure all data required under the legislative framework is backed up at least once daily;

b) store a copy of the backup data

i. at an approved off-site location,

ii. using a secure cloud-based service provider that stores data within Canada, or

iii. in a fire- and theft-resistant safe;

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

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

e) ensure there is a disaster recovery plan in place as part of the policies and procedures of the pharmacy to restore patient data and systems as quickly as possible in the event of a data loss or system failure.

Domain 6 - Continuous quality improvement

Safe patient care relies on a culture in which all pharmacy team members embody genuine commitment to continuous quality improvement. Proprietors and licensees must support a just culture that acknowledges the role of systemic factors that contribute to practice incidents and prioritizes learning, not retribution, when practice incidents and close calls occur.

Risks to patients are exposed through a structured continuous quality improvement program that includes processes for reporting practice incidents and close calls. Contributing factors and root causes are identified, and pharmacy team members work together to develop and implement action plans to mitigate risks before incidents occur. Pharmacy teams monitor their action plans and make further improvements when the need is identified.

Patients are meaningfully involved in the continuous quality improvement process when concerns are identified. Policies and procedures are developed to support continuous quality improvement, ensuring consistency in the application of its processes.

Safety culture and just culture

6.1 A licensee and proprietor support safe patient care through the creation of a safety culture.

6.1.1 A licensee must

a) ensure that they and all pharmacy team members in the licensed pharmacy comply with the requirements of the college's continuous quality improvement program,

b) work with proprietors and the pharmacy team to foster a culture of patient safety and a just culture in order to promote learning and continuous quality improvement, and

c) facilitate support for pharmacy team members involved in a practice incident.

6.1.2 A proprietor must ensure that appropriate resources are in place to enable pharmacy team members to comply with the requirements of the college's continuous quality improvement program.

Prevention of practice incidents

6.2 A licensee mitigates risks to patients by developing, maintaining, and supporting continuous quality improvement systems, policies, and procedures.

6.2.1 A licensee must

a) develop policies and procedures for continuous quality improvement for the licensed pharmacy that

i. consider both operational and practice-related elements encompassing the full scope of practice of regulated members;

ii. analyze pharmacy systems to identify high-risk processes and potential sources of pharmacy incidents before they occur;

iii. provide for investigation, analysis, documentation, and reporting of practice incidents that occur in relation to services provided by the licensed pharmacy;

iv. include regular review and assessment of mechanisms to prevent practice incidents; and

v. include a process for responding to complaints or concerns;

b) establish clear and comprehensive written operational policies and procedures that minimize the risk of a practice incident occurring and ensure all pharmacy team members

i. review policies and procedures at the licensed pharmacy upon commencing employment and whenever changes are made; and

ii. evaluate, contribute to, and comply with policies and procedures at the licensed pharmacy;

c) review and update the policies and procedures referred to in Standard 6.2.1(b) at least annually based on findings from the continuous quality improvement analyses; and

d) monitor, facilitate access to training for, and support regulated members and unregulated employees of the licensed pharmacy to ensure they comply with the program, policies, and procedures referred to in Standards 6.2.1(a) and 6.2.1(b).

6.2.2 The policies and procedures referred to in Standard 6.2.1(b) must describe the pharmacy-specific processes required to meet each section within these standards.

Managing practice incidents

6.3 A licensee ensures that when a practice incident occurs, patients who have or may have been affected are promptly informed and provided appropriate care.

6.3.1 A licensee must ensure that when they become aware of a practice incident that affects a patient, they

a) have a discussion with the involved pharmacy team members about the circumstances of the practice incident as soon as reasonably possible;

b) disclose the incident to the patient and any health professionals or relevant individuals involved in the patient's circle of care, including

i. details about how the practice incident occurred; and

ii. any actions, policies, or procedures being implemented by the licensee to ensure a similar incident does not reoccur;

c) take action as required and provide the patient with appropriate recommendations to manage the incident, including any emergency measures required;

d) ensure completion of timely clinical follow-up with the patient or other health professionals providing care to the patient to monitor the effects of the incident on the patient's health and well-being; and

e) ensure the incident and clinical follow-up plan are documented in the patient record.

Analysis of practice incidents and close calls

6.4 A licensee supports safe patient care by identifying the contributing factors and root causes of practice incidents and close calls in order to reduce the likelihood of recurrence.

6.4.1 A licensee must

a) require all pharmacy team members involved in the practice incident or close call to document relevant details of the practice incident or close call for analysis;

b) as soon as reasonably possible, initiate an analysis of the practice incident or close call to determine contributing factors and root causes;

c) when possible, collaborate with the patient, individuals within the patient's circle of care, and other regulated health professionals involved in the patient's care in the analysis of practice incidents and close calls and the implementation of any subsequent updates to policies and procedures;

d) in response to continuous quality improvement analyses, work collaboratively with the pharmacy team to

i. determine appropriate actions to be taken to protect patients from similar incidents,

ii. review and update the licensed pharmacy's site policies and procedures, and

iii. implement practice and operational improvements identified as a result of the practice incident and close call findings; and

e) document the results of the practice incident or close call analysis in a format that

i. is in accordance with Standard 5.4.1,

ii. is retained as part of a patient's record of care,

iii. distinguishes whether it relates to a practice incident or a close call, and

iv. includes a description of factors contributing to the practice incident or close call and actions taken to prevent recurrence.

Follow-up process

6.5 A licensee assesses the effectiveness of policy and practice changes made in response to practice incidents and close calls.

6.5.1 A licensee must, at least every three months, work collaboratively with regulated members and unregulated employees to

a) review relevant sources of practice incident information that may complement the pharmacy's continuous quality improvement processes; and

b) review the practice incident and close call documentation for the licensed pharmacy to

i. analyze the effectiveness of the policy and procedural changes implemented in response to a practice incident or close call to determine if these changes were successful in advancing patient safety,

ii. determine whether additional measures are required to prevent future practice incidents, and

iii. document the results of the review.

6.5.2 Nothing in Standard 6.5.1 relieves a licensee from the duty to make changes or take preventative measures promptly in response to a practice incident if the protection of the public requires it.

Collecting patient feedback and managing patient concerns

6.6 A licensee creates a system and an environment where patient feedback and concerns are valued, welcomed, acknowledged, responded to, and acted upon.

6.6.1 A licensee must

a) create an environment where a patient feels empowered to provide feedback and express concerns to pharmacy team members;

b) ensure all team members have the skills, training, and confidence to receive and address complaints and concerns, within the scope of their responsibilities;

c) consider patient feedback to determine which elements of the delivery of care meet a patient's needs and expectations, and which elements may require improvement; and

d) when managing a patient's concerns, ensure regulated members

i. treat the patient with respect and courtesy;

ii. maintain ongoing communication with the patient;

iii. employ an appropriate method of communication, using plain language that the patient understands;

iv. clarify the context of the patient's concerns and respond and act upon them in a timely manner;

v. review concerns in an objective, equitable, and unbiased manner;

vi. identify situations where a negotiated outcome is required;

vii. work collaboratively with the patient and the patient's circle of care to identify and agree upon a preferred resolution;

viii. apply the principles of just culture;

ix. evaluate the success of the resolution actions taken by the regulated member to determine if the concerns have been successfully resolved or if additional measures are required;

x. reflect on factors that contributed to the concerns and identify practice changes that could avoid future concerns and improve the patient experience when professional services are provided; and

xi. follow up with the patient as required.

6.6.2 Despite Standard 6.6.1, a licensee and a proprietor must ensure that regulated members have the autonomy to terminate a professional relationship with a patient in accordance with Standard 1.11.1 of the Standards of Practice for Pharmacists and Pharmacy Technicians when appropriate.

Appendix A - Electronic infrastructure requirements

A1.1 System, equipment, and software requirements

A1.1.1 System, equipment, and software in a licensed pharmacy must

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

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

c) facilitate sharing, ease of use, and retrieval of necessary data in the patient record to facilitate continuity of patient care;

d) be capable of storing and reporting the information required in A1.1.1(a) and A1.1.1(b) for the time required by the legislative framework;

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

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

g) have the ability to control which functions may be accessed by each regulated member, other regulated health professional, and unregulated employee;

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

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

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

k) have backup and recovery systems that meet the requirements of Standard 5.5.1;

l) be documented on a privacy impact assessment that has been submitted to the Office of the Information and Privacy Commissioner of Alberta in accordance with the *Health Information Act*;[29] and

m) require an established, 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.

29 Details on preparing and submitting a privacy impact assessment can be found on the Office of the Information and Privacy Commission website.

Appendix B - Pharmacy record requirements

B1.1 Required licensed pharmacy records

B1.1.1 Licensed pharmacy records include

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

b) records of all prescriptions received by the licensed pharmacy;

c) records of the professional services provided by regulated members or other regulated health professionals who are part of the pharmacy team at the licensed pharmacy including records identifying all individuals involved in the processing of prescriptions and dispensing drugs, 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 licensed pharmacy to another licensed pharmacy;

e) records of delivery required by Standard 4.5.1(c);

f) patient records; and

g) any record created or received by a proprietor, licensee, regulated member, or other person associated with the licensed pharmacy that relates to

i. the acquisition, dispensing, or sale of drugs; or

ii. the provision of professional services.