

**FOUNDATIONAL REQUIREMENTS:
GUIDANCE DOCUMENT FOR OPENING A
LICENSED COMMUNITY PHARMACY**



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1. BACKGROUND

The Alberta College of Pharmacy (ACP) governs pharmacists, pharmacy technicians and pharmacies in Alberta.

According to the *Pharmacy and Drug Act*,

(3) Subject to section 4 and the regulations, no person shall provide a pharmacy service¹ unless the service is provided

- a) from a licensed pharmacy with an appropriate category of licence, and
- b) in accordance with this Act and any conditions imposed on the licence.

(5) The following categories of licence may be issued under this Act:

1. **A community pharmacy licence** authorizes the provision of community pharmacy services² from the community pharmacy that is the subject of the licence.
2. **A compounding and repackaging pharmacy licence** authorizes the provision of compounding and repackaging pharmacy services³ from a compounding and repackaging pharmacy that is the subject of the licence, but does not authorize the dispensing or selling of a drug to or for a patient unless the licensee also holds a community pharmacy licence.
3. **A mail order pharmacy licence authorizes** the provision of mail order pharmacy services⁴ from the community pharmacy that is the subject of the licence.
4. **A satellite pharmacy licence** authorizes the provision of satellite pharmacy services⁵ by the community pharmacy that is the subject of the licence at the location stated on the licence.

An application to the registrar for a pharmacy licence must be in the form required by the registrar. **According to Section 5.01(1), the registrar may issue a pharmacy licence to an applicant if the registrar is satisfied that**

- **the applicant,**
 - is a clinical pharmacist;
 - meets the licensing requirements set out in the regulations;

¹“pharmacy service” means the storing, compounding, dispensing, or selling of drugs.

²“community pharmacy service” means a pharmacy service provided to or for a patient for which the patient or patient’s agent attends to receive the service at the pharmacy.

³“compounding and repackaging pharmacy service” means (i) compounding drugs, or (ii) repackaging drugs for a licensed pharmacy or institution pharmacy that dispenses or sells those drugs.

⁴“mail order pharmacy service” means a pharmacy service provided to or for a patient for which neither the patient nor the patient’s agent attends at the community pharmacy to receive the service.

⁵“satellite pharmacy service” means a community pharmacy service provided at a satellite pharmacy.

- will personally manage, control and supervise the practice of pharmacy in the licensed pharmacy; and
- will comply with this Act, any condition imposed on the licence, and any order made under this Act;
- **the proprietor** will act in accordance with this Act;
- **the pharmacy,**
 - meets the requirements set out in the regulations; and
 - will be operated in compliance with this Act, any condition imposed on the licence and any order made under this Act;
- **the pharmacy services** will be provided without undermining patient safety, the quality of patient care, or the integrity of the drug distribution system; and
- the applicant has paid the fees, dues and levies prescribed in the bylaws and any arrears or penalties.

Upon receiving an application for a pharmacy licence, the registrar will consider the application, make a decision and give the applicant a copy of the decision as soon as reasonably possible. Upon issuing a pharmacy license, the registrar must state on the licence the category of licence, the name of the licensee and the name and location of the pharmacy with respect to which the licence is issued and the date on which the licence expires.

Once a pharmacy is opened and operational, the licensee must notify the registrar and when applicable **request approval if any of the information that was provided to the registrar (as part of their application for a licence or renewal of a licence) has changed.** According to the Pharmacy and Drug Act and its regulation, this includes, but is not limited to

- a change in the licensee or proprietor,
- a pharmacy renovation or relocation,
- a change in the types of pharmacy services provided,
- a change in the employment of any regulated pharmacy professional at the pharmacy,
- a change in the hours of operation, and
- a request to store patient records at a location other than the pharmacy.

2. PURPOSE AND EXPECTATIONS OF THIS DOCUMENT

This document provides guidance regarding the foundational requirements that must be met prior to opening a licensed community pharmacy. These requirements correspond to sections of the

- [Pharmacy and Drug Act \(PDA\)](#),
- [Pharmacy and Drug Regulation \(PDR\)](#),
- [Standards for the Operation of Licensed Pharmacies \(SOLP\)](#), and
- [Standards of Practice for Pharmacists and Pharmacy Technicians \(SOP\)](#).

The overall objectives of this document are to

- clearly state and compile in one document the foundational requirements for community pharmacies per legislation,
- provide the Alberta College of Pharmacy's interpretation of the legislation (guidelines) to clarify expectations and ensure consistency, and
- support licensees and proprietors with understanding and complying with the foundational requirements prior to opening and operating a licensed community pharmacy.

All pharmacies must have the adequate space, equipment, and policies and procedures to perform the activities of the pharmacy. **This document focuses on these foundational requirements to opening a community pharmacy**, such as its facilities, equipment, systems, and operating policies and procedures. Pharmacies that compound sterile preparations must meet additional requirements and standards that are NOT outlined in this document. This document also does NOT include operational and/or practice requirements. Lastly, as outlined in legislation, requirements for the other categories of pharmacy licence may vary.

2.1 Expectations for the use of the Standards and Guidelines

Standards

Standards establish requirements. Standards use the language of "must." A regulated member must comply with each standard. Failure to comply with a standard may be considered unprofessional conduct.

Guidelines

Guidelines establish the professionally accepted means by which regulated members can achieve compliance with the standards. Guidelines use the

language of “should.” Guidelines are not recommendations; they establish the expected conduct of regulated members. A regulated member may only depart from a guideline, if the regulated member can demonstrate that

- the regulated member achieved compliance with the applicable standard,
- the regulated member’s departure from the guideline
 - did not detract from the safety, effectiveness, or appropriateness of patient care; or
 - did not undermine the integrity of the professions of pharmacists and pharmacy technicians.

Failure to comply with a guideline may be considered unprofessional conduct if the regulated member did not achieve compliance with the standard or if the departure from the guideline detracted from the quality of patient care or undermined the integrity of the professions of pharmacists and pharmacy technicians.

A licensee must ensure that their pharmacy meets the legislative requirements, including the guidelines (ACP’s interpretation of the requirements), prior to being issued a pharmacy licence. A licensee and proprietor should refer to these foundation requirements

- prior to opening and operating a community pharmacy,
- prior to relocating a pharmacy,
- prior to renovating a pharmacy,
- when there is a change of licensee or a change of proprietor, or
- prior to applying for renewal of a community pharmacy licence to ensure compliance with the requirements.

Upon written request, the registrar may approve a pharmacy that does not meet the requirements if the registrar is satisfied that pharmacy services will be provided without undermining patient safety, the quality of patient care or the integrity of the drug distribution system. Should an application for a pharmacy licence be issued with conditions, or declined, the registrar will provide reasons for the decision. In such cases, the applicant may appeal the decision to Council according to legislation.

3. PHARMACY PREMISES

According to the Pharmacy and Drug Act

- a **“pharmacy”** is defined as: “the premises or part of premises in or from which a pharmacy service is provided.”

In the Pharmacy and Drug Regulation,

- a **licensed pharmacy** is referred to as the **“prescription department”** which includes a **“dispensary”** and a **“patient services area.”**
 - **“dispensary”** means the area of a licensed pharmacy that is not accessible to the public and in which pharmacists
 - dispense, provide for sale, and sell drugs referred to in sections 31 and 32 of the Act, and
 - compound drugs referred to in sections 31, 32 and 33 of the Act;
 - **“patient services area”** means the area of a licensed pharmacy located outside and adjacent to the dispensary where
 - patients receive pharmacy services from pharmacists, and
 - drugs referred to in section 33 of the Act may be provided for sale;
- **“public area”** means the area of a licensed pharmacy located outside the prescription department.

The foundational requirements to open a licensed community pharmacy are listed below under the following headings

- prescription department (licensed pharmacy),
- dispensary,
- patient services area, and
- additional requirements.

3.1 Prescription department (licensed pharmacy) - Requirements 1-9

According to the Pharmacy and Drug Regulation, Section 1(1)

- (a) **“prescription department”** means the dispensary and the patient services area, and
- (b) **“public area”** means the area of a licensed pharmacy located outside the prescription department.

⁶“pharmacy service” means the storing, compounding, dispensing or selling of drugs.

#	Requirements per legislation	Corresponding legislation	Guidelines
1	<p>A prescription department must be at least 33 m² in area.</p>	<p>PDA 5.01(1)(d) PDR</p> <ul style="list-style-type: none"> • 13(1)(a), • 14, and • 15. <p>SOLP 4</p>	<p>To ensure patient safety, the quality of patient care, and the integrity of the drug distribution system, a pharmacy must have the adequate and dedicated space to perform the activities of a pharmacy. The prescription department (dispensary and the patient services area) must meet the minimum size requirement.</p> <p>Areas outside of the prescription department (i.e., public area) and/or areas that are not dedicated for “pharmacy use” do not count towards the overall size of the prescription department. Premises/rooms shared with other businesses (e.g., waiting room) are considered a public area and do not count towards the overall size of the prescription department.</p> <p>If the prescription department is part of a larger business enterprise or if sharing premises with another health professional or business, the pharmacy and the adjoining business must be able to operate independently of one another. The prescription department must be physically delineated from the adjoining business and/or public space as outlined in Requirement #2.</p>
2	<p>A prescription department must be physically delineated from the public area by the use of</p> <ul style="list-style-type: none"> • variations in décor, flooring, or fixtures; or • physical separation. <p>A prescription department must also be differentiated from the public area by a sign that reads</p> <ul style="list-style-type: none"> • pharmacist, • prescriptions, • prescription department, • pharmacy, or • professional services. <p>The signage would not be required if the public area comprises 15% or less of the premises of the pharmacy.</p>	<p>PDR 16(1) and 16(2)</p> <p>SOLP 4.4, 4.5, and 4.6</p>	<p>A licensee must ensure that the prescription department is clearly differentiated from public areas and/or adjoining businesses by physical delineation so that patients can recognize</p> <ul style="list-style-type: none"> • when they have entered the licensed pharmacy, and • that an adjoining business (e.g., a medical clinic) is separate from the pharmacy. <p>Signage used to differentiate the prescription department from adjoining businesses and/or public areas must be clear to the public and conspicuously visible from the patient services area.</p> <p>The pharmacy and the adjoining business must not engage in any practice or enter into any arrangement that unduly interferes with independent patient choice.</p>

#	Requirements per legislation	Corresponding legislation	Guidelines
3	<p>A prescription department must have security systems and procedures, including security systems and procedures for information technology, to ensure</p> <ul style="list-style-type: none"> • protection against theft, diversion, and tampering with drugs/health care products; and • that unauthorized individuals do not obtain access to drugs or to patient information. <p>The dispensary must only be accessible to personnel approved by the licensee.</p>	<p>PDR 25(d) SOLP 4.1(b), (c) and 5.11</p>	<p>All drugs and patient records must be secured from unauthorized personnel.</p> <p>If a prescription department shares premises⁷, the pharmacy must operate as a lock and leave pharmacy as outlined in Requirement #4. The prescription department must have its own security system separate from the other business to monitor and detect any unauthorized entry when the prescription department is closed.</p> <p>If the pharmacy employs personnel (e.g., cleaning staff, cash office associate) who work when the pharmacy is not providing pharmacy services, there must be a security system to prevent access to the dispensary and ensure security of the drugs and patient records. This security system for the dispensary must include</p> <ul style="list-style-type: none"> • adequate security grilles that facilitate key-control policies, and/or • its own alarm zone and security camera to monitor and detect any unauthorized access to the dispensary. <p>Access to the dispensary must be limited to personnel vetted and approved by the licensee. A licensee must ensure that approved personnel who are not regulated members are given clear direction regarding the scope of their actions and the limitations of their actions within the pharmacy. When the licensee provides this authorization, they must ensure</p> <ul style="list-style-type: none"> • records are secure, • narcotics and controlled drugs are secure, • a confidentiality agreement is in place, and • the individual receiving the licensee’s authorization is informed and acknowledges the times and conditions under which they are authorized to have this access. <p>The licensee must ensure that only authorized individuals have access to narcotics, controlled drugs, and patient records.</p>

⁷Per PDA, a “pharmacy” is defined as: “the premises or part of premises in or from which a pharmacy service is provided” and includes the dispensary and patient services area. A pharmacy (i.e. prescription department) shares premises if the pharmacy is part of a larger business enterprise or when the area outside and adjacent to the prescription department (i.e., public area) is not dedicated for “pharmacy use” and shared with or used for another business or health professional practice.

#	Requirements per legislation	Corresponding legislation	Guidelines
4	<p>If a licensed pharmacy is located where it does not occupy all of the premises, and operates for fewer hours than the hours that the premises are open to the public, the licensee must advise the registrar that the pharmacy is operating as a lock and leave pharmacy.</p> <p>The licensee of a pharmacy operating as a lock and leave pharmacy must ensure that when the pharmacy is closed</p> <ul style="list-style-type: none"> the dispensary and all drugs (including Schedule 3) are locked up to prevent unauthorized access; and no drugs are dispensed, provided for sale, or sold from the pharmacy. 	PDR 18(1), 18(2) and 18(4)	<p>The dispensary, scheduled drugs (including Schedule 3) and patient records must be secured from unauthorized personnel and locked up appropriately. A pharmacy operating as a lock and leave must have:</p> <ul style="list-style-type: none"> a secure lockable barrier that effectively prevents access to the dispensary, scheduled drugs (including Schedule 3), and patient records when the pharmacy is closed. (Unauthorized personnel should not easily be able to access the dispensary either over, under, or through the secure lockable barrier), adequate key-control policies, and its own security system as outlined in Requirement #3. <p>If a prescription department shares premises with another health professional or business, then the prescription department must operate as a lock and leave to prevent unauthorized access, even if both businesses intend to operate for the same hours. Circumstances may require the adjoining business to open/operate when the pharmacy is closed and accordingly, the licensee must ensure that the dispensary and all drugs and records are locked up to prevent unauthorized access.</p>
5	A prescription department must have adequate lighting, ventilation, and humidity and temperature control.	SOLP 4.1(a)	<p>Pharmacy professionals must have sufficient lighting to provide safe and effective pharmacy services and to ensure pharmacy services are provided without undermining patient safety, the quality of patient care, or the integrity of the drug distribution system.</p> <p>To ensure the safety and comfort of personnel and protect the integrity, quality and safety of the drugs, health care products and supplies in the prescription department, the pharmacy must have adequate ventilation, humidity and temperature control.</p>
6	A prescription department must have the proper storage facilities to ensure that the quality and integrity of drugs and health care products are maintained.	PDR 25(f)	Drugs, health care products, and supplies must be stored appropriately and protected from contamination. Refer to Requirement #18 for information regarding drug storage in the dispensary.

#	Requirements per legislation	Corresponding legislation	Guidelines
7	<p>Drugs must be kept in the appropriate locations within the prescription department, having regard for their scheduling under Part 4 of the <i>Pharmacy and Drug Act</i>.</p> <ul style="list-style-type: none"> Schedule 1 and 2 drugs must be stored and sold in the dispensary. Schedule 3 drugs must be stored and sold either in the dispensary or in the patient services area. 	<p>PDA 31, 32, and 33 SOLP 5.9 SOP 9</p>	<p>To ensure pharmacists can monitor customers and are readily available and accessible to offer assistance to a person who wishes to purchase a Schedule 3 drug, Schedule 3 drugs must be stored within visual sight from the dispensary.</p> <p>As outlined in Requirement #4, the dispensary and all drugs (including Schedule 3) must be locked up when the pharmacy is closed to prevent unauthorized access.</p>
8	<p>The prescription department is maintained in a clean and orderly condition.</p>	<p>SOLP 4.2</p>	<p>The prescription department, including the facilities, private consult rooms, counters, fixtures, equipment, supplies, and signage, must:</p> <ul style="list-style-type: none"> be cleaned and maintained (e.g., be orderly, sanitary, and clutter-free), and when applicable, with a suitable surface disinfectant, appear professional, in good condition, and aesthetically pleasing (e.g., does not appear dirty, dusty, worn or unfinished), portraying the image of a professional healthcare facility, and not pose risk to the provision of safe and effective pharmacy services. <p>Work surfaces and furniture, as well as floor and wall surfaces, must be designed to facilitate repeated cleaning.</p>
9	<p>The following signs must be posted in the pharmacy:</p> <ul style="list-style-type: none"> Pharmacy licence in a conspicuous public part of the pharmacy, Patient Concerns poster in the prescription department, Hours of operation at all public entrances to the pharmacy, and Code of Ethics in the prescription department. 	<p>PDA 8 and 29.1(5) PDR 11(2)(b) and 22(a), (b), (c)</p>	<p>Signage must be clearly visible to all patients who access pharmacy services (i.e., not in a consult room or hidden).</p>

3.2 Dispensary - Requirements 10-18

According to the Pharmacy and Drug Regulation, Section 1(1):

- (e) “dispensary” means the area of a licensed pharmacy that is not accessible to the public and in which pharmacists
- (i) dispense, provide for sale, and sell drugs referred to in sections 31 and 32 of the Act, and
 - (ii) compound drugs referred to in sections 31, 32 and 33 of the Act;

#	Requirements per legislation	Corresponding legislation	Guidelines
10	A dispensary must be at least 18 m ² in area.	PDR 13(1)(b) SOLP 9.2 and 11.3	A dispensary must have sufficient space to allow the practice of pharmacy to be conducted effectively and safely. Therefore, a dispensary must be one area that meets the minimum size requirement and may not consist of different areas/rooms that are separated by a publicly accessible space. If a separate space is required to conduct pharmacy services, a licensee must request for approval as a separate pharmacy licence may be required.
11	A dispensary must have a physical barrier that excludes access by an unauthorized individual.	PDR 14(1) SOLP 9.2 and 11.3	A dispensary must be enclosed by walls, gates, and/or doors to prevent access by unauthorized individuals. As outlined in Requirements #3 and #4, the pharmacy must have security systems and procedures to ensure only approved personnel have access to the dispensary. If the pharmacy shares premises or employs personnel who work when the pharmacy is closed to the public, the pharmacy must operate as a lock and leave to ensure all drugs and patient records are secured from unauthorized personnel.

#	Requirements per legislation	Corresponding legislation	Guidelines
12	<p>A dispensary must have sufficient space to allow the practice of pharmacy to be conducted effectively and safely including</p> <ul style="list-style-type: none"> • a semi-private area for receiving prescriptions, • a counter with at least 1.5m² of unrestricted work area for preparing drugs for dispensing, • working aisles that are at least 90 cm wide, • adequate shelf and storage space, and • an area for compounding drugs. <p>The requirements for non-sterile compounding are based on the complexity and risks associated with compounding the preparation and handling the substances used to make the preparations. It is necessary to examine many factors in assessing the risk associated with using a certain substance and determining the appropriate level of requirements. Pharmacists should undertake a risk assessment and identify the appropriate level of requirements needed to guarantee a high-quality product and adequate protection for personnel. Refer to the Standards for Pharmacy Compounding of Non-Sterile Preparations and its accompanying Guidance Document.</p> <p>For sterile compounding, refer to the Model Standards for Compounding of Non-Hazardous Sterile Preparations and the Model Standards for Compounding of Hazardous Sterile Preparations.</p>	<p>PDR 14(2)(a)(c)(d) and 14(3)</p> <p>SOLP</p> <ul style="list-style-type: none"> • 4.7(a); • 9.2; and • 11.3 	<p>To ensure patient confidentiality, as outlined in Requirement #19, areas used for dropping off and/or picking up prescriptions must</p> <ul style="list-style-type: none"> • have suitable sound barriers that prevent conversations from being overheard by unauthorized individuals; • have visual barriers to prevent others from seeing what drug, health care products, aids or devices are being provided to or for the patient; and • be a suitable distance away from patient waiting or high-traffic areas. <p>To ensure pharmacy personnel have sufficient space to conduct pharmacy services effectively and safely, there must be a counter with at least 1.5m² of unrestricted work area. This counter space must be dedicated for preparing drugs for dispensing and be free of equipment/items such as phones and/or computer monitors/keyboards that would interrupt the work space.</p> <p>A dispensary must have a separate space designated for compounding that is in accordance with the compounding standards. The level of requirements, including infrastructure needs, is dependent on the type and associated risk of compounding services. As an initial step, a pharmacist should determine the types of preparations and services that will be provided and complete a risk assessment accordingly.</p> <p>Compounding areas must be large enough for compounding personnel to work comfortably and safely. The heat source and sink must be available in, or close to, the compounding area. There must be room to store equipment and products in an orderly fashion, in clean and secure surroundings. Pharmacy personnel must not store or consume food or drink in the compounding area. The compounding area must be kept free and dedicated for compounding drugs.</p> <p>The compounding area should be designed and arranged to prevent cross-contamination between products and should be located away from parts of the pharmacy where there is a considerable amount of traffic to avoid contamination of the compounded product with dust and dirt, as well as to avoid interrupting or distracting compounding personnel.</p>

#	Requirements per legislation	Corresponding legislation	Guidelines
13	<p>A dispensary must have a</p> <ul style="list-style-type: none"> • refrigerator or appropriate temperature-controlled area, <ul style="list-style-type: none"> ○ a device that indicates the minimum and maximum temperatures reached since the last reading, • sink with hot and cold running water, • lockable drug locker or cupboard, and • heat source for extemporaneous compounding. <p>All fixtures and equipment must be dedicated for the use of the licensed pharmacy for the provision of professional services and, if the licensed pharmacy is part of a larger business enterprise, must not be used to support that larger business enterprise.</p>	<p>PDR 14(2)(b)</p> <p>SOLP</p> <ul style="list-style-type: none"> • 4.7(b), (c), (d), (e); • 4.8; • 5.3 (a); • 9.2; and • 11.3 	<p>The refrigerator should be laboratory grade or a full size domestic refrigerator (i.e., bar refrigerator units are not acceptable). The device used to monitor the refrigerator's temperature should be digital to ensure accuracy.</p> <p>To prevent contamination and to protect the integrity and quality of the dispensary's equipment, all equipment must only be used to provide professional services and not be used for personal reasons. For example, the refrigerator and heat source (e.g., microwave) must not be used to store and/or heat up food.</p> <p>The heat source and sink must be available in, or close to, the compounding area.</p>
14	<p>A dispensary must have</p> <ul style="list-style-type: none"> • a computer with an operating internet connection that provides unrestricted access to relevant health and pharmacist and pharmacy technician practice information required to practice according to the standards, • a mechanism to send and receive faxes, and • equipment to allow the pharmacy to make and receive telephone calls. <p>All fixtures and equipment must be dedicated for the use of the licensed pharmacy for the provision of professional services and, if the licensed pharmacy is part of a larger business enterprise, must not be used to support that larger business enterprise.</p>	<p>SOLP</p> <ul style="list-style-type: none"> • 4.7(f), (g), (h), (i), 4.8, 4.9(a); • 9.2; and • 11.3 	

#	Requirements per legislation	Corresponding legislation	Guidelines
15	<p>A dispensary must have access to the Alberta Netcare electronic health record system operated by Alberta Health and accordingly, the computer system must be able to facilitate submission of patient record information to Alberta Netcare and provide authorized personnel access to Alberta Netcare.</p>	<p>SOLP 4.9(b), (c)</p>	<p>To ensure pharmacists comply with the standards and have access to important patient information required for assessment, a dispensary must have the Alberta Netcare electronic health record system set up upon opening and operating as a licensed pharmacy.</p> <p>Contact eHealth Support Services to initiate the process.</p> <ul style="list-style-type: none"> • Phone: 1.855.643.8649 • Email: ehealthsupport@cgi.com <p>To satisfy this requirement at pre-opening inspection, the licensee must have submitted the expedited Privacy Impact Assessment (PIA) requirements to the Office of the Information and Privacy Commissioner (OIPC). This includes</p> <ul style="list-style-type: none"> • the policies and procedures that support Sections B and E of the OIPC PIA requirements, and • the OIPC cover letter. <p>Both documents must be available upon request during the pre-opening inspection.</p>
16	<p>A pharmacy must have an adequate library, including all required reference sources set out on the Alberta College of Pharmacy’s website, to which a regulated member in the dispensary can have immediate access to the references.</p>	<p>SOLP</p> <ul style="list-style-type: none"> • 4.15, 4.16, 4.17, 4.18, 4.19; • 9.2; and • 11.3 	<p>All required reference sources must be dedicated for the use by pharmacy professionals of the licensed pharmacy. To ensure immediate access, a pharmacy must have its own set of required references that are not shared with other sites and/or non-pharmacy personnel.</p>

#	Requirements per legislation	Corresponding legislation	Guidelines
17	<p>A dispensary must have the following compounding and dispensing equipment</p> <ul style="list-style-type: none"> • a prescription or electronic balance with a sensitivity to a minimum of 10 mg, • a set of metric weights or a calibration weight, and • any other equipment required to support the professional services that are provided in the dispensary. <p>For non-sterile compounding, refer to the Standards for Pharmacy Compounding of Non-Sterile Preparations and its accompanying Guidance Document.</p> <p>For sterile compounding, refer to the Model Standards for Compounding of Non-Hazardous Sterile Preparations and the Model Standards for Compounding of Hazardous Sterile Preparations.</p>	<p>SOLP</p> <ul style="list-style-type: none"> • 4.10; • 9.2; and • 11.3 	<p>All components, equipment and containers must be stored off the floor in a manner that prevents contamination and allows for appropriate cleaning. All equipment, instruments, and accessories must be routinely maintained to ensure proper performance.</p> <p>Compounding personnel must</p> <ul style="list-style-type: none"> • wear a clean lab coat reserved for compounding, • wear powder free gloves, and • use any personal protective equipment or equipment indicated on the Master Formulation Record. <p>Refer to the NIOSH list, MSDS, and WHMIS to determine the level of risk to the compounding personnel. Consider the need for personal protective equipment (e.g., goggles, gloves, clothing, respirator, adequate mechanical ventilation, hood, eye wash, shower). Compounding areas must contain an eyewash station and other emergency or safety equipment that is required.</p> <p>Refer to Requirements #12 and #13 for other compounding requirements.</p>

#	Requirements per legislation	Corresponding legislation	Guidelines
18	<p>Drugs in a dispensary must be stored in an appropriate manner and location that</p> <ul style="list-style-type: none"> • protects the integrity, quality and safety of the drugs <ul style="list-style-type: none"> ○ at appropriate temperatures, ○ under appropriate conditions, and ○ in accordance with any manufacturer's requirements to ensure stability; • minimizes the possibility of dispensing errors <ul style="list-style-type: none"> ○ drugs for external use must be stored separately from drugs for internal use and injectable drugs; and ○ outdated, recalled, damaged, deteriorated, misbranded or adulterated drugs are kept separately from other drugs until they are destroyed or returned to their supplier; and • ensures the security of the drugs against theft, loss, or diversion. 	SOLP 5	<p>To ensure vaccine efficacy and safety, appropriate storage and handling of vaccines is essential. Pharmacy professionals must comply with Alberta Health Vaccine Cold Chain Policy.</p> <p>Refer to Requirement #13 for refrigerator requirements.</p>

3.3 Patient services area - Requirement 19

According to the Pharmacy and Drug Regulation, Section 1(1):

- (h) “patient services area” means the area of a licensed pharmacy located outside and adjacent to the dispensary where
 - (i) patients receive pharmacy services from pharmacists, and
 - (ii) drugs referred to in section 33 of the Act may be provided for sale;

#	Requirements per legislation	Corresponding legislation	Guidelines
19	<p>A patient services area must have a private or semi-private area that ensures patient confidentiality.</p> <p>This area must have</p> <ul style="list-style-type: none"> • suitable sound barriers that prevent conversations from being overheard by unauthorized individuals; and • suitable visual barriers to prevent others from seeing what drug, health care products, aids or devices are being provided to or for the patient. <p>This area must be kept free for use for communicating with patients or patients' agents and must not be used to store or display anything other than health care products, aids, or devices or patient information materials.</p> <p>A pharmacist who administers a drug or vaccine must ensure that the environment within which the drug or vaccine will be administered is clean, safe, appropriately private and comfortable for the patient.</p>	<p>PDA 5.01(1)(d)</p> <p>PDR 15(1)</p> <p>SOLP</p> <ul style="list-style-type: none"> • 4.12, 4.13(a), (b), 4.14; and • 5 <p>SOP 16.3</p>	<p>A pharmacy professional must ensure that any communication with a patient about their health is conducted in a manner that maintains confidentiality. To ensure patient confidentiality and the quality of patient care, all areas used for communicating with patients, including drop-off and/or pick-up areas must</p> <ul style="list-style-type: none"> • have suitable sound barriers (e.g., have background noise); • have suitable visual barriers (e.g., have partitions or partial walls that obscure the view of the products being provided to or for the patient). The barriers must be of adequate height and depth and not be transparent; and • be a suitable distance away from patient waiting or high-traffic areas (e.g., seated areas, busy hallways, entrances, or shelves with merchandise). <p>Private area (i.e., consult room)</p> <p>If providing injection services, a private area must be available to a patient to facilitate patient privacy as required.</p> <p>The private area must be publicly accessible. It must NOT be located within, or require public access to, the dispensary.</p> <p>If there is direct access to the dispensary from the private area, there must be a physical barrier that prevents access to the dispensary by an unauthorized individual. Additionally, the dispensary must have another access point to prevent disrupting pharmacy services occurring in the private area.</p> <p>Private areas must be clean, safe, well-lit, and an adequate size to facilitate quality care, patient safety and comfort, and accommodate barrier free access for patients with mobility needs (e.g., wheelchairs, walkers).</p> <p>If designated as a private area for patients, it must be dedicated for this purpose and kept free for use for communicating with patients. It may not be used as an office or storage room for patient records, drug inventory, or expired medications.</p> <p>Specific and limited drug inventory and/or records may be stored in the private area if the drugs/records support the patient services being provided in the private consult room (e.g., vaccines). These drugs and records must be stored under appropriate conditions, locked up, and secured from unauthorized personnel.</p>

3.4 Additional requirements - Requirements 20-23

#	Requirements per legislation	Corresponding legislation	Guidelines
20	<p>If a pharmacy has a public website, the website must prominently display</p> <ul style="list-style-type: none"> • a copy of the pharmacy licence; • the pharmacy's location, mailing address, email address, and telephone number; • the licensee's name, practice permit number, and business address; • a statement that the licensee is required to provide, on the request of a patient, the name and practice permit number of any regulated member who provides a pharmacy service to the patient or who engages in the practice of pharmacy with respect to a patient; • the proprietor's name and business address; • if the proprietor is a corporation, the name of the proprietor's representative; and • the Patient Concerns poster. 	PDR 23	

#	Requirements per legislation	Corresponding legislation	Guidelines
21	<p>Each employee or regulated member must have and wear a name tag that clearly identifies whether the individual is a regulated member.</p> <p>A licensee must ensure that each employee and each regulated member who works in a licensed pharmacy has the appropriate education, experience, training, and registration required to perform the duties and responsibilities assigned to that employee or regulated member.</p> <p>A licensee must inform the Alberta College of Pharmacy of the regulated members employed at the pharmacy, including part-time, temporary, and relief pharmacists and/or pharmacy technicians.</p> <p>A licensee must ensure that each regulated member who will practice in a licensed pharmacy undergoes a suitable period of supervision, training, observation, and evaluation of skills and knowledge.</p>	<p>PDA 9</p> <p>SOLP 3.3, 3.4, 3.5, and 3.6</p>	<p>Licensees must ensure all staff have undergone a suitable orientation to the pharmacy's operational policies and procedures, are given clear direction regarding the scope of and limitations on their actions with respect to the provision of restricted activities, and are familiar with the location of the pharmacy's policies and procedures manual.</p> <p>Access to the dispensary must be limited to personnel vetted and approved by the licensee. Refer to Requirement #3 for more guidance.</p>

#	Requirements per legislation	Corresponding legislation	Guidelines
22	<p>A pharmacy must have policies and procedures that ensure that each regulated member practising in the pharmacy can comply with the law that governs pharmacy operations, drug distribution, and the practice of pharmacists and pharmacy technicians.</p> <p>A licensee must ensure that each regulated member who will practice in a licensed pharmacy undergoes a suitable orientation to the pharmacy's operational policies and procedures.</p> <p>A licensee must be aware of changes in the law and adjust practice, policies, and procedures to ensure compliance with changes.</p>	<p>PDR 25(d)</p> <p>SOLP</p> <ul style="list-style-type: none"> • 1.1, 1.2(b), 1.2(c); • 3(b), 3.6(a), 3.8, 3.9, 3.11; • 5.6, 5.12, 5.13; and • 6 <p>SOP 16 and 17</p>	<p>To enable pharmacies to operate in accordance with the law that governs pharmacy operations, drug distribution, and the practice of pharmacy, policies and procedures must be developed and in place prior to opening and operating as a licensed pharmacy.</p> <p>Sufficient policies and procedures will support pharmacy professionals with providing pharmacy services safely and effectively.</p> <p>For guidance, the Alberta College of Pharmacy offers a Policies and Procedures Manual template that may be used to develop a pharmacy's policies and procedures.</p> <ul style="list-style-type: none"> • Licensees who do not use ACP's template must develop and use policies and procedures that address the areas outlined in ACP's Policies and Procedures Manual template table of contents, as appropriate for their pharmacy. • Licensees who use generic corporate policies and procedures must ensure that all areas outlined in ACP's Policies and Procedures Manual template table of contents are addressed. Licensees may need to adapt and/or develop additional policies and procedures accordingly and as appropriate for their pharmacy. • Licensees who have a compounding and repackaging licence, mail order licence, and/or satellite license require additional policies and procedures.
23	<p>A pharmacy must have an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records. The records must be stored securely to ensure that only persons authorized by the licensee have access to the records.</p> <p>Unless otherwise authorized by the registrar, a licensee must maintain the records at the pharmacy.</p>	<p>PDR 12(3)</p> <p>SOLP 8</p>	<p>The system and security of the records must be in accordance with legislation, including but not limited to, the <i>Pharmacy and Drug Act</i> and its regulation, Health Information Act, and the Standards for the Operation of Licensed Pharmacies.</p>



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