

FOUNDATIONAL REQUIREMENTS - COMPLIANCE CHECKLIST

Pharmacy name: _____ Practice site #: _____

Licensee name: _____ Registrant #: _____

This compliance checklist is based on and reference requirements outlined in the *Foundational Requirements: Guidance Document for Opening a Licensed Community Pharmacy*. Please refer to this document for the complete list of requirements and guidelines

Prior to opening a new or relocated pharmacy to the public to provide pharmacy services, the licensee must ensure that his/her pharmacy meets the requirements and guidelines as outlined in the *Foundational Requirements: Guidance Document for Opening a Licensed Community Pharmacy*. A practice consultant will conduct a pre-opening inspection and use this compliance checklist to document compliance with these legislative requirements. The licensee must, to the best of his/her knowledge and understanding, meet all legislative requirements prior to scheduling the pre-opening inspection. Depending on the pharmacy, additional requirements may apply.

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
1, 10	The physical facilities, size, and layout of the prescription department match the scale drawing submitted and approved by ACP at the time of application.		
2	The prescription department is physically delineated from the public area by the use of <ul style="list-style-type: none"> • variations in décor, flooring, or fixtures; or • physical separation. 		
2	The prescription department is differentiated from the public area by a sign that reads <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>		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
3	<p>The prescription department has 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 is only accessible to personnel approved by the licensee.</p>		
4	<p>The dispensary, scheduled drugs (including Schedule 3), and patient records are secure from unauthorized personnel and locked up appropriately when the pharmacy is closed. If applicable, the pharmacy operates as a lock and leave pharmacy.</p>		
5	<p>The prescription department has adequate lighting, ventilation, and humidity and temperature control.</p>		
6	<p>The prescription department has the proper storage facilities to ensure that the quality and integrity of drugs and health care products are maintained.</p>		
7	<p>Drugs are kept in the appropriate locations within the prescription department, having regard for their scheduling under Part 4 of the Pharmacy and Drug Act.</p>		
8	<p>The prescription department is maintained in a clean and orderly condition.</p>		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
9	<p>The following signs are 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>For the pre-opening inspection, the pharmacy must have all of the above signs posted or placeholders demonstrating their final location. The pharmacy licence will be mailed out once approved by ACP.</p>		
11	The dispensary has a physical barrier that excludes access by an unauthorized individual.		
12	<p>The dispensary has 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, and • adequate shelf and storage space. 		
12	The dispensary has an area for compounding drugs that is in accordance with the compounding standards and the types of preparations and compounding services that will be provided.		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
13	<p>The dispensary has 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. 		
14	<p>The dispensary has</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>The listed equipment must be operational for the pre-opening inspection.</p>		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
15	<p>The dispensary has 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>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>The pharmacy has 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>		
17	<p>The dispensary has 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. 		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
18	<p>Drugs in the dispensary are stored in an appropriate manner and location that</p> <ul style="list-style-type: none"> • protects the integrity, quality and safety of the drugs; • minimizes the possibility of dispensing errors; and • ensures the security of the drugs against theft, loss, or diversion. 		
19	<p>The patient services area has a private or semi-private area that ensures patient confidentiality. This area has</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 is 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>		
19	<p>If the pharmacy provides injection services, a private area is available to the patient and is clean, safe, and appropriately private and comfortable for the patient.</p>		

Requirement (s)	Description	Compliant (✓, ✗, or N/A)	Comments
20	<p>If the pharmacy has a public website, the website prominently displays</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. 		
21	<p>Each employee or regulated member has and wears a name tag that clearly identifies whether the individual is a regulated member.</p>		
21	<p>ACP is informed of the regulated members employed at the pharmacy, including part-time, temporary, and relief pharmacists and/or pharmacy technicians.</p>		
22	<p>The pharmacy has a policies and procedures manual that addresses the areas outlined in ACP’s Policies and Procedures Manual template table of contents, as appropriate for their pharmacy.</p>		
23	<p>The pharmacy has an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records.</p>		

PRE-OPENING INSPECTION

Practice site #: _____ Inspection date: _____

Practice consultant name: _____

If deficiencies identified

Any deficiencies identified by the practice consultant during the pre-opening inspection must be corrected before the pharmacy can open and begin to provide pharmacy services.

Once all identified deficiencies have been corrected, contact the practice consultant as directed below.

Next step(s) for the licensee

- Email the practice consultant digital evidence (e.g., photos) demonstrating compliance.
- Email the practice consultant a completed and signed Professional Declaration form.
- Email the practice consultant to schedule a re-inspection. A re-inspection fee will apply.
- Other:

When the practice consultant has confirmed compliance with the legislative requirements, they will inform the licensee that the inspection is complete and to wait for a subsequent email from the registration team. A registration team member will receive a signed copy of this document and email the licensee when the condition on the licence has been removed and the pharmacy may open and begin to provide pharmacy services.

The pharmacy cannot provide any pharmacy services until approved by the Alberta College of Pharmacy. Any individual who does not comply with the condition imposed on the licence will be subject to disciplinary action.

When compliant with all requirements

I, the practice consultant, can confirm that this pharmacy has met the legislative requirements and is ready to provide pharmacy services.

Proposed pharmacy opening date (per licensee): _____

Pharmacy phone #: _____ Pharmacy Fax #: _____

Practice consultant's signature

Date

PROFESSIONAL DECLARATION

This form is to be completed by the licensee if directed by the practice consultant. Once the identified deficiencies have been corrected, complete this form and email a signed copy to the practice consultant.

I, _____, the licensee, declare that all deficiencies identified by the practice consultant during the pre-opening inspection have been corrected for the following pharmacy.

Practice site #: _____

Proposed pharmacy opening date: _____

I will not open the pharmacy to provide pharmacy services until the condition on the licence has been removed and I have been notified by a member of the registration team.

I acknowledge that the registration team and the ACP will be relying on the truth and accuracy of this professional declaration in determining whether to permit the pharmacy to open and provide pharmacy services. I understand that if there are any false or misleading statements in this professional declaration, this may result in a determination that the requirements for the pharmacy licence have not been met. I also understand that any false or misleading statements or representations made in this professional declaration may constitute as "unprofessional conduct" and may result in a referral to the Complaints Director as a formal complaint.

Licensee's signature

Date