

Pharmacy inspection compliance checklist

Pharmacy name: _____ Practice site #: _____

Licensee name: _____ ACP registration #: _____

Licence type (select all that apply): Community Compounding and repackaging Mail order

Pharmacy practice consultant name: _____ Inspection date: _____

Inspection type (select all that apply): Opening Renovation Relocation Non-sterile compounding

Accompanying inspections (select all that apply): Sterile compounding Other: _____

This compliance checklist references requirements outlined in the [Foundational Requirements: Guidance Document for Opening a Licensed Pharmacy](#). Prior to applying for a new pharmacy licence, relocating an existing pharmacy to a new space, or renovating an existing pharmacy, the pharmacy must meet all legislative requirements. Depending on the pharmacy services provided, additional requirements may apply.

Requirement(s)	Compliant	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. A prescription department must be at least 355.2 ft ² (33 m ²) in area. A dispensary must be at least 193.8 ft ² (18 m ²) in area.		
2 The prescription department is physically delineated from the public area by the use of <ul style="list-style-type: none"> • variations in decor, 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 is not required if the public area comprises 15% or less of the premises of the pharmacy.</p>		

Requirement(s)		Compliant	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> <p>The dispensary is accessible only to personnel approved by the licensee.</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 will be kept in the appropriate locations within the prescription department, according to their scheduling under Part 4 of the <i>Pharmacy and Drug Act</i>.</p>		
8	<p>The prescription department is maintained in a clean and orderly condition.</p>		

Requirement(s)	Compliant	Comments
<p>9</p> <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, • Code of Ethics in the prescription department, and • Council-approved signage as per the Standards for the Operation of Licensed Pharmacies 4.13(e). <p>NOTE: The pharmacy must have all of the above signs posted. For newly opening pharmacies, a placeholder demonstrating the location of the pharmacy licence must be in place and posted once the licence is received.</p>		
<p>11</p>	<p>The dispensary has a physical barrier that excludes access by an unauthorized individual.</p>	
<p>12</p>	<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 drop off and pick up area <ul style="list-style-type: none"> ○ located a suitable distance from patient waiting and high traffic areas, ○ that has suitable sound and visual barriers to maintain patient confidentiality when communicating with patients; • a counter with at least 16.1 ft² (1.5m²) of unrestricted work area for preparing drugs for dispensing; • aisles and entrance ways at least 3 ft (90 cm) wide; • adequate shelf and storage space; and • an area for compounding drugs. 	

Requirement(s)	Compliant	Comments
<p>12</p>	<p>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.</p> <p>The licensee should complete the linked non-sterile compounding self-assessment and, if applicable, the linked sterile compounding self-assessment prior to the inspection to assess their compliance.</p> <p>NOTE: All pharmacies must meet Level A non-sterile compounding requirements. Those providing higher levels of non-sterile compounding must additionally meet the requirements of the level of compounding provided.</p> <p>The pharmacy practice consultant will complete additional inspections for the following practices if performed at the pharmacy:</p> <ul style="list-style-type: none"> • sterile compounding; • other practices or services provided. 	
<p>13</p>	<p>A dispensary must have a</p> <ul style="list-style-type: none"> • laboratory grade or full-size domestic refrigerator or appropriate temperature controlled area with a digital temperature monitoring device, <ul style="list-style-type: none"> ○ device that indicates the minimum and maximum temperatures reached since the last reading; • sink with hot and cold running water that is readily accessible for hand hygiene at all times, located outside of segregated compounding rooms; • metal safe that is secured in place and equipped with a time delay lock set at a minimum of five minutes, or in accordance with the standards; and • heat source for extemporaneous compounding. 	

Requirement(s)	Compliant	Comments
<p>14</p>	<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, 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>NOTE: The equipment must be operational for the inspection. Health information must not be transmitted using an enabling technology that was not submitted in a Privacy Impact Assessment (PIA) to the Office of the Information and Privacy Commissioner (OIPC) and approved for use.</p>	
<p>15</p>	<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>NOTE: The licensee must have submitted the expedited PIA requirements to the 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 inspection.</p>	
<p>16</p>	<p>The pharmacy has an adequate library, including all required reference sources set out in the standards, to which a regulated member in the dispensary can have immediate access to the references.</p>	

Requirement(s)	Compliant	Comments
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 provided in the dispensary. 	
18	<p>Drugs in the dispensary will 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; • minimizes the possibility of dispensing errors; and • ensures the security of the drugs against theft, loss, or diversion. 	

Requirement(s)	Compliant	Comments
<p>19</p>	<p>A licensed pharmacy must have a private consultation area within the patient services area that ensures patient confidentiality.</p> <p>The private consultation area must</p> <ul style="list-style-type: none"> • be publicly accessible and not located within or require public access to the dispensary; • not be the only access point to the dispensary; • be clean, safe, and well-lit; • be an adequate size to facilitate quality care; • be dedicated to that purpose and 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; • accommodate barrier-free access for patients with mobility limitations; • have suitable sound barriers that prevent conversations from being overheard by unauthorized individuals; and • have suitable visual barriers to prevent others from seeing what drug, health care products, aids, devices, or pharmacy services are being provided to or for the patient. 	

Requirement(s)	Compliant	Comments
20	<p>If the pharmacy has a public website, it 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; • The persons name of the corporation is required, 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 general policies and procedures manual that addresses the areas outlined in ACP’s Policies and Procedures Manual template, and a non-sterile compounding policies and procedures manual that addresses the areas outlined in ACP’s Non-Sterile Compounding Policies and Procedures Manual template, 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>	

Additional comments:

A large, empty rectangular box with a black border, intended for providing additional comments.

Compliance readiness

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If deficiencies identified

Any deficiencies identified by the pharmacy practice consultant during the inspection must be corrected. For newly opening pharmacies, all deficiencies must be corrected before the pharmacy is issued a pharmacy license, and for renovating pharmacies, all deficiencies must be corrected before using the renovated pharmacy space. Once all identified deficiencies have been corrected, contact the pharmacy practice consultant as directed below.

Next step(s) for the licensee

Submit your signed Professional Declaration form to the pharmacy practice consultant.

Submit digital evidence (e.g. photos) demonstrating compliance to the pharmacy practice consultant.

Complete a re-inspection. A re-inspection fee will apply.

Other:

When the pharmacy 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 will email the licensee to confirm the opening date and issue the pharmacy licence.



Professional declaration

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

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

Practice site #: _____

Proposed pharmacy opening date: _____

I acknowledge that the ACP will be relying on the truth and accuracy of this professional declaration in determining whether to permit the pharmacy to 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