

# Foundational requirements - Compliance checklist

## Stand-alone compounding and repackaging licence

Pharmacy name: \_\_\_\_\_ Practice site #: \_\_\_\_\_

Licensee name: \_\_\_\_\_ ACP registration number: \_\_\_\_\_

A compounding and repackaging pharmacy licence authorizes the provision of compounding and repackaging pharmacy services<sup>1</sup> 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.

This compliance checklist is based on and references requirements outlined in the [Foundational Requirements: Guidance Document for Opening a Licensed Pharmacy](#). Please refer to this document for the complete list of requirements and guidelines.

Prior to applying for a standalone compounding and repackaging pharmacy, 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 Pharmacy. A pharmacy practice consultant will conduct an inspection and use this compliance checklist to document compliance with legislative requirements pursuant to this category of licence. 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.		
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"> <li>• protection against theft, diversion, and tampering with drugs/health care products; and</li> <li>• that unauthorized individuals do not obtain access to drugs or to patient information.</li> </ul> <p>The dispensary is only accessible to personnel approved by the licensee.</p>		

<sup>1</sup> “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;

Requirement(s)	Description	Compliant (✓, ✗, or N/A)	Comments
4	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.		
5	The prescription department has adequate lighting, ventilation, and humidity and temperature control.		
6	The prescription department has the proper storage facilities to ensure that the quality and integrity of drugs and health care products are maintained.		
7	Drugs are 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> .		
8	The prescription department is maintained in a clean and orderly condition.		
11	The dispensary has a physical barrier that excludes access by an unauthorized individual.		
12	<p>If the compounding and repackaging pharmacy is not a community pharmacy, the pharmacy must, at a minimum, meet the minimum size (at least 18 m<sup>2</sup> in area) and equipment requirements of a dispensary in a community pharmacy and include:</p> <ul style="list-style-type: none"> <li>• a counter with at least 1.5m<sup>2</sup> of unrestricted work area for preparing drugs,</li> <li>• working aisles that are at least 90 cm wide, and</li> <li>• adequate shelf and storage space.</li> </ul>		

Requirement(s)	Description	Compliant (✓, ✗, or N/A)	Comments
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.		
13	<p>The dispensary has a</p> <ul style="list-style-type: none"> <li>• refrigerator or appropriate temperature controlled area, <ul style="list-style-type: none"> <li>○ a device that indicates the minimum and maximum temperatures reached since the last reading</li> </ul> </li> <li>• sink with hot and cold running water,</li> <li>• a 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</li> <li>• heat source for extemporaneous compounding.</li> </ul>		
14	<p>The dispensary has</p> <ul style="list-style-type: none"> <li>• 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,</li> <li>• a mechanism to send and receive faxes, and</li> <li>• equipment to allow the pharmacy to make and receive telephone calls.</li> </ul> <p><b>The listed equipment must be operational for the pre-opening inspection.</b></p>		
16	The pharmacy has an adequate library, including all <a href="#">required reference sources</a> 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.		

Requirement(s)	Description	Compliant (✓, ✗, or N/A)	Comments
17	<p>The dispensary has the following compounding and dispensing equipment</p> <ul style="list-style-type: none"> <li>• a prescription or electronic balance with a sensitivity to a minimum of 10 mg,</li> <li>• a set of metric weights or a calibration weight, and</li> <li>• any other equipment required to support the professional services that are provided in the dispensary.</li> </ul>		
18	<p>Drugs in the dispensary will be stored in an appropriate manner and location that</p> <ul style="list-style-type: none"> <li>• protects the integrity, quality and safety of the drugs;</li> <li>• minimizes the possibility of dispensing errors; and</li> <li>• ensures the security of the drugs against theft, loss, or diversion.</li> </ul>		
20	<p>If the pharmacy has a public website, the website prominently displays</p> <ul style="list-style-type: none"> <li>• a copy of the pharmacy licence;</li> <li>• the pharmacy’s location, mailing address, email address, and telephone number;</li> <li>• the licensee’s name, practice permit number, and business address;</li> <li>• the proprietor’s name and business address; and</li> <li>• if the proprietor is a corporation, the name of the proprietor’s representative.</li> </ul>		
21	<p>Each employee or regulated member <b>has and wears a name tag</b> that clearly identifies whether the individual is a regulated member.</p>		

Requirement(s)	Description	Compliant (✓, ✗, or N/A)	Comments
21	ACP is informed of the regulated members employed at the pharmacy, including part-time, temporary, and relief pharmacists and/or pharmacy technicians.		
22	The pharmacy has a general policies and procedures manual that addresses the areas outlined in ACP's <a href="#">Policies and Procedures Manual template</a> , and a non-sterile compounding policies and procedures manual that addresses the areas outlined in ACP's <a href="#">Non-Sterile Compounding Policies and Procedures Manual template</a> , as appropriate for their pharmacy.		
23	The pharmacy has an effective system for the creation, maintenance, secure storage and availability for retrieval of all required records.		

**Additional comments:**

# Pre-opening inspection

Practice site #: \_\_\_\_\_ Inspection date: \_\_\_\_\_

Pharmacy practice consultant name: \_\_\_\_\_

## If deficiencies identified

Any deficiencies identified by the pharmacy practice consultant during the pre-opening inspection must be corrected before the pharmacy is issued a pharmacy licence.

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

## Next step(s) for the licensee

- Email the pharmacy practice consultant digital evidence (e.g., photos) demonstrating compliance.
- Email the pharmacy practice consultant a completed and signed Professional Declaration form.
- Email the pharmacy practice consultant to schedule 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 email the licensee to confirm the opening date and issue the pharmacy licence.

### When compliant with all requirements

I, the pharmacy 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 #: \_\_\_\_\_

\_\_\_\_\_

Pharmacy practice consultant's signature

\_\_\_\_\_

Date

## 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 pre-opening inspection have been corrected for the following pharmacy.

Practice site #: \_\_\_\_\_

Proposed pharmacy opening date: \_\_\_\_\_

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