

New Pharmacy Letter of Intent

Prior to submitting your New Pharmacy Letter of Intent, ensure you are familiar with the [Five Steps to Opening Your New Pharmacy](#) and the [Foundational Requirements: Guidance Document for Opening a Licensed Community Pharmacy](#).

You should submit your Letter of Intent and floor plans to our office by fax, mail or email (pharmacy@abpharmacy.ca) at least 60 days prior to the intended date of opening.

Section One: Pharmacy Information

Proposed pharmacy opening date: _____
(This date can be changed and is dependent on when ACP grants final approval)

Pharmacy Operating Name _____

Pharmacy Address (if available) _____

City _____ Postal Code _____

Section Two: Proprietor Information

Name of the corporation, partnership, or individual opening the pharmacy _____

Mailing address of the corporation, partnership, or individual opening the pharmacy _____

City _____ Province _____ Postal Code _____

Name of Director(s) or Partners (if applicable): _____

Section Three: Contact Information

Contact name: _____ print clearly ACP Reg #: _____ if applicable

Email address: _____ Phone #: _____

New Pharmacy Letter of Intent

Section Four: Pharmacy Operations and Services

Licensee name (if available): _____ ACP Reg #: _____

The number of hours per week the pharmacy is open to the public: _____

The number of hours per week the licensee, on average, will be present at this pharmacy: _____

The legislation was developed on the premise that a licensee is a clinical pharmacist, practicing at the pharmacy for which they hold a licence, and who would be present for a regular and significant portion of the time that services are provided from the pharmacy. This presence is important for the licensee to personally manage, control, and supervise the day-to-day operation of the pharmacy. Being present means being in attendance at the pharmacy. It does not mean that the licensee must be engaged in patient care activities for the duration of this time, as time is required to fulfill their licensee responsibilities. This also excludes vacation and/or short-term illnesses that are less than 90 consecutive days.

- a) Will the pharmacy provide pharmacy services to or for a patient for which the patient or patient's agent attends the pharmacy to receive the service? Yes No
- If yes, a community pharmacy licence is required
- b) Will the pharmacy provide pharmacy services to or for a patient for which neither the patient nor the patient's agent regularly attends the pharmacy to receive the service? Yes No
- If yes, a mail order pharmacy licence may be required
- c) If yes to b), will a pharmacist regularly attend personally on the patient to assess the patient and monitor the patient's response to drug therapy? Yes No
- If yes, exempt from requiring a mail order pharmacy licence
- d) Will the pharmacy compound or repackage drugs for a licensed pharmacy or institution pharmacy that dispenses or sells those drugs? Yes No
- If yes, a compounding and repackaging pharmacy licence is required
- e) Will the pharmacy dispense methadone or buprenorphine-naloxone for opioid dependency? Yes No
- f) Will the pharmacy provide services to individuals who reside outside of Alberta? Yes No
- This does not include services provided to those who are in Alberta on an incidental basis for vacation or work.
- g) Will the pharmacy operate as a lock and leave pharmacy? Yes No
- h) Will the pharmacy be located in a shared premises¹ (for example, with a medical clinic)? Yes No
- If yes to shared premises, you will need to provide a detailed floor plan of the pharmacy itself and an overall floor plan of the shared facility. If you are in a shared premises, you will need to operate as a lock and leave pharmacy.

¹ According to the [Foundational Requirements: Guidance Document for Opening a Licensed Community Pharmacy](#), the pharmacy and an adjoining business must be able to operate independently of one another; patients must be able to recognize when they have entered the licensed pharmacy, and that an adjoining business (e.g., a medical clinic) is separate from the pharmacy. The pharmacy and the adjoining business must not engage in any practice or enter into any arrangement that unduly interferes with independent patient choice.

New Pharmacy Letter of Intent

Section Five: Compounding Services

All pharmacies must have an area for compounding drugs and be equipped to provide compounding services.

Non-sterile compounding

Prior to completing the following section and before your pre-opening inspection, you must:

1. Review the [Standards for Pharmacy Compounding of Non-sterile Preparations](#) and the [Guidance Document for Pharmacy Compounding of Non-sterile Preparations](#) and other [related documents](#).
2. Determine the active pharmaceutical ingredients (APIs) that the pharmacy will use to compound. For each API, refer to the National Institute for Occupational Safety and Health ([NIOSH](#)) [list](#) and the Safety Data Sheet (in particular, Sections 2 and 8) to determine the level of risk to personnel, the appropriate personal protective equipment, and the engineering controls required for the pharmacy. When there is uncertainty as to the level of risk, you must adhere to the higher standard. Retain copies of all Safety Data Sheets and the assessments of risk.

What APIs will the pharmacy use during compounding?

Check One	Ingredients/Compounds	Physical requirements*
<input type="checkbox"/> Yes <input type="checkbox"/> No	Hazardous drugs which are classified by NIOSH as Group 1	Level C <ul style="list-style-type: none"> • Separate room • Appropriate containment device (C-PEC) for materials being compounded • Well-ventilated with appropriate air exchange • Negative pressure
<input type="checkbox"/> Yes <input type="checkbox"/> No	Hazardous materials classified by WHMIS as a health hazard, such as those very irritating to the respiratory track, the skin, and the mucous membrane	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Drugs which are classified by NIOSH as Group 2 or 3 where large quantities of APIs are used routinely	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Complex compounds as defined in USP <795>	When there is uncertainty as to the level of risk, then you must adhere to the higher standard (e.g., Level C). Level B <ul style="list-style-type: none"> • Separate room (ventilated or with containment device) • Larger workspace and appropriate equipment • Environment conducive to little or no interruptions • Greater protection from cross contamination • May require a ventilated containment device when certain powders, aromatic products or hazardous products are compounded Level B is limited to when, based on the assessment of risk, <ul style="list-style-type: none"> • the requirements will provide an environment that is safe for the compounding personnel, and • you can justify and provide evidence on how the risk is low and can be mitigated. Risk mitigation and rationale must be documented in the risk assessment.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Small quantities of ingredients or preparations which require ventilation	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Simple and moderate compounds as defined in USP <795>	When there is uncertainty as to the level of risk, then you must adhere to the higher standard (e.g., Level B). Level A <ul style="list-style-type: none"> • Separate space designated for compounding

* Requirements are excerpts from the [Standards for Pharmacy Compounding of Non-sterile Preparations](#) and must not be read in isolation. Refer to the standards for complete requirements.

Your accompanied floor plan must indicate the location of the engineering controls (e.g., fume hood, eyewash station, safety shower) required for the pharmacy based on the APIs with which you will be compounding, the corresponding Safety Data Sheets, and your assessments of risk. This information, along with compounding policies and procedures, master formulation records, and a quality assurance program, must be available upon request during the pre-opening inspection.

Sterile compounding

If your pharmacy will be compounding sterile preparations, you must comply with the [Model Standards for Compounding Hazardous and Non-Hazardous Sterile Preparations](#). An ACP Pharmacy Practice Consultant (PPC) will provide consultation by reviewing your floor plans and completing at least one pre-opening inspection. These processes may result in a 3-4 month timeframe before your pharmacy can open to provide pharmacy services.

Will the pharmacy be compounding sterile preparations?

Yes No

If yes, indicate risk level(s)/use:

High Medium Low Immediate use

- Risk levels are per the [Model Standards](#)

Will the pharmacy be compounding *hazardous* sterile products?

Yes No

If yes, indicate microbial risk level(s):

High Medium Low

- Risk levels are per the [Model Standards](#)

New Pharmacy Letter of Intent

Section Six: Floor Plans

You must submit a copy of the pharmacy floor plan(s) with this completed document. The floor plans must comply with the below floor plan requirement guide. An incomplete document or floor plans that do not comply with this guide will not be reviewed.

Criteria	✓
Is the floor plan clear, accurate and legible ?	
Is the floor plan drawn to scale ?	
Does the floor plan include exact measurements (in ft.) of all dimensions (e.g., walls and entry points) so that the area of the dispensary and patient services area may be easily calculated?	
Does the floor plan clearly identify the <ul style="list-style-type: none"> • dispensary • patient services area • surrounding public area 	
Does the floor plan clearly indicate the size (in square feet) of the <ul style="list-style-type: none"> • dispensary (must be at least 193.8 ft² (18 m²) in area), • patient services area • total prescription department (a prescription department (dispensary + patient services area) must be at least 355.2 ft² (33 m²) in area) 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.	
Does the floor plan clearly indicate all entry points into the dispensary ? <ul style="list-style-type: none"> • indicate whether there is a gate, lift-up countertop, or door • the only access to the dispensary cannot be through a counselling room or office. 	
Does the floor plan clearly identify the following within the dispensary? <ul style="list-style-type: none"> • a counter with at least 16.1 ft² (1.5 m²) of uninterrupted work space (i.e., free of computer terminals, phones, etc.) • working aisles that are at least 3 ft. (90 cm) wide • adequate shelving and storage • compounding area, in accordance with the compounding standards <ul style="list-style-type: none"> ○ location of the sink and heat source for compounding ○ any fume hoods, eyewash stations, safety showers, as applicable • refrigerator (bar refrigerator units are not acceptable) • lockable drug locker or cupboard • computer terminal(s) 	
Does the floor plan clearly identify a semi-private area for receiving prescriptions (e.g., a service counter with suitable visual and sound barriers and away from patient waiting- or high-traffic areas)?	
Does the floor plan clearly identify any private area(s) used for injection services (must be publicly and wheelchair accessible)?	
Does the floor plan clearly indicate any security grilles used to secure the dispensary?	
Does the floor plan clearly identify all areas intended for pharmacy use?	
If sharing premises, have you included an additional floor plan depicting the overall facilities, space and layout of the premises? <ul style="list-style-type: none"> • If the pharmacy shares a premise, the prescription department must operate as a lock and leave. 	

Section Seven: Applicants Signature

I declare that the information on this application or any information supplied in support of this application is true to the best of my knowledge.

Applicant's Name (Please Print)

Applicant ACP Reg # (if applicable)

Applicant's signature

Date

New Pharmacy Letter of Intent

Section Seven: Fee Payment

Practice Site Application Assessment Fee..... **\$1050.00 (\$1000.00 plus \$50.00 GST)**

Payment Options

Cheque # _____ (Make cheque payable to the Alberta College of Pharmacy)

Credit Card - Visa or MasterCard Only

Credit Card Information

Credit Card Number _____

Name on Credit Card _____

Expiry Date (MM/YY) _____ Security Code (3 digits on back of card) _____

Cardholder's signature _____ Date _____

Cardholder's phone # _____ Cell # _____

For Office Use Only

Date Transaction Processed: _____