

Alberta College of Pharmacy 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](#)
- [Foundational Requirements: Guidance Document for Opening a Licensed Pharmacy.](#)

Along with this application form, you will need to submit a floor plan depicting the physical facilities, space, and entire layout of the licensed pharmacy. The scale drawing must reflect any areas in which pharmacy services are being provided. This floor plan must comply with the [Floor Plan Requirements Guide](#). Floor plans submitted that do not clearly indicate all elements listed within this guide will be rejected.

The physical facilities, space, and layout of a licensed pharmacy must remain as depicted in the scale drawing approved by the Alberta College of Pharmacy (ACP) at the time of application. Any changes to the physical facilities, proposed use of space or layout of a licensed pharmacy are considered renovations and require advanced notice and approval by the registrar prior to implementing these changes.

The completed application form and floor plan(s) must be submitted to our office at least 60 days prior to the proposed opening date. Application submission can be accepted via email to pharmacy@abpharmacy.ca.

*****All requested documentation must be submitted together as one submission otherwise your application is considered incomplete*****

Section One: Pharmacy Information

Proposed operating name of the pharmacy _____

Physical address (if available) – PO Box # not acceptable here _____

City _____ Province _____ Postal code _____

Phone # - include area code _____ Fax # - include area code _____ Toll-free # (if applicable) _____

Website address (if applicable) _____

Pharmacy hours: Monday-Friday _____ Saturday _____ Sunday/Holidays _____

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

The number of hours per week the licensee, on average, will be present at this pharmacy¹: _____

¹ 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.

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Section Two: Application Information

Please check off which license category you are applying for:

	Licence category
<input type="checkbox"/>	Community standalone
<input type="checkbox"/>	Community & Compounding and Repackaging – combination
<input type="checkbox"/>	Community & Mail Order – combination
<input type="checkbox"/>	Community & Compounding & Mail Order – combination
<input type="checkbox"/>	Compounding and Repackaging standalone (products cannot be dispensed directly to patients)

Proposed pharmacy opening date: _____ (This date can be changed and is dependent on when ACP issues the license)

Proposed opening dates should be **at least 60 days** from the date ACP receives a complete Letter of Intent.

Proprietor’s Representative Contact Information

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

Email address: _____ Phone #: _____

Section Three: Pharmacy Staff – If information is available

Pharmacy staff: Identify ALL pharmacists and technicians that are currently employed at this pharmacy location. Assistants are not regulated members. The licensee (manager) is responsible for notifying ACP of future staff changes via e-mail at pharmacy@abpharmacy.ca

Pharmacy licensees and staff pharmacists are automatically granted narcotic signing authority for all locations in which they are employed. Students, Interns and Technicians cannot hold narcotic signing authority.

Note: Ensure the below list is accurate and complete as ACP will add/remove employees accordingly

ACP Registration #	Name	Pharmacist, Intern, Student, Technician, or Provisional technician	Licensee Yes/No

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Section Four: Pharmacy Operations and Services

Part A: General Questions

<p>a) Will the pharmacy provide pharmacy services to or for a patient for which the patient or patient's representative attends the pharmacy to receive the service?</p> <ul style="list-style-type: none"> If yes, a community pharmacy licence is required A community pharmacy licence is required if pharmacy services are provided directly to patients 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>b) Will the pharmacy provide pharmacy services to or for a patient for which neither the patient nor the patient's representative regularly attends the pharmacy to receive the service?</p> <ul style="list-style-type: none"> If yes, a community pharmacy license is required, and a mail order pharmacy licence may be required If yes, what percentage of the business will be conducted via mail order? 	<input type="checkbox"/> Yes <input type="checkbox"/> No Percentage _____%
<p>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?</p> <ul style="list-style-type: none"> If yes, exempt from requiring a mail order pharmacy licence 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>d) Will the pharmacy use virtual care to provide pharmacy services?</p> <ul style="list-style-type: none"> Virtual care is defined in the Virtual Care Guidelines as any professional interaction between a regulated member and a patient that occurs remotely using an enabling technology. If yes, what percentage of the professional interactions will be conducted via virtual care? 	<input type="checkbox"/> Yes <input type="checkbox"/> No Percentage _____%
<p>e) Will the pharmacy be providing pharmacy services, drug products, or compounds for use in animals?</p> <ul style="list-style-type: none"> If yes, what percentage of the business is for non-human use? 	<input type="checkbox"/> Yes <input type="checkbox"/> No Percentage _____%
<p>f) Will the pharmacy provide services to individuals who reside outside of Alberta?</p> <ul style="list-style-type: none"> This does not include services provided to those who are in Alberta on an incidental basis for vacation or work. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>g) Will the pharmacy be compounding preparations for another licensed pharmacy or institution that dispenses or sells those products?</p> <ul style="list-style-type: none"> If yes, a compounding and repackaging pharmacy licence is required 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>h) Will the pharmacy be preparing compliance packaging or repackaging medications for another licensed pharmacy or institution that dispenses or sells those drugs?</p> <ul style="list-style-type: none"> If yes, a compounding and repackaging pharmacy licence is required 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>i) Will the pharmacy routinely compound narcotic medications for another licensed pharmacy or institution that dispenses or sells those drugs?</p> <ul style="list-style-type: none"> If yes, the pharmacy must hold a licensed dealer permit issued by Health Canada 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>j) Will the pharmacy compound benzodiazepines or other targeted substances, not pursuant to a prescription, for another licensed pharmacy or institution that dispenses or sells those drugs?</p> <ul style="list-style-type: none"> If yes, the pharmacy must hold a licensed dealer permit issued by Health Canada 	<input type="checkbox"/> Yes <input type="checkbox"/> No

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<p>k) Will the pharmacy provide any pharmacy services, including compounding or repackaging, in a space where the pharmacy personnel must leave the dispensary and go through a non-dispensary area to access this space?</p> <ul style="list-style-type: none"> If yes, a separate pharmacy licence for the non-contiguous space may be required. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>l) Will the pharmacy provide Opioid Agonist Therapy (OAT) for opioid dependency?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>m) Will the pharmacy be located in a shared premise² (for example, with a medical clinic)?</p> <ul style="list-style-type: none"> If yes, need to provide a detailed floor plan of the pharmacy itself and an overall floor plan of the shared facility. If yes, need to operate as a lock and leave pharmacy. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>n) Will the pharmacy operate as a lock and leave pharmacy?</p> <ul style="list-style-type: none"> A pharmacy operating as a lock and leave must have a secure, lockable barrier that effectively prevents access to the dispensary, adequate key-control policies, and its own security system to monitor and detect any unauthorized entry. 	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p>o) Will the pharmacy have off-site storage of records outside of the dispensary?</p> <ul style="list-style-type: none"> If yes, need to submit an Application to Maintain Records at a Location Other than the Pharmacy 	<input type="checkbox"/> Yes <input type="checkbox"/> No

² According to the [Foundational Requirements: Guidance Document for Opening a Licensed 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.

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Part B: Compounding Services

Non-sterile compounding

All pharmacies must have an area for compounding drugs and be equipped to provide compounding services, as per Section 14(2)c.iii of the *Pharmacy and Drug Regulation*.

Prior to completing the following section 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 to what level of risk the pharmacy will operate at by considering the active pharmaceutical ingredients (APIs) that the pharmacy will use to compound and in what quantities. 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 and room 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? Applicants must check “Yes” to at least one category

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, entirely closed off room with a sink with external ventilation through HEPA filtration • Containment device (C-PEC) must have either redundant HEPA filters in a series or be externally ventilated (the preferred option). • Negative pressure of at least -2.5 Pa to the surrounding areas • Appropriate air exchange of at least 12 ACPH (air changes per hour)
<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, well-ventilated room with a door, containing a sink, which may require a ventilated containment device when powders, aromatic products or hazardous products are compounded. • Compounding room must be internally ventilated using high-efficiency particulate air (HEPA) filtration or externally ventilated with or without HEPA filtration. • Containment device must have either redundant HEPA filters in a series or be externally ventilated (the preferred option). • Larger workspace and appropriate equipment • Heating and air conditioning systems must occur through professionally designed HVAC systems that avoid decomposition and contamination of chemicals; air vents cannot be located over work stations. • Environment conducive to little or no interruptions
<input type="checkbox"/> Yes <input type="checkbox"/> No	Small quantities of ingredients or preparations which require ventilation	When there is uncertainty as to the level of risk, then you must adhere to the higher standard (e.g., Level B). Level A Separate space designated for compounding, large enough for compounding personnel to work safely, with an adjacent heat source and sink.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Simple and moderate compounds as defined in USP <795>	

* 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., containment hood, room ventilation, HEPA filters, eyewash station, safety shower, sink, doors etc.) 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, documentation related to compounding personnel, sample master formulation and compounding records, maintenance and certification reports, and a quality assurance program, must be available upon request during the compounding and repackaging inspection.

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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](#).

- 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](#)

Part C: Floorplan Information

Floor plans submitted that do not clearly indicate and comply with all elements listed within this guide will not be reviewed.

Criteria	✓
Is the floor plan clear, accurate and legible ? <ul style="list-style-type: none"> • Floor plans must be professionally drawn (either digitally created or drawn on a grid) to scale with the scale or conversion included in the drawing 	
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"> • dispensary³, • patient services area⁴, and • surrounding public area⁵? 	
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, and • 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 areas where drug product or patient records will be stored? <ul style="list-style-type: none"> • If you are storing records outside of the dispensary, you will need to submit the Application to Maintain Records at a Location Other than the Pharmacy 	
Does the floor plan clearly indicate all areas where pharmacy services will be provided?	
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. • You cannot have the only access to the dispensary be through a counselling room or office. 	
Does the floor plan clearly identify the following within the dispensary?	

³ “dispensary” means the area of a licensed pharmacy that is not accessible to the public and in which regulated members dispense, compound, provide for sale, and sell drugs, referred to in sections 31, 32 and 33 of the [Pharmacy and Drug Act \(PDA\)](#), and
⁴ “patient services area” means the area of a licensed pharmacy located outside and adjacent to the dispensary where: patients receive pharmacy services from regulated members, and schedule 3 drugs are provided for sale; referred to in section 33 of the Act
⁵ “public area” means the area of a licensed pharmacy located outside the prescription department

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<ul style="list-style-type: none"> • a counter with at least 16.1 ft² (1.5 m²) of uninterrupted workspace (i.e., free of computer terminals, phones, etc.) • all aisles and entrance ways/gates at least 3 ft (90 cm) wide • adequate shelving and storage space • compounding area, in accordance with the compounding standards <ul style="list-style-type: none"> ○ location of the sink and heat source for compounding ○ eye wash station ○ any fume hoods and safety showers, as applicable • a refrigerator that is laboratory grade or full-size domestic refrigerator or appropriate temperature-controlled area with a digital temperature monitoring device (Bar refrigerator units are not acceptable) • a sink with hot and cold running water that is readily accessible for hand hygiene at all times, located outside of segregated compounding rooms. • a metal safe that is secured in place and equipped with a time-delay lock set at a minimum of five minutes • computer terminal(s) 	
<p>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)?</p>	
<p>Does the floor plan clearly identify a private room(s) within the patient services area that ensures patient confidentiality?</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. 	
<p>Does the floor plan clearly indicate any security grilles used to secure the dispensary?</p>	
<p>If sharing premises⁶ (for example, with a medical clinic), have you included an additional floor plan depicting the overall facilities, space and layout of the premises?</p> <ul style="list-style-type: none"> • If the pharmacy shares a premise, the prescription department must operate as a lock and leave to prevent unauthorized access, even if both businesses operate with the same business hours • the pharmacy and the adjoining business must be able to operate independently of one another. • If the pharmacy shares a premise, you must submit a Shared Premise application. 	

⁶ According to the [Foundational Requirements: Guidance Document for Opening a Licensed 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.

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Section Five: Licensee Information

Licensee Name (if available): _____ ACP Registration Number _____

Section Six: Proprietor Information

Part A: Ownership Information

If the owner is a corporation, you will need to submit a copy of the **corporate documents** or **last annual return** showing the incorporation of the organization and the names and addresses of all the directors and shareholders and the percentage of shares held.

Please check (✓) one

Sole Proprietorship

(a business owned by one individual, which is **not** organized as a corporation)

Partnership

(a business owned by two or more people which is **not** organized as a corporation)

Corporation

(a business that is a separate legal entity chartered under provincial or federal laws with owners that are called shareholders)

name of the sole proprietor, partnership, or corporation – If partnership, include information for all partners

mailing address

city province postal code

phone # - include area code fax # - include area code toll-free # (if applicable)

email address website address (if applicable)

name of the sole proprietor, partnership, or corporation – If partnership, include information for all partners

mailing address

city province postal code

phone # - include area code fax # - include area code toll-free # (if applicable)

email address website address (if applicable)

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Part B: Declaration and Acknowledgement in Support of Letter of Intent

(must be completed by the proprietor's representative or licensee)

I, _____, declare that

- a. all the information provided in the accompanying Letter of Intent is true, and
- b. the accompanying floor plans are accurate.

I confirm that I have reviewed and understand the following documents:

- [Five Steps to Opening Your New Pharmacy](#)
- [Foundational Requirements: Guidance Document for Opening a Licensed Pharmacy](#)
- [Standards for Pharmacy Compounding of Non-Sterile Preparations](#)
- [Guidance Document for Pharmacy Compounding of Non-Sterile Preparations; and](#)
- [Floor Plan Requirements Guide](#)

I acknowledge that:

- submitting a Letter of Intent and floor plans is only a preliminary step in the pharmacy licensure process and is **not** an application for a pharmacy licence;
- only a clinical pharmacist can apply for a pharmacy licence;
- additional steps and information are required before the Registrar⁷ will consider an application for a pharmacy licence; and
- no person can provide pharmacy services from any facility before a pharmacy licence is issued.

While the Registrar will provide feedback regarding the Letter of Intent and proposed floor plans, I acknowledge that the applicant for the pharmacy licence has sole responsibility

- a. for understanding and ensuring compliance with
 - the *Pharmacy and Drug Act*;
 - the Pharmacy and Drug Regulations;
 - the Standards for the Operation of Licensed Pharmacies;
 - the Code of Ethics;
 - Standards for Pharmacy Compounding of Non-sterile Preparations; and
 - Guidance Document for Pharmacy Compounding of Non-sterile Preparations (collectively "the Requirements"); and
- b. ensuring that the physical facilities, space, and layout of the pharmacy
 - will comply with the Requirements; and
 - will be conducive to the safe and effective practice of pharmacy.

I acknowledge that the proposed licensee and the proposed pharmacy must comply with the Requirements before a licence may be issued.

I acknowledge that the proposed pharmacy will still have to undergo a pre-opening inspection, which is satisfactory to the Registrar, before the Registrar approves the application and issues a pharmacy licence to the proposed licensee.

I acknowledge that if any deficiencies are identified during the pre-opening inspection, those deficiencies must be corrected before the Registrar will consider issuing a pharmacy licence.

I acknowledge that

- the Registrar will rely on the truth and accuracy of information submitted throughout the pharmacy licensure process in determining whether to issue a pharmacy licence; and
- if there are any false or misleading statements provided during the pharmacy licensure process, this may result in the Registrar determining that the requirements for obtaining a pharmacy licence have not been met.

I also understand that any false or misleading statements or representations made during the pharmacy licensure process may constitute "unprofessional conduct" or "proprietary misconduct" and may result in a referral to the Complaints Director of the ACP.

Signature

Printed name

Date

⁷ In this Declaration and Acknowledgement there is a reference to the Registrar. Wherever this appears it includes any employee of ACP to whom the Registrar may delegate a role in the registration process.

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Section Seven: Fee and Payment information

Pharmacy Name *(if applicable)* _____

Pharmacy Licence Number *(if applicable)* _____

Please submit all documentation via email to pharmacy@abpharmacy.ca

Fee Amount

Practice Site Application Assessment Fee **See the ACP [Fee Schedule](#) for fee plus GST**

Current fee amount plus GST..... \$ _____ + \$ _____ = \$ _____
Fee *GST* *Total*

Payor Information

Cardholder's Name: _____ Registration Number *(if applicable)*: _____

Signature Authorizing Payment: _____ Date: _____

Cardholder's phone # _____ Cell # _____
Area code-phone # *Area code-phone #*

Payment Options

- Cheque # _____ (Make cheque payable to the Alberta College of Pharmacy)
- Credit Card - Visa or MasterCard Only (no Visa Debit or Mastercard Debit) *****Do not provide any credit card information on this form*****

Payment Information

Credit Card Payment Please complete the Registrant Information section above. Once the application is received via email **an ACP representative will contact you at the number provided above and take your credit card information over the phone.** Please email the completed application to the ACP office at pharmacy@abpharmacy.ca

Cheque If you choose to pay the fee via cheque this will require the application to be mailed in with the cheque payment. Please use the mailing address below – **Attn: Registration Assessor.** Note: choosing a cheque payment option will significantly increase processing times.

For Office Use Only

Date Transaction Processed: _____