

Alberta College of Pharmacy Application for Change of Licensee

Changes to the licensee require advanced notice and approval from the Alberta College of Pharmacy. **If requesting a change, the licensee must complete and submit this application** to our office by email (pharmacy@abpharmacy.ca), fax, or mail. The change will take effect within 3-5 working days of receipt and you will be issued a new pharmacy licence.

If there is a change of ownership, you must complete and submit a different application form.

Section One: Pharmacy Information

Current operating name of the pharmacy _____ Licence # _____

Physical address – 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: _____

Section Two: Proprietor's Agent Information

A Proprietor's Agent is either the owner or the designated representative of the owner(s) / corporation who fulfils the responsibilities and obligations of a proprietor under the legislative framework

Name of Proprietor's Agent (please print clearly) _____ (ACP Registration # if applicable) _____

Position and/or relationship to proprietor _____

Email Address (please print clearly) _____ Phone Number _____

Proprietor's Agent Signature: _____ Proprietor's Agent ACP Reg # (if applicable) _____

Dated at _____ this _____ day of _____, 20____
(name of city or town) (day) (month)

Section Three: Pharmacy Operations and Services

- 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.
- i) Will the pharmacy have off-site storage of records outside of the dispensary? Yes No

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.

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Section Four: 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 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
<input type="checkbox"/> Yes <input type="checkbox"/> No	Small quantities of ingredients or preparations which require ventilation	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	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](#).

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](#)

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Section Seven: Statutory Declaration – must be completed by the new licensee

CANADA)
PROVINCE OF ALBERTA)
TO WIT:)

I, _____, of _____
(name of applicant) (name of city/ town)
in the Province of, _____ an applicant for a pharmacy licence under
(province)

the *Pharmacy and Drug Act*, do solemnly declare:

that I have not been convicted of an indictable offence related to misconduct, fraud or commercial matters within Canada or a similar offence outside Canada.

I make this solemn declaration conscientiously believing it to be true and knowing that it is of the same force and effect as if made under oath.

DECLARED before me at the _____)
(insert city or town)

Signature of Declarant

of _____)
(name of city or town)

in the Province of Alberta, this _____)
(date, i.e.: 25th)

day of _____, A.D. 20 18)
(month) (year)

A Commissioner for Oaths in and for
the Province of Alberta

Section Eight: Licensee Responsibilities

Pharmacy Licensee Responsibilities

The responsibilities of a pharmacy licensee (manager) can be as varied as the locations of employment are. Responsibilities are dependent on the pharmacy proprietor, the number of staff supervised (both pharmacist, and non-pharmacist), the types of pharmacy services provided, the location of the pharmacy, and the requirements of ACP. Responsibilities of licensees are outlined in detail in the *Standards for the Operation of Licensed Pharmacies*. This document provides a summary of the typical responsibilities of a pharmacy licensee.

Pharmacy Staffing and Operation

- ✓ The licensee is responsible to ensure the pharmacy is **adequately staffed** to undertake safe and effective pharmacy practice. This includes pharmacists, pharmacist locums, students, interns and technicians. Licensees must indicate to the college which pharmacists hold narcotic signing authority and the beginning and end dates of employment for all pharmacists, pharmacist locums, students, interns and technicians. {PPR 41 (1) (j), 41 (2), PDA 9, Reg 3 (1) (h-i), 17 (a-b incl.), 20 (1) (b-c incl.), 25 (e), Stds 1.2(b), 2-3 incl.}
- ✓ The licensee must advise ACP of the **pharmacy hours of operation** and any changes being made to these hours. {Reg 3 (1) (e) (vii), 11 (1-2) incl.}
- ✓ If the pharmacy is operating as a **lock and leave**, the licensee must advise ACP and ensure the lock and leave operation is safely and properly run. {Reg 18 (1-4) incl.}
- ✓ A licensee must ensure legislated requirements are met if the pharmacy **will be operating temporarily without a pharmacist**. {Reg 17 (a-b) incl.}
- ✓ When a **change in pharmacy licensee** occurs (whether permanent or temporary extending over 90 days, i.e.: maternity leave, etc.), ACP must be advised. The pharmacy licence will need to be updated to reflect the new licensee's name. The new pharmacy licence cannot be issued until the *Application for Pharmacy Licensee Change* and payment have been received. This application form can be downloaded from our website (pharmacists.ab.ca) or be obtained by contacting the ACP registration department. {PDA (6(1), 9, 14(1)(b), 14(2), Bylaw 65)}

Physical Environment

- ✓ The licensee must ensure the **physical requirements** of a pharmacy adhere to the legislation and standards. {PDA 13, Reg 13(1) (a-b) incl., 14 (1) – 16 (2) incl., 25 (a-f) incl., Std 4}
- ✓ The licensee must ensure the licensed pharmacy has **adequate equipment and systems** in place. {Reg 25 incl., Std 4.10 – 4.14 incl.}
- ✓ The licensee must ensure pharmacy staff have **adequate resources** available within the pharmacy. {Stds 4.15-4.19 incl.}
- ✓ The licensee must ensure **appropriate records** are maintained. {Reg 12-12.1 incl., Stds 8,10,2}
- ✓ The licensee must ensure **products are maintained and stored** appropriately within the pharmacy. {Reg 21 (a-b) incl., Std 5}
- ✓ The licensee must ensure that a **quality assurance process** is implemented and maintained in the licensed pharmacy. {Std 6}
- ✓ The licensee is responsible to ensure **specific documents**, such as the pharmacy license, are **appropriately displayed** in the pharmacy. {PDA 8, 22 (a-c) incl.}
- ✓ The licensee and proprietor must **cooperate with practice visits** conducted in accordance with legislation. {PDA 21}

Corporate Environment

- ✓ The licensee is responsible to ensure that the licensed pharmacy **operates in accordance with the legislation** and complies with any conditions imposed on the license. {PDA 10(1)a-c incl., Std 1}
- ✓ The licensee is responsible for **all applications and documents** required in order to complete the process for opening a **new pharmacy, a pharmacy change of owner, a relocation or a renovation**. For all of these changes except a pharmacy change of ownership, the licensee is also responsible to ensure **adequate floor plans** have been provided to ACP. ACP will provide the licensee with a document detailing what information these floor plans must include.
 - Applying for licensure as a new pharmacy: {PDA 5.01 in its entirety, Reg 3 (1) (a-m) incl.}
 - Pharmacy Changes of Ownership: {PDA 5.01(5)(d), 14(1)(e)-14(1)(e.1), Reg 20 (1) d-e incl.}
 - Pharmacy Relocation: {Reg 8, 20(1) (a)}
 - Pharmacy Renovation: {Reg 10(1-3) incl.}
- ✓ The licensee is responsible to ensure **any website established** for the pharmacy **conforms to legislated requirements**. {Reg 23 (a-h) incl.}
- ✓ The licensee is responsible to **report any proprietor who attempts or directs the management** of a licensed pharmacy **in a way that contravenes** or could result in a contravention of **any legislation or standards**. {PDA 10 (3) (a-c) incl., 11(2) (a-f) incl., Std 2.3}

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Fee Payment

Pharmacy Name: _____ Licence Number: _____

Change the licensee..... **\$216.30 (\$206.00 plus \$10.30 GST)**

Payment Options

Cheque # _____

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 # _____
Area code-phone # Area code-phone #

For Office Use Only

Date Transaction Processed: _____