

Pharmacy Permits

Opening a New Pharmacy

The Saskatchewan College of Pharmacy Professionals (SCPP) is the regulatory authority for Saskatchewan pharmacies and pharmacy professionals.

SCPP requires a minimum of **90 days' notice** for the proposed establishment of a pharmacy (regardless of whether it will be located at an existing premise or newly constructed building).

PRIOR to moving forward with establishment and construction and/or renovation of the premises, the **proposed pharmacy manager of SCPP record must notify** the SCPP office:

- General Office: 306-584-2292 / info@saskpharm.ca
- Attention: Caroline Zareba, Manager, Pharmacy Permits Pharmacy Relations

To initiate the opening of a file with SCPP, the pharmacy manager must email the New Pharmacy Notification & Details form to info@saskpharm.ca.

Summary of Requirements

The proposed Pharmacy Manager must submit the following, meeting requirements of *The Pharmacy and Pharmacy Disciplines Act* and SCPP Regulatory Bylaws and policies. SCPP communicates directly with the proposed Pharmacy Manager. **Detailed requirements** are found in the pages following the summary.

PROPRIETARY PHARMACY PERMIT APPLICATION & DOCUMENTATION

	Email the New Pharmacy Notification & Details form to info@saskpharm.ca
	Submit the ISC Corporate Registry Profile Report of the proprietary operating corporation. Meet corporate directors and proprietary operating corporation bylaws
	Designate a Privacy Officer and meet bylaw and training requirements
	Designate a COMPASS QI Coordinator and meet bylaw and training requirements
	Submit the online Pharmacy Permit Application form and pay the pharmacy permit $\underline{\text{fees}}$ and/or COMPASS $\underline{\text{fee(s)}}$
	Email the Data Sharing Agreement (DSA) form to ISMP
П	Incoming Pharmacy Manager Declaration

FIE	ELD OFFICE and SCHEMATICS
	Submit drawing(s)/schematics that are labelled with checklist items (pursuant to Part J of the Regulatory Bylaws requirements) *incomplete drawings will be returned *New Pharmacy Notice form to be submitted to SCPP prior to submitting schematics
	Submit samples/mock-ups of prescription labels and patient profile
	Submit examples of proposed exterior and interior signage
	Contact the assigned Field Officer 3-5 weeks ahead of desired inspection date Communicate with an SCPP field officer about construction progress and opening date
DRUG	PLAN, PIP, JSAP, Connectivity (Pharmacy Permit Application Requirements)
	Contact Drug Plan and Extended Benefits Branch (DPEBB) to arrange for signing of the DPEBB contract and network installation, provide DPEBB Contract # to SCPP
	Contact eHS PIP regarding signing the JSAP contract
	Contact eHS PIP regarding completing eHS PIP Approver Training
Phar	macy Manager Responsibilities
	narmacy manager must be a Practising pharmacist in Saskatchewan who will be a sible for the day-to-day operations of the pharmacy. Documents for review:
	Pharmacy Manager Responsibilities Directors' Duties and Responsibilities

Pursuant to *The Pharmacy and Pharmacy Disciplines Act*, a proprietary pharmacy permit may only be issued to the proprietor in the name of the pharmacy manager (of SCPP record) only when all legislated requirements have been met and approved.

Federal and Provincial Legislation: available on the <u>SCPP website</u>.

Legislation

- The Pharmacy and Pharmacy Disciplines Act
 - S. 19 Application for Permit; S. 20 Permits
- SCPP Regulatory Bylaws:
 - o Part I Proprietary Pharmacies
 - Part J Conditions of Sale for Drugs and Related Requirements for Pharmacists, Pharmacy Technicians and Pharmacies

Detailed Guidelines

Pharmacy Manager to provide minimum notice of 90 days prior to opening:

Complete and email the <u>New Pharmacy Notification & Details form</u> to <u>info@saskpharm.ca</u> (includes the following):

- Proposed Opening Date
- Contact Name, Address, Email, Phone Number(s)
- Pharmacy Manager Name and Member (D) Number
- Pharmacy Name (Trade Name)
- Proprietary Operating Corporation Name
- Corporate Directors' Names and Corporate Address
- Pharmacy Location and Mailing Addresses
- Pharmacy Phone, Fax and Email Address

Online Pharmacy Permit Application & <u>Fee(s)</u>

Once the database profile is created:

- SCPP will email login and instructions for completion to the pharmacy manager
- Proposed manager to login to the "pharmacy manager portal" from the SCPP website:
- Select the Pharmacy Permit Application link (in left-hand column)

Drawings Including Checklist Items

Prior to construction:

- Provide a clear/legible drawing (schematic) to the field officer for review and comment
- Include all required measurements drawn to scale
- Label the locations of items in the New Pharmacy Notification & Details/ Part J of the Regulatory Bylaws
- Provide extra descriptions if required

• Signage: Interior and Exterior

- Provide examples/mock-ups of interior and exterior signage for approval
- o Provide photographs of the pharmacy hours signage
- Cover installed signs until pharmacy permit approved (see bylaws)
- Pharmacy exterior signs must be visible prior to the opening date

Director Requirements & Proprietary Operating Corporation/Documentation

- * Regulatory Bylaws and The Pharmacy and Pharmacy Disciplines Act S.19(1).
- Set up Corporation with Information Services Corporation (ISC) Corporate Registry
- Email to SCPP the Corporate Registry Report of the proprietary operating corporation

- o Corporate Registry must be submitted to SCPP prior to the permit valid date
- Pharmacy manager <u>must be a Director</u> of the corporation
- o Pool of corporate directors must be made up of a <u>majority of SCPP-registered members</u>
- Related Documents (website: www.saskpharm.ca / Reference Manual)
 - Pharmacy Manager Responsibilities
 - Directors' Duties & Responsibilities

Online Proprietary Pharmacy Permit Application Form and Permit Fee(s)

- Pharmacy manager must complete and submit the online Pharmacy Permit Application
- Access the application from in the Pharmacy Manager Portal (bottom left-hand column)
- o Login information will be emailed to pharmacy manager once database profile set up
- Submit online application form, declarations, corporate/director documentation
- Please refer to the detailed fee schedule.
- Meet Corporate Director requirements of the Regulatory Bylaws
 - Pharmacy manager must be a Director of the proprietary operating corporation
 - Of the pool of Corporate Directors, the majority must be SCPP members
 - Directors must be members in good standing with SCPP
 - Submit a current ISC Corporate Registry Profile Report to SCPP

Assign a Privacy Officer

- Privacy officer must be an SCPP Practising member
- Must be privacy officer in only one pharmacy
- Training must be completed within one year after the effective date of the new pharmacy permit; but no later than Nov. 1 (being the permit renewal deadline without penalty)
- Training must be re-done every three (3) years
- Privacy Officer Certification online training available through Continuing Professional Development for Pharmacy Professionals (<u>CPDPP</u>), University of Saskatchewan: 306-966-6350.
- At the end of the online training module, complete the SURVEY at the end.
- Meet Regulatory Bylaw requirements: Sections 8(1)-(7) of PART I:
 - **8**(1) Every pharmacy must have a designated privacy officer.
 - (2) The pharmacy manager for each pharmacy, or any other licensed pharmacist employed at that pharmacy as may be appointed by the pharmacy manager, shall be designated as the privacy officer for that pharmacy.
 - (3) The pharmacy manager for each pharmacy must report to the College:
 - (a) the name of the designated privacy officer for that pharmacy;
 - (b) any changes to the privacy officer for that pharmacy; and
 - (c) the initial privacy training and re-certification training undertaken by the designated privacy officer for that pharmacy.
 - (4) Every privacy officer shall undertake privacy training approved by Council before the expiration of the subsisting permit, or until such other time as may be approved by the Registrar, but no longer than within one year of his designation.

- (5) Every privacy officer shall participate in re-certification training once every three years.
- (6) If the requirements set out in subsections 8(1), (2), (3), (4) and (5) of Part I are not met, the pharmacy permit for the applicable pharmacy may be suspended or cancelled by the Registrar. The pharmacy permit may be reinstated upon the provision of satisfactory evidence that the requirements set out in subsections 8(1), (2), (3), (4) and (5) of Part I have been met.
- (7) The College shall record in the register for each pharmacy:
- (a) the designated privacy officer, as identified by the pharmacy manager in accordance with subsection 8(3) of Part I;

Assign a COMPASS Quality Improvement (CQI) Coordinator

- meet bylaw and training requirements
- training available through Continuing Professional Development for Pharmacy Professionals (CPDPP) at University of Saskatchewan: 306-966-6350.
- QI Coordinator must be an SCPP Practising member
- QI Coordinator must have training complete within 6 months after the effective date
 of the permit; or by November 1 of the permit year (deadline for permit renewal
 without penalty)

Fax the Data Sharing Agreement (DSA) to ISMP for COMPASS CPhIR Enrolment

- DSA form available in "Pharmacy Manager Portal" bottom, left-hand column under Application Forms
- Pharmacy manager must read, sign and fax the form to ISMP
- SCPP must receive notice from ISMP of the CPhIR enrolment date

Lock and Leave Permit and Installation

- Additional fee required for installation of a Lock and Leave system
- Indicate Lock and Leave = YES on page 1 of permit application form
- Submit description of the Lock and Leave Installation
- Review Regulatory Bylaws Part J Lock and Leave
- Lock and Leave Installation fee please refer to the detailed fee schedule.

Drug Plan & Extended Benefits Branch (DPEBB) Contract and Network Installation

- Minimum 30 business days' notice
- o Sign the DPEBB Contract and provide the contract # to SCPP

Rhonda Cowan, Government of Saskatchewan

Financial Assistant, Sask. Ministry of Health,

DP & EBB, Financial Unit, 2nd Floor - 3475 Albert St, Regina SK S4S 6X6

Bus: (306) 787-8304 / Fax: (306) 787-8679 /

Email: rhonda.cowan@health.gov.sk.ca

Contact eHealth – Pharmaceutical Information Program (PIP)

- ☐ Incoming Pharmacy Manager Declaration
- Minimum 30 business days' notice
- Sign the Joint Service Access and Policy (JSAP)

- Complete the PIP Approver training
- Review the eHealth Guidance Document

Contact Express-Scripts Canada (NIHB)

- Minimum 30 business days' notice
- Express Scripts Canada Pharmacy Central
 114-1790 Wellington Avenue, Winnipeg, Manitoba R3H 1B2
 Toll-Free: 1-855-550-MEDS (6337)

Contact Computer Vendor &Third Parties

- o Contact to initiate the process regarding system connectivity, etc.
- Remind third party payors in your community, such as Non-Insured Health Benefits (NIHB), RCMP, DVA and private third-party payors

• Pictures of Exterior and Interior Signage

 Submit examples of exterior and interior pharmacy and professional services area signage

• Pre-Opening Inspection

- To book a pre-opening inspection, contact an SCPP field officer in the pharmacy area
- o Advance notice of three to five (3-5) weeks prior to opening date is required
- Inspection will only be conducted if ALL requirements are met according to The Pharmacy and Pharmacy Disciplines Act and SCPP Regulatory Bylaws
- If pharmacy is **not fully functional** and/or stocked for the inspection, contact the field officer to re-schedule the date
- An additional pre-opening inspection fee will be charged for subsequent inspections

Prescription Labels, Patient Profiles, Exterior Signage After the Pre-Opening Inspection, provide

- o **de-identified samples** of prescription label (with trade name, legal street address including postal code, and phone number including area code) and patient profile
- o photographs of exterior and interior signage

Drawings

Submit drawings to the Field Officer assigned.

Indicate directly on the schematics the pharmacy opening checklist items pursuant to:

Regulatory Bylaws, PART J - Conditions of Sale for Drugs and Related Requirements for Pharmacists, Pharmacy Technicians and Pharmacies.

Drawings not labelled properly will be returned.

Ensure the following are indicated clearly in the drawings:

- Accurate measurements (sq. ft.) of entire dispensary: dispensing area, counter height/space, length, width, compounding area
- Compounding area location, level of compounding (consider proximity to busy areas)
- Location, proximity of compounding equipment
- Appropriate space/storage for compounding, compliance packaging
- Description of countertop materials
- Sink with hot and cold running water and sewage disposal
- Heat source for compounding (such as microwave)
- Gates, swing gates: locations, type of gate and how used, locks
- Fax machine: consider placement with regards to privacy
- Computers, monitors, printers: show placement in dispensary, counselling room
- Customer waiting area
- Refrigerator: type/model, size, location,
- Does refrigerator meet vaccine and cold chain requirements? <u>Refrigerator and Temperature</u> <u>Monitoring Equipment Requirements</u>
- Fixtures
- Prescription storage shelving, safe
- Prescription drop-off and pick-up areas and cash register
- Washrooms (staff-only?)
- Patient Care/Private Counseling Area: <u>Proposed Patient Care Area Guidelines</u>
- Professional Services Area: Professional Services Area Delineation of the Pharmacy
- **Security Measures:** security arrangements for a dispensary stocked with drugs and chemicals and related supplies adequate to provide a full prescription service including

- gates (description of gates and use of); alarm systems, fire codes and safety codes met, locked safe, second exit for safety (suggested).
- Lock and Leave System: submit drawings and explanation if installing. A separate <u>fee</u> and application are required for installation and lock and leave permit.

Pharmacy Services Offered via the Internet

Provide the SCPP office with information if this pharmacy proposes to offer **pharmacy services via the Internet**. The SCPP bylaws require disclosure of international prescription services (IPS), regardless of whether or not the services are promoted over the Internet:

Regulatory Bylaws Part I, S2 - Permit Restrictions, Terms and Conditions

- **2** Every proprietary pharmacy permit that is granted pursuant to the Act is granted subject to the proprietor and the pharmacy manager at all times complying with the Act and these bylaws, regulations, rules and standards made there under, as well as the following additional restrictions, terms and conditions:
- (a) the proprietor shall not, without the written approval of the College, allow, or provide for, the shipment of drugs from the pharmacy, or the shipment of drugs ordered or procured by the pharmacy, to a location outside of Canada, or to another location in Canada where the proprietor has reason to believe that the drugs are likely to be shipped outside of Canada (by mail, courier, or otherwise) in circumstances where:
 - (i) the pharmacy's services associated with such shipment are; or
 - (ii) the sale of drugs associated with such shipment is in any way, directly or indirectly, advertised or otherwise promoted via e-mail, the Internet or via any other means or method accessible outside of Saskatchewan.

Approval of the proprietary pharmacy permit will not be granted prior to all requirements as stated in *The Pharmacy and Pharmacy Disciplines Act* and the Bylaws of the Saskatchewan College of Pharmacy Professionals being met.

No pharmacy services are to be offered until approval has been confirmed.