

## **INSPECTION & AUDIT FORM**

### Telepharmacy (Community)

A telepharmacy must be inspected and audited by the manager of a central pharmacy or a full pharmacist designated by the manager at least 4 times each year, at intervals of not less than 2 months.

Keep a copy of this form at the telepharmacy AND the central pharmacy when completed.

This form must be readily available upon request by the College.

### Instructions:

It is recommended that you review the previous *Inspection & Audit Form* for your telepharmacy before you begin this inspection and audit so that you can determine whether any actions or follow-ups are needed to be done this time. On the day of audit, review the requirements in each section below at the telepharmacy. Confirm whether the requirements are met or not. If not, record action(s) or follow-up to be taken including timelines.

TELEPHARMACY	Operating Name	External Signage Name	PharmaCare Code	
	Listed in PODSA Schedule (Check all that apply):			
	□ <u>Schedule F</u> (Community & Telepharmacy) □ <u>Schedule G</u> (Staff exemption) □ None			
	Last Inspection/Audit Date:			

CENTRAL PHARMACY	Operating Name	External Signage Name	PharmaCare Code

INSPECTION AND AUDIT TO BE COMPLETED BY				
Last Name	First Name	Inspection & Audit Completion Date		
Signature	Relationship of the person named above to the telepharmacy:			
	Pharmacy Manager  Staff Pharmacist from the Central Pharmacy			
	Owner (Pharmacist)			
Email address of the person named above	Phone number of the person named above	Fax number of the person named above		

• • • •

# External to Dispensary

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws s.12.1</u> ( <u>1)(c)</u>	The registrar must not issue a telepharmacy licence to a central pharmacy unless the proposed name on the external signage of the telepharmacy described in section 18(2)(r) includes the word "telepharmacy".		
<u>PODSA Bylaws</u> <u>s.18(2)(r)</u>	The manager must, if the pharmacy is a central pharmacy, ensure that at a minimum, the name on the external signage of a telepharmacy must be correctly and consistently used on labels and directory listings;		
<u>PODSA Bylaws s.26(3)</u>	(RE: Telepharmacy signage) A community pharmacy and a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.		
<u>PODSA Bylaws</u> <u>s.27(2)(a)</u>	The registrar is notified of the hours during which a full pharmacist is not present.		
<u>PODSA Bylaws</u> <u>s.27(2)(c)</u>	The hours when a full pharmacist is on duty are posted.		
PODSA s.4.1(2)	A direct owner and the manager must display the licence issued under subsection (1) in a place within the pharmacy where it is conspicuous to the public.		
<u>PODSA Bylaws s.25(4)</u>	In all new and renovated community pharmacies or telepharmacies, an appropriate area must be provided for patient consultation that (a) ensures privacy and is conducive to confidential communication, and (b) includes, but is not limited to, one of the following: (i) a private consultation room; (ii) a semiprivate area with suitable barriers.		
PODSA Bylaws s.25(1)	In locations where a community pharmacy or telepharmacy does not comprise 100 per cent of the total area of the premises, the community pharmacy manager or the central pharmacy manager in the case of a telepharmacy, must ensure that (a) the professional products area extends not more than 25 feet from the perimeter of the dispensary and is visually distinctive from the remaining areas of the premises by signage, and (b) a sign reading "Medication Information" is clearly displayed to identify a consultation area or counter at which a member of the public can obtain a full pharmacist's advice.		
PODSA Bylaws s.19(2)	A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.		
PODSA Drug Schedule Reg s.2(3)	Schedule III drugs may be sold by a pharmacist to any person from the self-selection Professional Products Area of a licensed pharmacy.		
PODSA Drug Schedule Regulations s.2(3)	Schedule II drugs may be sold by a pharmacist on a non- prescription basis and which must be retained within		

### • • • •

Reference	Requirements	Compliant	Comment
	the Professional Service Area of the pharmacy where there is no public access and no opportunity for patient self-selection.		
PPP-40 Policy Statement #1	Repackaged nonprescription drugs must not be sold from the Professional Products Area of licensed pharmacies.		

# Dispensary

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.25(2)</u>	The dispensary area of a community pharmacy or a telepharmacy must (a) be at least 160 square feet, (b) be inaccessible to the public by means of gates or doors across all entrances, (c) include a dispensing counter with at least 30 square feet of clear working space, in addition to service counters, (d) contain adequate shelf and storage space that is clean and organized, (e) contain a double stainless steel sink with hot and cold running water, (f) contain an adequate stock of drugs to provide full dispensing services, and (g) contain a refrigerator.		
	<b>NOTE:</b> <i>PODSA Bylaws</i> <b>s.25(3)</b> A telepharmacy that was authorized by the registrar to provide pharmacy services as a telepharmacy remote site as of January 1, 2017 is exempt from the requirements in subsections (2)(a) and (c) until such time as it commences a renovation of all or part of the premises.		
<u>PODSA s.4.1(3)</u>	A direct owner must give to the registrar 30 days' written notice of any changes respecting the name or layout of the pharmacy.		
<u>Food and Drugs</u> <u>Act s.8(a)</u>	No person shall sell any drug that was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.5</u>	A registrant may delegate technical functions relating to the operation of the community pharmacy to a pharmacy assistant if the registrant directly supervises the pharmacy assistant and implements procedures, checks and controls to ensure accurate and safe delivery of community pharmacy services.		

# Security

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.31 (1)</u>	A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present on duty at the telepharmacy, unless (a) a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the Telepharmacy Standards of Practice, and (b) subject to subsection (2), a pharmacy technician is physically present on duty at the telepharmacy. <b>NOTE:</b> <i>PODSA Bylaws s.31(2)</i>		

Reference	Requirements	Compliant	Comment
	A telepharmacy located at an address listed in Schedule "G" is exempt from the requirements in subsection (1)(b).		
Narcotic Control Regulations s.43	A pharmacist shall take all reasonable steps that are necessary to protect narcotics on his premises or under his control against loss or theft.		
<u>PODSA Bylaws</u> s.20(4)	All drug shipments must be delivered unopened to the pharmacy or an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure.		
<u>PODSA Bylaws</u> <u>s.19(4)</u>	Every registrant practising in a pharmacy is responsible for the protection from loss, theft or unlawful sale or dispensing of all Schedule I, II, and III drugs and controlled drug substances in or from the pharmacy.		
<u>PODSA Bylaws</u> <u>s.26(1)</u>	A community pharmacy or telepharmacy must keep Schedule IA drugs in a locked metal safe that is secured in place and equipped with a time delay lock set at a minimum of five minutes; (b) install and maintain a security camera system that: (i) has date/time stamp images that are archived and available for no less than 30 days, and (ii) is checked daily for proper operation; (c) install and maintain motion sensors in the dispensary.		
<u>PODSA Bylaws</u> <u>s.26(4)</u>	The manager, direct owner or indirect owner(s) of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises.		
<u>PPP-74 Policy</u> Statement #4	Under the Personal Information Protection Act (PIPA) pharmacies are required to post visible and clear signage informing customers that the premise is monitored by cameras.		
<u>PODSA Bylaws</u> <u>s.26(2)</u>	<ul> <li>When no full pharmacist is present and the premise is accessible to non-registrants, (a)(i) the dispensary area must be secured by a monitored alarm; and (ii) schedule I and II drugs, controlled drug substances and personal health information, are secured by physical barriers.</li> <li>(b) if the pharmacy is closed but other areas of the premises in which the pharmacy is located are open: (i) the dispensary area must be secured by a monitored alarm, (ii) schedule I, and II drugs, controlled drug substances and personal health information are secured by physical barriers; and (iii) schedule I, and II drugs, controlled drug substances and personal health information are secured by physical barriers; and (iii) schedule II drugs are inaccessible to anyone other than full pharmacists, temporary pharmacists and pharmacy technicians.</li> <li>NOTE: PODSA Bylaws s.26(2.2)</li> <li>For the purposes of subsection (2), a full pharmacist is</li> </ul>		
	deemed to be present at a telepharmacy when he or she is engaged in direct supervision of the telepharmacy.		
<u>PODSA Bylaws</u> <u>s.31.1(3)</u>	A telepharmacy must have a security system that prevents the public and non-pharmacy staff from accessing the professional services area and the dispensary area, including any area where personal health information is stored.		

### • • • •

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.26(3)</u>	(RE: Security signage) A community pharmacy and a telepharmacy must clearly display at all external entrances that identify the premises as a pharmacy, and at the dispensary counter signage provided by the College.		
<u>PODSA Bylaws</u> <u>s.27(1)</u>	<b>Telepharmacies listed in PODSA Schedule F only (when</b> <b>operating as a community pharmacy):</b> Except as provided in subsection (2), a community pharmacy must not be open to the public unless a full pharmacist is present.		
<u>PODSA Bylaws</u> <u>s.27(2)(b)</u>	<b>Telepharmacies listed in PODSA Schedule F only (when</b> <b>operating as a community pharmacy):</b> A community pharmacy may operate without a full pharmacist present if all the following requirements are met: (b) the pharmacy is secured in accordance with section 26(2);		
<u>PODSA Bylaws</u> <u>s.27(3)</u>	Telepharmacies listed in PODSA Schedule F only (when operating as a community pharmacy): If the requirements of subsection (2) are met, only the following activities may be carried out: (a) pharmacy technicians may access the dispensary to perform activities outlined in section 4 of the Community Pharmacy Standards of Practice that do not require pharmacist supervision, except if any such activity involves patient interaction; and (b) receive drug shipments under section 20(4).		

# **Equipment and References**

Reference	Requirements	Compliant	Comment
PPP-59 Policy Statement #1	The dispensary of all community pharmacies and telepharmacies at a minimum must have the following equipment as per PODSA Bylaw 18(2)(v): (a) telephone, (b) fax machine or other equipment with fax capability, (c) digital prescription balance with a readability of 0.01g or smaller, and associated calibration tools, (d) at least one 10mL graduated cylinder, (e) mortar and pestle, (f) spatula, (g) funnel, (h) stirring rod, (i) ointment slab or parchment paper, (j) counting tray, (k) soap in a dispenser, and (m) plastic or metal garbage containers to be used with plastic liners		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.7(1)(b)</u>	The facsimile equipment is located within a secure area to protect the confidentiality of the prescription information		

Reference	Requirements	Compliant	Comment
PPP-68 Policy Statements	For a drug that requires cold chain management, the pharmacy manager must ensure 1. the drug is maintained in accordance with the manufacturer's requirements and any other applicable requirements. 2. the pharmacy is equipped with cold storage equipment that must be purposed for drugs only, must maintain only one temperature range enclosed by a door with an air-tight seal (a standard "bar" fridge (combination fridge/freezer with one exterior door) is not acceptable as it does not maintain even temperatures), and is equipped with a digital thermometer or temperature monitoring system; 3. temperatures of the cold storage equipment are monitored and recorded manually at least twice each working day, preferably at opening and closing of the pharmacy, documenting the current temperature, and the minimum and maximum temperatures reached since the last temperature recording, or automatically with a temperature monitoring system that records temperatures at a frequency that can determine current temperatures, and minimum and maximum temperatures reached at least twice a day, and monitors and notifies pharmacy staff when a temperature excursion occurs; 4. establish written policies and procedures that include processes to ensure proper cold chain management, to record temperatures of the cold storage equipment, to determine and document actions taken when a temperature excursion occurs, and for regular maintenance that ensures functionality of cold storage equipment and documenting those processes; 5. all pharmacy staff are trained on the policies and procedures necessary to maintain cold chain management; 6. the following documentation must be retained and easily retrievable for at least three years, the temperature records of the cold storage equipment and the documentation resulting from actions taken when a temperature excursion occurs, and regular maintenance that ensures functionality of the cold chain equipment.		
PPP-3 Policy Statement 1	All community pharmacies and telepharmacies are required to have access to the most current versions of all legislation relevant to pharmacy practice and management; CPBC professional practice policies and guidelines; and CPBC ReadLinks published within the last three years. Electronic formatted files and electronic database references are acceptable for any of the authorized choices within any of the required categories, provided that they are as comprehensive and current as the printed version, as well as readily accessible within the dispensary.		

Reference	Requirements	Compliant	Comment
<u>PPP-3 Policy</u> Statement 2	All community pharmacies and telepharmacies at a minimum must have one of the following authorized library references in each of the categories listed as per PODSA Bylaw 18(2)(w). [which are: Compendium (current year); Complementary/Alternative (within the last 4 years); Dispensatory (within last 9 years); Drug Interactions (in its entirety every 2 years, or continual updates); Nonprescription Medication (most current issue of BOTH references required); Medical Dictionary (within the last 15 years); Pregnancy and Lactation (within the last 3 years); Pediatrics (within the last 4 years); Therapeutics (within last 4 years)]		
PPP-3 Policy Statement 2	In addition to the above list, pharmacies must be equipped with current references relevant to the services provided (examples including but not limited to: Opioid Agonist Treatment, Veterinary, Psychiatric, Geriatric and Compounding)		
<u>PODSA Bylaws</u> <u>s.23.3(1)</u>	A pharmacy may maintain electronic records containing personal health information if the pharmacy has the equipment, software and systems necessary for the input, storage, use, protection and retrieval of records that are required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy.		
PODSA Bylaws s.23.3(2)	For purposes of subsection (1), the equipment, software and systems must: (a) be capable of storing the electronic records for the periods required by applicable law; (b) keep the records secure from unauthorized access, use, disclosure, modification and destruction; (c) for audit purposes, be capable of uniquely identifying each time an electronic record is accessed and modified; (d) be capable of restricting the functions that may be used by an authorized person; (e) be capable of tracing alterations to records by identifying the original entry, the identity of the individual who made the alteration and the date of the alteration; (f) be capable of searching and sorting electronic prescription records chronologically, and by drug name, drug strength, patient, prescriber, prescription number and transaction number; (g) ensure that electronic records can be stored, backed up and recovered in accordance with subsection (3); and, (h) provide for a deliberate and auditable procedure to be carried out by the pharmacy manager or by an authorized person prior to the destruction of any electronic record that includes information identifying the pharmacy manager or authorized person who destroyed the record and the date, time and reason for its destruction.		

• • • •

# Prescription

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.31(4)</u>	Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.		
<u>PODSA Bylaws</u> <u>s.31(4.1)</u>	Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule "F" must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.5(2)</u>	An original physical prescription may be submitted to a telepharmacy and, upon receipt, must be marked with the date of receipt and the name of the telepharmacy.		
<u>PODSA Bylaws</u> <u>s.31(9)</u>	All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(1)</u>	A registrant must ensure that a prescription is authentic.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(2)</u>	Upon receipt from the practitioner, a prescription must include the following information: (a) the date the prescription was written; (b) the name of the patient; (c) the name of the drug or ingredients and strength if applicable; (d) the quantity of the drug; (e) the dosage instructions including the frequency, interval or maximum daily dose; (f) refill authorization if applicable, including number of refills and interval between refills; (g) the name and signature of the practitioner for written prescriptions.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.10(5)</u>	A registrant must not dispense a prescription more than one year from the prescribing date, except for oral contraceptives which may be dispensed for up to two years.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(8)</u>	A registrant must not dispense a prescription issued for more than one patient.		
ReadLinks Vol 38 No 4 - Jan 10 2014 On Call - Accepting an Electronic Prescription	Electronic prescriptions are only permitted if the electronic prescriber's signature is unique. Health Canada considers a unique electronic signature to be equivalent to a paper and pen signature. Therefore the signature must be a fresh new signature written on the prescription with an electronic pen pad, similar to signing a pen and paper prescription. Cutting and pasting a signature into an electronic prescription is not permitted.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(4)</u>	At the time of dispensing, a prescription must include the following additional information: (a) the address of the patient; (b) the identification number from the practitioner's regulatory college; (c) the prescription number; (d) the date on which the prescription was dispensed; (e) the manufacturer's drug identification number or the brand name of the product dispensed; (f) the quantity dispensed; (g) written confirmation of the registrant who (i) verified the patient identification, (ii) verified the patient allergy information, (iii) reviewed the personal health information		

Reference	Requirements	Compliant	Comment
	stored in the PharmaNet database in accordance with section 11(4), (iv) performed the consultation, (v) performed the final check including when dispensing a balance owing, and (vi) identified and addressed a drug therapy problem, if any.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9.1(1)(d)</u>	A registrant who prepares a prescription product must ensure that his or her identity is documented in writing.		
<u>Narcotic Control</u> <u>Regulations s.37;</u> <u>CPBC Prescription</u> <u>Regulation Chart</u>	A pharmacist shall not use an order or prescription, written or verbal, to dispense a narcotic after the quantity of the narcotic specified in the order or prescription has been dispensed. The narcotic prescription must specify the total quantity to be dispensed, the part fill quantities and the interval between the part fills.		
<u>PODSA Bylaws</u> <u>s.19(6)</u>	Drugs included in the controlled prescription program (CPP) must not be sold or dispensed unless (a) the registrant has received the prescription on the prescription form approved by both the board and the College of Physicians and Surgeons of British Columbia, and (b) the prescription form is signed by the patient or the patient's representative upon receipt of the dispensed drug.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.7(3)</u>	A registrant must not dispense a prescription authorization received by facsimile transmission for a drug referred to on the Controlled Prescription Drug List.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.7(1)(c)</u>	Prescription authorizations may be received by facsimile from a practitioner to a pharmacy, if (c) in addition to the requirements of section 6(2), the prescription includes (i) the practitioner's telephone number, facsimile number and unique identifier if applicable, (ii) the time and date of transmission, and (iii) the name and fax number of the pharmacy intended to receive the transmission.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(7)</u>	A registrant must make a written record of a verbal authorization, and include his or her signature or initial.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.6(9)</u>	For refill authorizations, a registrant (a) may accept a refill authorization for Schedule I drugs from a practitioner's agent if confident the agent consulted the practitioner and accurately conveyed the practitioner's direction, and (b) must (i) cancel any unused refill authorizations remaining on any previous prescription if a patient presents a new prescription for a previously dispensed drug, (ii) advise the other pharmacy of the new prescription if unused refills are at another pharmacy, and (iii) create a new prescription number.		
<u>PPP-31 Policy</u> Statement #1(d)	Pharmacist must obtain the informed consent of the patient or patient's representative before undertaking an emergency supply.		
<u>PPP-31 Policy</u> <u>Statement</u> #1(e)(i)	Pharmacists must document in the client's record any emergency supply of the prescription, the rationale for the decision, and any appropriate follow-up plan.		

Reference	Requirements	Compliant	Comment
<u>PPP-31 Policy</u> <u>Statement</u> <u>#1(e)(ii)</u>	Pharmacists must use their CPBC pharmacist registration numbers in the PharmaNet practitioner ID field to identify the pharmacist responsible for the decision.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.8(3)</u>	Upon request, a registrant must transfer to a pharmacy licenced in Canada a prescription for a drug if (a) the drug does not contain a controlled drugsubstance, and (b) the transfer occurs between a registrant and another registrant or an equivalent of a registrant in another Canadian jurisdiction.		
<u>Benzodiazepines</u> <u>and Other</u> <u>Targeted</u> <u>Substances</u> <u>Regulations s.54</u>	A pharmacist may transfer a prescription for a targeted substance to another pharmacist, except a prescription that has already been transferred.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.8(4)(b)</u>	A registrant who transfers a prescription to another registrant under subsection (3) must (b) transfer all prescription information listed in subsection (2) (a) to (f) [which are: (a) the name and address of the patient, (b) the name of the practitioner, (c) the name, strength, quantity and directions for use of the drug, (d) the dates of the first and last dispensing of the prescription, (e) the name and address of the community pharmacy, (f) the number of authorized refills remaining.]		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.7(4)</u>	Prescription transfers may be completed by facsimile transmission if (a) the transferring registrant includes his or her name and the address of the pharmacy with the information required in section 8(4), and (b) the name of the registrant receiving the transfer is known and recorded on the document to be faxed.		
PharmaNet Professional and Software Compliance Standards Volume 2 – Business Rules (2010) s.3.17.2	All sales of medications for use by the practitioner must be transmitted to PharmaNet using the pharmacy's O-Med PHN and corresponding keyword.		
<u>PODSA Bylaws</u> <u>s.20(3)</u>	A registrant must record a transfer of drugs that occurs for any reason other than for the purpose of dispensing in accordance with a practitioner's prescription.		
PharmaNet Professional and Software Compliance Standards Volume 3 – Technical Rules (2010) s.3.2.22	The local software must record the sale of emergency quantities of all drug inventories. This must be handled by functionality separate from 'filling of a prescription'. These transactions must not be transmitted to PharmaNet. These sales must be auditable through inventory facilities.		
<u>PharmaNet</u> <u>Professional and</u>	Prescriptions dispensed for animals (written by veterinarians) must be transmitted to PharmaNet and recorded on the local		

• • • •

Reference	Requirements	Compliant	Comment
Software Compliance Standards Volume 2 – Business Rules (2010) s.3.13.2(4) and (5)	system. Prescriptions for animals are processed under the owner's PHN.		
<u>PODSA Bylaws</u> <u>s.23.1(1)</u>	All records required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy shall be readable, complete, filed systematically and maintained in a manner that is secure, auditable and allows for easy retrieval.		
<u>PODSA Bylaws</u> <u>s.23.1(4)</u>	With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form must be retained, regardless of whether or not such prescription form has also been stored electronically.		
<u>PODSA Bylaws</u> <u>s.23.1(5)</u>	Prescriptions stored electronically must accurately reflect the original prescription, including the original colour composition of that prescription.		
<u>Narcotic Control</u> <u>Regulations</u> <u>s.40(1)</u>	A pharmacist shall maintain a special narcotic prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions for narcotics dispensed and the written record of all verbal prescription narcotics dispensed pursuant to a verbal order or prescription.		
<u>Food and Drug</u> <u>Regulations</u> <u>s.G.03.009</u>	A pharmacist shall maintain a special prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions in writing for controlled drugs dispensed and the written record of all controlled drugs dispensed pursuant to a prescription or order verbally given.		

# Confidentiality

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.34</u>	A pharmacy must connect to PharmaNet		
PharmaNet Professional and Software Compliance Standards Volume 5 – Security (2010) s.2.3.1(1) to (4)	Unique User IDs must be assigned to each individual who requires access. Individual providers must assign a unique password to their User ID. User IDs must be authorized to access an authorized set of system functions (e.g., filling prescriptions, stock control, etc.). User IDs must not be shared. To ensure individual accountability, each User ID is to be assigned to a single person who is accountable for all activities of that User ID.		
HPA Bylaws s.74	A registrant must ensure that all records pertaining to his or her practice, and containing personal information about patients are safely and securely stored at the pharmacy, or off site.		

### • • • •

Reference	Requirements	Compliant	Comment
<u>HPA Bylaws s.75</u>	A registrant must ensure that records are disposed of or destroyed only by (a) transferring the record to another registrant, or (b) destroying the records in a manner that ensures that they cannot be reconstructed.		
<u>HPA Bylaws</u> <u>s.77(1)</u>	A registrant must protect personal information about patients by making reasonable security arrangements against such risks as unauthorized access, collection, use, disclosure or disposal.		
<u>HPA Bylaws</u> <u>s.77(2)</u>	A registrant must take reasonable measures to ensure that a third party, including a volunteer, employee or contractor of the registrant, or a limited pharmacist does not access, collect, use, disclose, store or dispose of personal information about patients except in accordance with this Part.		
<u>HPA Bylaws s.78</u>	A registrant must ensure that, if personal information about patients is transferred to any person or service organization for processing, storage or disposal, a contract is made with that person which includes an undertaking by the recipient that confidentiality and physical security will be maintained.		
<u>HPA Bylaws s.79</u>	A registrant must take appropriate measures to remedy any unauthorized access, use, disclosure or disposal of personal information about patients under this Part as soon as possible after the breach is discovered, including (a) taking steps to recover the personal information or to ensure its disposal if it cannot be recovered, (b) taking steps to ensure that any remaining personal information is secured, (c) notifying (i) anyone affected by the unauthorized access including patients and other health care providers, (ii) the college, and (iii) law enforcement officials, if criminal action may have contributed to the unauthorized action, and (d) modifying existing security arrangements to prevent a re- occurrence of the unauthorized access		
<u>HPA Bylaws</u> <u>s.80(2)</u>	If a patient or a patient's representative makes a request for access to personal information about the patient, the registrant must comply as soon as practical but not more than 45 days following the request.		

# **Inventory Management**

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.20(4)</u>	All drug shipments must be delivered unopened to the pharmacy or an area of the premises other than the pharmacy if the storage of the drug shipment is temporary, safe and secure.		
<u>PODSA Bylaws</u> <u>s.25(2)(f)</u>	The dispensary area of a community pharmacy or a telepharmacy must contain an adequate stock of drugs to provide full dispensing services.		
<u>Policy on</u> <u>Manufacturing</u> <u>and</u> <u>Compounding</u>	Healthcare professionals who provide compounding related services and products to patients/clients must be able to demonstrate that a patient-healthcare professional relationship exists.		

Reference	Requirements	Compliant	Comment
<u>Drug Products in</u> <u>Canada s5.1(a)</u>			
<u>PODSA Bylaws</u> <u>s.19(2)</u>	A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.		
<u>PODSA Bylaws</u> s.22	No registrant may accept for return to stock or reuse any drug previously dispensed.		
<u>PODSA Bylaws</u> <u>s.20(5)</u>	Non-usable and expired drugs must be stored in a separate area of the pharmacy or a secure storage area until final disposal.		
<u>ReadLinks Vol 32</u> <u>No 6 Nov/Dec</u> <u>2007 Take Sharps</u> <u>Back</u>	Regardless of where a pharmacy is located in B.C., it should accept and safely dispose of sharps from patients who purchased them at that pharmacy.		
<u>PODSA Bylaws</u> <u>s.35(4)</u>	A registrant must reverse information in the PharmaNet database, for any drug that is not released to the patient or patient's representative, and record the reason for the reversal no later than 30 days from the date of the original entry of the prescription information in PharmaNet.		
<u>PODSA Bylaws</u> <u>s.35(3)</u>	A registrant must revise information in the PharmaNet database pertaining to corrected billings for prescriptions billed to the patient or a payment agency other than PharmaCare and record the reason for the revision within 120 days of the original entry on PharmaNet.		
<u>PPP-65 Policy</u> Statement #2	The pharmacy manager must ensure that narcotic counts and reconciliations are completed for the pharmacy, pharmacy satellites and all areas of a facility where narcotics are stored: at a minimum of every 3 months; after a change of pharmacy manager; after a break and enter or robbery; after an identified drug diversion; when a pharmacy closes and ceases to operate its business, and after any event where the security of the narcotic drugs may have been compromised.		
<u>PPP-65 Policy</u> statement #1(a)	Pharmacies must maintain a separate perpetual inventory for each narcotic drug.		
<u>PPP-65 Policy</u> statement #1(b)	A perpetual inventory log may be manual or automated, and must include entries for: i. purchases, ii. transfers, iii. losses, iv. purchases returned, expired or destroyed, v. quantities dispensed, and vi. a running balance.		
<u>PPP-65 Policy</u> Statement #1(c)	Each entry in the perpetual inventory log must have an associated record, including but not limited to the following i. purchase record, ii. prescription, iii. loss and theft reports, and iv. record for purchase returned, expired, transferred, or destroyed.		
<u>PPP-65 Policy</u> Statement #1(d)	Any adjustment to an entry in a perpetual inventory log must be documented, including: i. the reason for the adjustment, ii. the date adjusted, and iii. the identity of the person who made the adjustment and iv. the identity of a full pharmacist authorizing the adjustment.		

Reference	Requirements	Compliant	Comment
<u>PPP-65 Policy</u> <u>Statement</u> <u>#2(b)(i)</u>	A physical inventory count for each narcotic drug must be conducted prior to each inventory reconciliation in accordance to the following requirements: (i) all inventory must be counted, including: i. active inventory, ii. compounded mixtures, and iii. expired inventory.		
<u>PPP-65 Policy</u> <u>Statement</u> <u>#2(b)(ii)</u>	When completing a physical inventory count, the following information must be documented: the name, strength, quantity and DIN/brand of the drug counted, the date and signature of the person(s) who completed the count, and the date and signature of the responsible pharmacist.		
<u>PPP-65 Policy</u> <u>Statement</u> <u>#2(b)(iii)</u>	The count must not be conducted by the same person who enters narcotic purchases into the records.		
<u>PPP-65 Policy</u> Statement #2(c)	An inventory reconciliation must include the following components: i. the physical inventory count is compared with the perpetual inventory count for accuracy and discrepancies; ii. associated records of the perpetual inventory log are audited for completeness, accuracy and discrepancies; and iii. discrepancies must be investigated, addressed, and documented on a narcotic incident report together with relevant supporting information.		
<u>PPP-65 Policy</u> Statement #2(d)	The completion of each physical inventory count and reconciliation must be verified and signed by the pharmacy manager.		
<u>PPP-65 Policy</u> <u>Statement</u> <u>#3(a)(b)</u>	The perpetual inventory record must be retained for a period of not less than 3 years. The physical inventory count and reconciliation documentation must be maintained and retained in chronological order in a separate and dedicated record for a period of not less than 3 years.		
<u>PPP-65 Policy</u> Statement #3(c)	If a loss or theft of a narcotic is discovered, the pharmacy manager must: i. notify the College within 24 hours of the incident in accordance with PPP-74 Community Pharmacy Security; ii. report the loss or theft within 10 days in accordance with Health Canada's requirements; and iii. forward to the College a copy of any report sent to Health Canada in accordance with PPP-74 Community Pharmacy Security.		
<u>PODSA Bylaws</u> <u>s.31(6)</u>	A telepharmacy located at an address listed in Schedule "G" must perform a monthly count of narcotics at the telepharmacy and retain a record of each monthly count signed by the supervising pharmacist for three years at both the central pharmacy and the telepharmacy location, and provide the signed record to the registrar immediately upon request.		

• • • •

# **Dispensed Products**

Reference	Requirements	Compliant	Comment
<u>PODSA Bylaws</u> <u>s.31(4)</u>	Prescriptions and labels relating to prescriptions dispensed at a telepharmacy must identify the prescription as having been dispensed at that telepharmacy.		
<u>PODSA Bylaws</u> <u>s.31(4.1)</u>	Prescriptions and labels relating to prescriptions dispensed at a pharmacy listed in Schedule "F" must distinguish between those dispensed when it is operating as a telepharmacy from when it is operating as a community pharmacy.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(1)</u>	All drugs dispensed pursuant to a prescription or a full pharmacist-initiated adaptation, must be labeled.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(2)</u>	The label for all prescription drugs must include (a) the name, address and telephone number of the pharmacy, (b) the prescription number and dispensing date, (c) the full name of the patient, (d) the name of the practitioner, (e) the quantity and strength of the drug, (f) the practitioner's directions for use, and (g) any other information required by good pharmacy practice.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(3)</u>	For a single-entity product, the label must include (a) the generic name, and (b) at least one of (i) the brand name, (ii) the manufacturer's name, or (iii) the drug identification number (DIN).		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(4)</u>	For a multiple-entity product, the label must include (a) the brand name, or (b) all active ingredients and at least one of (i) the manufacturer's name or (ii) the drug identification number (DIN).		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(5)</u>	For a compounded preparation, the label must include all active ingredients.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(6)</u>	If a drug container is too small to accommodate a full label in accordance with subsection (2), (a) a trimmed prescription label must be attached to the small container, (b) the label must include (i) the prescription number, (ii) the dispensing date, (iii) the full name of the patient, and (iv) the name of the drug, and (c) the complete prescription label must be attached to a larger container and the patient must be advised to keep the small container inside the large container.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.9(7)</u>	All required label information must be in English, but may contain directions for use in the patient's language following the English directions.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.10(4)</u>	All drugs must be dispensed in a container that is certified as child-resistant unless (a) the practitioner, the patient or the patient's representative directs otherwise, (b) in the registrant's judgment, it is not advisable to use a child- resistant container, (c) a child-resistant package is not suitable because of the physical form of the drug or the manufacturer's packaging is designed to improve patient		

#### • • • •

Requirements	Compliant	Comment
compliance, or (d) child-resistant packaging is unavailable, or		
		compliance, or (d) child-resistant packaging is unavailable, or

# Documentation

Reference	Requirements	Compliant	Comment
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.11(1)</u>	A patient record must be established and maintained for each patient for whom a Schedule I drug is dispensed.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.11(2)</u>	The patient record must include (a) the patient's full name, (b) the patient's personal health number, (c) the patient's address, (d) the patient's telephone number if available, (e) the patient's date of birth, (f) the patient's gender, (g) the patient's clinical condition, allergies, adverse drug reactions and intolerances if available including the source and date the information was collected, (h) the date the drug is dispensed, (i) the prescription number, (j) the generic name, strength and dosage form of the drug, (k) the drug identification number, (l) the quantity of drug dispensed, (m) the intended duration of therapy, specified in days, (n) the date and reason for discontinuation of therapy, (o) the directions to the patient, (p) the identifications from the prescribing practitioner, (q) special instructions from the prescribing practitioner, (q) special instructions from the prescribed drug therapy including the drug name, strength, dosage, frequency, duration and effectiveness of therapy, (s) the identification of any drug therapy problem and the description of any action taken, (t) the description of compliance with the prescribed drug regimen, and (u) Schedule II and III drug use if appropriate.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.8(4)(a)</u>	A registrant who transfers a prescription to another registrant under subsection (3) must (a) enter on the patient record (i) the date of the transfer, (ii) the registrant's identification, (iii) identification of the community pharmacy to which the prescription was transferred, and (iv) identification of the person to whom the prescription was transferred.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.8(1)</u>	If requested to do so, a registrant must provide a copy of the prescription to the patient or the patient's representative, or to another registrant.		
<u>HPA Bylaws</u> <u>Schedule F Part 1</u> <u>s.8(2)</u>	A prescription copy must contain (a) the name and address of the patient, (b) the name of the practitioner, (c) the name, strength, quantity and directions for use of the drug, (d) the dates of the first and last dispensing of the prescription, (e) the name and address of the community pharmacy, (f) the number of authorized refills remaining, (g) the signature of the registrant supplying it, and (h) an indication that it is a copy.		
<u>PharmaNet</u> <u>Professional and</u> <u>Software</u>	Messages sent by CPBC relating to written forgeries, verbal forgeries, stolen prescription pads and other important		

Reference	Requirements	Compliant	Comment
<u>Compliance</u> <u>Standards</u> <u>Volume 2 –</u> <u>Business Rules</u> <u>s.2.1.2(3) and (5)</u>	announcements approved by the CPBC. Printed messages must be filed for future reference.		
<u>PODSA Bylaws</u> <u>s.23(1)</u>	All prescriptions, patient records, invoices and documentation in respect of the purchase, receipt or transfer of Schedule I, II and III drugs and controlled drug substances must be retained for a period of not less than three years from the date (a) a drug referred to in a prescription was last dispensed, or (b) an invoice was received for pharmacy stock.		
<u>PODSA Bylaws</u> <u>s.23(2)</u>	Despite subsection (1), a registrant must not destroy prescriptions, patient records, invoices and documentation as described in subsection (1) until the completion of any audit or investigation for which the registrant has received notice.		
<u>PODSA Bylaws</u> <u>s.23.1(1)</u>	All records required to be kept under bylaws of the college or other legislation that regulates the practice of pharmacy shall be readable, complete, filed systematically and maintained in a manner that is secure, auditable and allows for easy retrieval.		
<u>PODSA Bylaws</u> <u>s.23.1(2)</u>	Notwithstanding subsection (1), a prescription record that is valid must be retrievable immediately.		
<u>PODSA Bylaws</u> <u>s.23.1(4)</u>	With respect to prescriptions for drugs included in the controlled prescription program, the original prescription form must be retained, regardless of whether or not such prescription form has also been stored electronically.		
<u>PODSA Bylaws</u> <u>s.23.1(5)</u>	Prescriptions stored electronically must accurately reflect the original prescription, including the colour composition of that prescription.		
<u>HPA Bylaws</u> <u>s.69(2)</u>	In addition to correcting personal information in a record in accordance with section 70, a registrant who discovers an error or omission in such a record must amend the record to correct the error or omission and that amendment must reflect the original record entry, the identity of the registrant amending the record, the date of the amendment and the reasons for the amendment.		
<u>HPA Schedule F</u> <u>Part 6 s.8(1)</u>	Subject to subsection (2), all prescriptions, patient records, invoices and documentation in respect of prescriptions must be stored at the central pharmacy and otherwise in accordance with the requirements of s. 8 of the PODSA Bylaws.		
<u>HPA Schedule F</u> Part 6 s.8(2)	The telepharmacy must transfer all original prescriptions, patient records, invoices and documentation in respect of prescriptions to the central pharmacy at least on an annual basis.		

### • • • •

# Pharmacy Manager's Responsibilities

Reference	Requirements	Compliant	Comment
<u>PODSA s.11</u>	Subject to this Act and the bylaws, a pharmacist named in a pharmacy license as manager must personally manage and be responsible for the operation of the pharmacy.		
<u>PODSA Bylaws</u> <u>s.18(1)</u>	A full pharmacist may not act as manager of more than one pharmacy location, unless the pharmacy of which the full pharmacist is manager includes (a) a telepharmacy, (b) a hospital pharmacy, (c) a hospital pharmacy satellite, or (d) a pharmacy education site.		
PODSA Bylaws	A manager must do all of the following:		
<u>s.18(2)</u>	<ul> <li>(a) personally manage and be responsible for the daily operation of the pharmacy;</li> </ul>		
	<ul> <li>(b) ensure compliance with all legislation, bylaws, policies and procedures applicable to the operation of a pharmacy;</li> </ul>		
	(c) establish policies and procedures		
	<ul> <li>(i) to specify the duties to be performed by registrants and support persons,</li> </ul>		
	(ii) for inventory management, product selection, and proper		
	destruction of non-usable drugs and devices,		
	(iii) for pharmacy security,		
	(iv) for emergency preparedness, and		
	<ul><li>(v) for drug recall of pharmacy inventory;</li></ul>		
	<ul><li>(d) ensure all policies and procedures are in writing and regularly maintained;</li></ul>		
	<ul><li>(e) ensure that pharmacy staff are trained in policies and procedures;</li></ul>		
	<ul><li>(f) ensure that all steps in the drug recall procedure are documented, if the procedure is initiated;</li></ul>		
	(g) ensure that all individuals working in the pharmacy who present themselves as registrants have been granted and maintain registration with the College, in accordance with the policies approved by the board;		
	<ul> <li>(h) notify the registrar of any appointments, resignations or terminations of registrants employed at the pharmacy as those changes occur;</li> </ul>		
	(i) cooperate with inspectors acting under section 17 of the Act or section 28 or 29 of the Health Professions Act;		
	(j) ensure that		
	<ul> <li>(i) registrant and support persons staff levels are commensurate with workload volumes and patient care requirements are met at all times in accordance with the bylaws, Code of Ethics and standards of practice, and</li> </ul>		
	<ul> <li>(ii) meeting quotas, targets or similar measures do not compromise patient safety or compliance with the bylaws, Code of Ethics or standards of practice;</li> </ul>		
	<ul><li>(k) ensure that all records related to the purchase and receipt of controlled drug substances are signed by a full pharmacist;</li></ul>		
	(I) ensure safe and secure storage of all Schedule I, II, and III drugs and controlled drug substances for all aspects of		

Reference	Requirements	Compliant	Comment
	pharmacy practice, in accordance with the policies approved by the board;		
	(m) ensure that pharmacy records containing personal information about patients are secure from unauthorized access, use, disclosure, modification and destruction;		
	<ul> <li>(n) ensure that each individual working in the pharmacy presents themselves to the public in a manner that clearly identifies their registration class;</li> </ul>		
	(o) ensure that registrants identify themselves in a manner that clearly differentiates them from other individuals working in the pharmacy who are not registrants;		
	(p) immediately notify the registrar in writing of ceasing to be the pharmacy's manager;		
	(q) ensure that at a minimum, the name on the external signage of a community pharmacy must be correctly and consistently used on labels and directory listings;		
	<ul> <li>(r) if the pharmacy is a central pharmacy, ensure that at a minimum, the name on the external signage of a telepharmacy must be correctly and consistently used on labels and directory listings;</li> </ul>		
	(s) ensure that narcotic reconciliation is performed in accordance with the policies approved by the board;		
	(t) notify the registrar of any incident of loss of narcotic and controlled drug substances within 24 hours;		
	(u) advise the registrar if the pharmacy is providing pharmacy services over the internet, and provide to the registrar the internet address of every website operated or used by the pharmacy;		
	(v) ensure the pharmacy contains the reference material and equipment in accordance with the policies approved by the board;		
	(w) require anyone who will access the in-pharmacy computer system to sign an undertaking in a form approved by the registrar to maintain the confidentiality of patient personal health information;		
	<ul> <li>(x) retain the undertakings referred to in subsection (w) in the pharmacy for 3 years after employment or any contract for services has ended;</li> </ul>		
	(y) provide the registrar with access to the pharmacy and premises as defined in section 20(1) in cases where a pharmacy licence has been cancelled or suspended due to loss of eligibility under section 3 of the Act;		
	(z) ensure that no incentive is provided to a patient or patient's representative for the purpose of inducing the patient or patient's representative to		
	<ul> <li>(i) deliver a prescription to a particular registrant or pharmacy for dispensing of a drug or device specified in the prescription, or</li> </ul>		
	<ul> <li>(ii) obtain any other pharmacy service from a particular registrant or pharmacy;</li> </ul>		

Reference	Requirements	Compliant	Comment
	(aa) notify the registrar of persistent non-compliance by a direct owner and indirect owner(s) with their obligations under the bylaws to the Act;		
	(bb) notify the registrar of any change of telephone number, fax number, electronic mail address or any other information		
	previously provided to the registrar; (cc) in the event of an anticipated temporary closure, which is permitted for no more than 14 consecutive days,		
	<ul> <li>(i) notify patients and the public of the anticipated temporary closure at least 30 days prior to the start of the closure in accordance with the policies approved by the board,</li> </ul>		
	(ii) document steps taken to comply with the bylaws and applicable policies on anticipated temporary closures,		
	(iii) contact all patients whose prepared prescriptions are ready for pick-up to advise of the closure and provide them with the		
	opportunity to obtain their prepared prescriptions prior to the closure start date,		
	(iv) make alternate arrangements with local prescribers, as appropriate, and		
	<ul><li>(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;</li></ul>		
	(dd) in the event of an unanticipated temporary closure due to unforeseen circumstances, which is permitted for no more than 90 days,		
	<ul> <li>(i) notify the registrar of closures of 15 to 90 days in accordance with the policies approved by the board,</li> </ul>		
	<ul> <li>(ii) where possible, contact all patients whose prescriptions are ready for pick-up to advise of the closure and provide them with the opportunity to obtain their prepared prescriptions,</li> </ul>		
	(iii) where possible, notify patients, the public, and local prescribers of the closure and alternate means of obtaining essential pharmacy services during the closure in accordance with the policies approved by the board,		
	(iv) apply for a new pharmacy licence if the closure will exceed 90 days, and		
	<ul><li>(v) return any prepared prescriptions in the pharmacy to inventory and reverse those prescriptions in PharmaNet;</li></ul>		
	(ee) in the event of a permanent pharmacy closure, cancellation, or expiry of the pharmacy licence		
	(i) provide for the safe and secure transfer and appropriate storage of all Schedule I, II, and III drugs and controlled drug substances,		
	(ii) advise the registrar in writing of the disposition of all drugs and prescription records at the time of a closure, in accordance with policies approved by the board,		
	(iii) provide the registrar with a copy of the return invoice and any other documentation sent to Health Canada in respect of the		

Reference	Requirements	Compliant	Comment
	<ul> <li>destruction of all controlled drug substances,</li> <li>(iv) arrange for the secure transfer and continuing availability of the prescription records at another pharmacy, or at storage facility that is monitored and secured from unauthorized access, and</li> <li>(v) remove all signs and advertisements from the closed pharmacy premises;</li> </ul>		
<u>PODSA Bylaws</u> <u>s.23.2(2)</u>	A pharmacy manager must ensure that a policy is in place that: (a) describes the pharmacy's records filing system, the records format and the method and system for storing records, (b) is compliant with the sections 23.1, 23.2 and 23.3 requirements; and (c) is readily accessible to and understood by pharmacy staff.		
<u>PODSA Bylaws</u> <u>s.23.2(2)</u>	With respect to electronic records, the policy must include a description of the process for the preservation, storage and backing up of records that is compliant with section 23.3 requirements		
<u>PODSA Bylaws</u> <u>s.23.3(3)</u>	A pharmacy manager must ensure that electronic records are preserved and backed up at least once daily and that such electronically preserved and backed up records are stored: (a) in a location resistant to environment perils including but not limited to fires and floods; (b) so that they are secure from unauthorized access, use, modification, destruction and disclosure; and, (c) in a manner that would enable the backed up records, once restored, to be compliant with section 23.1(1) requirements		
<u>PODSA Bylaws</u> <u>s.24(1)</u>	A community pharmacy's manager must develop, document and implement an ongoing quality management program that (a) maintains and enforces policies and procedures to comply with all legislation applicable to the operation of a community pharmacy, (b) monitors staff performance, equipment, facilities and adherence to the Community Pharmacy Standards of Practice, and (c) includes a process for reporting, documenting and following up on known, alleged and suspected errors, incidents and discrepancies.		
<u>PODSA Bylaws</u> <u>s.24(2)</u>	If a community pharmacy is a central pharmacy, the quality management program in subsection (1) must include all telepharmacies associated with the central pharmacy and must comply with the Telepharmacy Standards of Practice.		
<u>PODSA Bylaws</u> <u>s.31.1(8)</u>	A telepharmacy must have a policy and procedure manual on site that that outlines the methods for ensuring the safe and effective distribution of pharmacy products and delivery of pharmaceutical care by the telepharmacy.		
PPP-74 Policy Statement #1	Pharmacy security policies and procedures should be included in the pharmacy's policy and procedure document. The policies and procedures should contain information on the following: Training, Pharmacy security equipment, Emergency responses, Incident review, and Pharmacy security evaluation.		

### • • • •

Reference	Requirements	Compliant	Comment
<u>PPP-74 Policy</u> Statement #5	An emergency response kit should include a step-by-step guide on what to do in the event of a robbery or break and enter and be available to all pharmacy staff.		

# **Owner/Director Responsibilities**

Reference	Requirements	Compliant	Comments
<u>PODSA Bylaws</u> <u>s.18(7)</u>	A direct owner, directors and officers must do all of the following: (a) ensure compliance with subsections $(2)(c)(i)$ , $(c)(iii)$ , $(c)(iv)$ , $(c)(v)$ , $(i)$ , $(j)$ , $(1)$ , $(q)$ , $(r)$ , $(y)$ and $(z)$ ; (b) ensure that the requirements to hold a pharmacy licence under the Act are met at all times; and (c) notify the registrar of any change of name, address, telephone number, electronic mail address or any other information previously provided to the registrar;		
<u>PODSA Bylaws</u> <u>s.17(5)(c)</u>	If there is a change in layout of the pharmacy, the direct owner must submit the following (c) a diagram, photographs or video to demonstrate the changes in layout in accordance with section 3(2)(c),(d) and (e) for a community pharmacy		
<u>PODSA Bylaws</u> <u>s.17.1 (1)</u>	A direct owner of a pharmacy that is permanently closing must notify the registrar by submitting the following at least 30 days before closure: (a) an application in Form 4A; (b) the fee(s) specified in Schedule "A"; (c) documents demonstrating compliance with sections 18(2)(ee)(i), (ii), (iii) and (iv); and (d) photographs or video demonstrating compliance with section 18(2)(ee)(v).		
<u>PODSA Bylaws</u> <u>s.23(3)</u>	Registrants, support persons, managers, direct owners, and indirect owners must not, for commercial purposes, disclose or permit the disclosure of information or an abstract of information obtained from a prescription or patient record which would permit the identity of the patient or practitioner to be determined.		
<u>PODSA Bylaws</u> <u>s.26(4)</u>	The manager, direct owner or indirect owner(s) of a community pharmacy or telepharmacy that does not stock IA drugs must complete a declaration attesting that Schedule IA drugs are never stocked on the premises.		

# Direct Supervision at Telepharmacy

Reference	Requirements	Compliant	Comments
PODSA Bylaws Definitions	"direct supervision" means real time audio <u>and</u> visual observation by a full pharmacist of pharmacy services performed at a telepharmacy consistent with a pharmacy manager's responsibilities as set out in subsection 18(2).		
<u>PODSA Bylaws</u> <u>s.31(1)(a)</u>	A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present and on duty at a telepharmacy, unless a full pharmacist at the central pharmacy is engaged in direct supervision of the telepharmacy in accordance with the <i>Telepharmacy Standards of Practice</i> .		

#### • • • •

Reference	Requirements	Compliant	Comments
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.3</u>	"supervising pharmacist" means (a) the manager of a central pharmacy, (b) a full pharmacist employed at the central pharmacy responsible for providing direct supervision of pharmacy services in a telepharmacy, or (c) a full pharmacist who is physically present on duty at the telepharmacy.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.4(1)</u>	A supervising pharmacist must exercise direct supervision of persons performing pharmacy services at a telepharmacy that is commensurate with the qualifications and expertise of those persons and is of sufficient frequency and duration to satisfy the requirements under s. 18(2) of the PODSA Bylaws.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.4(2)</u>	A supervising pharmacist must be readily available at all times when a telepharmacy is open to: (a) provide direction and support to persons performing pharmacy services at the telepharmacy; and (b) provide pharmacist/patient consultation.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.4(3)</u>	A supervising pharmacist must be able to engage in direct supervision of the provision of pharmacy services at a telepharmacy independent of any action of or request by persons performing those services.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.4(4)&amp;(5)</u>	Subject to subsection (5), telepharmacy staff may only perform the activities described in s. 4(1) of the Pharmacists Regulation while under direct, continuous real-time audio and visual observation and direction of a supervising pharmacist. Subsection (5): Direct supervision does not require the supervising pharmacist to conduct real-time observation of a pharmacy technician performing work within his or her scope of practice.		

# Dispensing at a Telepharmacy

Reference	Requirements	Compliant	Comments
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.6(2)</u>	Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.6(1)</u>	All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy.		
<u>HPA Bylaws</u> <u>Schedule F Part 6</u> <u>s.7</u>	Unless a full pharmacist is physically present on duty at the telepharmacy, the supervising pharmacist must provide full pharmacist/patient consultation by real-time audio and visual link and otherwise in accordance with the requirements of Part 1 of Schedule F of the <i>Health Professions Act Bylaws</i> .		

# Opioid Agonist Treatment (OAT) Check this box and skip this section if your telepharmacy does not provide OAT services (MMT/BMT/SROM):

Reference	Requirements	Compliant	Comment
PPP-66 Policy Guide <u>BMT, MMT (2013),</u> <u>SROM</u> Principle 1.1.1	The pharmacy hours of service must be consistent with the supervised dosing requirements of your patient.		
PPP-66 Policy Guide BMT Principle 2.1.1	BMT prescriptions can only be accepted when written using an original Controlled Prescription Program form.		
<u>PPP-66 Policy Guide</u> <u>MMT (2013)</u> Principle 2.1.1	Methadone maintenance prescriptions can ONLY be accepted when written using an original Methadone Maintenance Controlled Prescription form.		
PPP-66 Policy Guide SROM Principle 2.1.1	SROM prescriptions can only be accepted when written using an original Controlled Prescription Program form.		
<u>PPP-66 Policy Guide</u> <u>MMT (2013)</u> <u>Principle 2.1.3</u>	Faxed Methadone Maintenance Controlled Prescription forms are not acceptable unless under extenuating circumstances where the prescriber has determined, following consultation with the pharmacist, that the urgency of the situation warrants it.		
PPP-66 Policy Guide MMT (2013) Principle 2.2.1	Alterations to the Methadone Maintenance Controlled Prescription form are the exception to the rule and should not be normal practice as they increase the likelihood of errors and drug diversion and put the public at risk. In the rare circumstance when an alteration is necessary to ensure the continuity of care pharmacists must always use due diligence to ensure authenticity and accuracy of the prescription. GUIDELINE: *Alterations are only permitted on the sections of the form that the prescriber completes provided that the prescriber has initialed the alteration. *Alterations are not permitted to the pre- printed sections of the form. *Pharmacists do not have independent authority to make any alterations or changes to a Methadone Maintenance Controlled Prescription form. Any required or requested change(s) must be patient-specific and authorized by the patient's prescriber through direct consultation with the pharmacist. Any prescriber-authorized changes must be confirmed in writing, signed by the prescriber, received by the pharmacy (fax is acceptable) prior to dispensing the medication whenever possible and attached and filed with the original prescription.		
<i>PPP-66 Policy Guide</i> <u>MMT (2013)</u> , <u>SROM</u> Principle 3.2.1	Pharmacists and pharmacy technicians must correctly identify the product as prescribed 'for pain' or 'Opioid Agonist Treatment (OAT)' by using the appropriate Drug Identification Number (DIN) or Product Identification Number (PIN) to ensure patient safety and accurate PharmaNet patient records.		
<u>PPP-66 Policy Guide</u> <u>MMT (2013)</u> Principle 3.2.4	The 'sig field' on the prescription label must include the start and end dates of the original current prescription.		

Reference	Requirements	Compliant	Comment
PPP-66 Policy Guide BMT Principle 3.1.1	Buprenorphine/Naloxone for maintenance must be dispensed to patients as an approved, commercially available formulation.		
PPP-66 Policy Guide MMT (2013) Principle 3.1.1	Methadone for maintenance must be dispensed to patients in a concentration of 10 mg/ml.		
PPP-66 Policy Guide MMT (2013) Principle 3.1.1	Methadone doses must be accurately measured in a calibrated device that minimizes the error rate to no greater than 0.1 ml.		
PPP-66 Policy Guide MMT (2013) Principle 3.3.1 Guidelines	All devices used to measure the methadone 10 mg/ml solutions should be distinctive and recognizable and must be used only to measure methadone solutions. Devices must be labeled with a "methadone only" label and a "poison" auxiliary label with the international symbol of the skull and cross bones.		
PPP-66 Policy Guide MMT (2013) Principle 4.1.6 Guidelines	Each dose must be dispensed in an individual, appropriately sized, child-resistant container.		
<u>PPP-66 Policy</u> <u>Guide SROM</u> <u>Principle 3.1.1</u>	SROM for maintenance must be dispensed in approved, commercially available strengths. Capsule contents cannot be split.		
PPP-66 Policy Guide BMT, MMT (2013), SROM Principle 4.1.1	A pharmacist must be present and witness the release of an OAT [buprenorphine/naloxone, methadone, SROM] prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff. A pharmacist must be present and witness the release of a methadone prescription to a patient. This function cannot be delegated to a pharmacy technician or any other pharmacy support staff.		
PPP-66 Policy Guide <u>BMT, MMT (2013)</u> , <u>SROM</u> Principle 4.1.2	Prior to releasing an OAT [buprenorphine/naloxone, methadone, SROM] prescription the pharmacist must assess the patient to ensure that the patient is not intoxicated, including by centrally-acting sedatives and/or stimulants or in any other acute clinical condition that would increase the risk of an adverse event. Prior to releasing a methadone prescription the pharmacist must assess the competence of the patient (i.e. ensure that the patient is not currently intoxicated or otherwise mentally impaired) to ensure that it is safe to release the medication to them.		
PPP-66 Policy Guide BMT Principle 4.1.3	Prior to releasing a buprenorphine/naloxone prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log.		
PPP-66 Policy Guide MMT (2013) Principle 4.1.3	Prior to releasing a methadone prescription the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log.		

Reference	Requirements	Compliant	Comment
<u>PPP-66 Policy Guide</u> <u>SROM Principle 4.1.3</u>	Prior to releasing a SROM prescription, the patient and pharmacist must acknowledge receipt by signing a patient/prescription-specific log.		
<u>PPP-66 Policy Guide</u> <u>BMT Principle 4.1.5</u>	If a prescriber orders the buprenorphine/naloxone to be dispensed as a 'Daily Witnessed Ingestion' or 'DWI', the pharmacist must directly observe the patient placing the medication under the tongue.		
<u>PPP-66 Policy Guide</u> <u>MMT (2013)</u> <u>Principle 4.1.5</u>	With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication, and be assured the entire dose has been swallowed.		
PPP-66 Policy Guide SROM Principle 4.1.4	With respect to witnessed ingestion doses, the pharmacist must directly observe the patient ingesting the medication and be assured that the entire dose has been swallowed.		
<u>PPP-66 Policy Guide</u> <u>BMT Principle 4.1.6</u>	If take home doses (carries) are prescribed, the first dose does not need to be witnessed, unless ordered by the prescriber. The subsequent take-home doses must be dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.		
<u>PPP-66 Policy Guide</u> <u>MMT (2013)</u> Principle 4.1.6	With respect to take-home doses, the first dose (whether it is stated on the prescription or not) must be a witnessed ingestion with all subsequent take-home doses dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient.		
<u>PPP-66 Policy Guide</u> <u>SROM Principle 4.1.5</u>	If take home doses (carries) are prescribed, the first dose must be a witnessed ingestion. The subsequent take- home doses must be dispensed in child-resistant containers with an explicit warning label indicating that the amount of drug in the container could cause serious harm or toxicity if taken by someone other than the patient. If a pharmacist determines that due to a specific patient circumstance a non-child-resistant container will be used for take-home doses, it must be documented on the patient record.		
PPP-66 Policy Guide BMT, MMT (2013), SROM Principle 5.1.1, and PPP-66 Policy Guide MMT (2013) Principle 5.2.1	Any OAT [buprenorphine/naloxone, methadone, SROM] prescription that has been processed and prepared but is not consumed or picked up by the patient on the prescribed day is considered cancelled and must be reversed on PharmaNet before the end of the business day.		
PPP-66 Policy Guide <u>BMT, MMT (2013),</u> <u>SROM</u> Principle	If a patient misses a dose, they cannot receive the missed dose at a later date.		Page 26 of 29

Reference	Requirements	Compliant	Comment
5.1.2, and <u>PPP-66</u> <u>Policy Guide MMT</u> (2013) Principle 5.2.2			
<u>PPP-66 Policy Guide</u> <u>BMT Principle 5.1.4</u>	If a patient misses 6 or more consecutive days, the prescription must be cancelled.		
BCCSU Appendix 1 Section 4 (MMT)	Pharmacists are required to notify prescribers of missed doses and clinicians must document review of PharmaNet profiles. Prescribers and patients should be aware that if three consecutive doses are missed, the dispensing pharmacy will cancel the prescription and notify the prescribing clinician.		
<u>PPP-66 Policy Guide</u> <u>SROM Principle 5.1.4</u>	SROM: If a patient misses 2 or more consecutive doses, the prescription must be cancelled.		
<u>PPP-66 Required</u> <u>References</u>	In addition to the currently required pharmacy reference materials (PPP-3), pharmacies providing methadone maintenance treatment services must also maintain as required references the following:		
	(1) CPBC Methadone Maintenance Treatment Policy Guide (2013) and subsequent revisions.		
	(2) The most recent version of the BCCSU A Guideline for the Clinical Management of Opioid Use Disorder.		
	(3) The most current version of the Centre for Addiction and Mental Health Opioid Agonist Maintenance Treatment: A Pharmacist's Guide to Methadone and Buprenorphine for Opioid Use Disorders.		
	(4) Product monographs for the commercially available 10mg/ml methadone oral preparations.		
PPP-66 Policy Statement #1	All pharmacy managers, staff pharmacists, and relief pharmacists employed in a community pharmacy that provides pharmacy services related to buprenorphine/ naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must: a. successfully complete the College of Pharmacists of BC (CPBC) Methadone Maintenance Treatment (MMT) training program (2013), or b. successfully complete the British Columbia Pharmacy Association (BCPhA) Opioid Agonist Treatment Compliance and Management Program for Pharmacy (OATCAMPP) training program, and c. record self- declaration of training completion in eServices.		
PPP-66 Policy Statement #2	All pharmacy technicians employed in a community pharmacy that provides pharmacy services related to buprenorphine/naloxone maintenance treatment, methadone maintenance treatment or slow release oral morphine maintenance treatment must: a. successfully complete the CPBC MMT training program (2013), or b. successfully complete the online component of the BCPhA OAT-CAMPP training program, and c. record self- declaration of training completion in eServices.		

### • • • •

Reference	Requirements	Compliant	Comment
<u>PPP-66 Policy</u> Statement #3	Pharmacy managers must: a. educate all non-pharmacist staff regarding their role in the provision of community pharmacy services related to opioid agonist treatment, and b. document the completion of the education of individual non-pharmacist staff members on a form signed and dated by the pharmacy manager and the nonpharmacist staff member, and retain the completed forms in the pharmacy's files.		

# Non-Sterile Compounding Preparations

Reference	Requirements	Compliant	Comments
<u>PPP-3 Page 2</u>	Pharmacies must be equipped with references relevant to their practices (compounding).		
<u>PODSA Bylaws</u> <u>s.19(2)</u>	A registrant must not sell or dispense a quantity of drug that will not be used completely prior to the manufacturer's expiry date, if used according to the directions on the label.		
<u>Health Canada</u> <u>Policy on</u> <u>Manufacturing and</u> <u>Compounding Drug</u> <u>Products in Canada</u> (2009) s.5.1(n)	The expiration date of the compounded product is based on known stability data. If stability data is not available, the expiration date should be short, usually limited to the duration of the prescription or use.		
<u>Health Canada</u> <u>Policy on</u> <u>Manufacturing and</u> <u>Compounding Drug</u> <u>Products in Canada</u> <u>s5.1(c)</u>	It is expected that healthcare professionals who compound products will have appropriate risk management processes in place to manage risks associated with the compounded product and the workplace (facilities, safety etc.), in line with the standards set by their provincial/territorial regulatory bodies (for example but not limited to the toxicology, pharmacology, therapeutic value, stability, adverse reactions, labelling requirements etc. of the compounded product).		
<u>Health Canada</u> <u>Policy on</u> <u>Manufacturing and</u> <u>Compounding Drug</u> <u>Products in Canada</u> <u>s5.1(d)</u>	A pharmacy may prepare drugs in very limited quantities, in anticipation of a prescription. For the purpose of this Policy, preparation involves compounding or repackaging of multiple units, not for immediate use, in a single process, by the same operator in accordance with a standardized batch preparation procedure		
<u>Health Canada</u> <u>Policy on</u> <u>Manufacturing and</u> <u>Compounding Drug</u> <u>Products in Canada</u> <u>s5.1(e)</u>	Compounding should only be done if there is a therapeutic need or lack of product availability and should not be done solely for economic reasons for the healthcare professionals.		
Health Canada Policy on Manufacturing and Compounding Drug Products in Canada s5.1(h)	Drugs should not be compounded in order to be sold to third parties who will in turn sell/deliver to patients outside of their defined patient-healthcare professional relationship (see definition of "sell"). Pharmacists that do not provide specific compounding services may contract this activity to another pharmacist who provides this type of specific compounding service.		

Reference	Requirements	Compliant	Comments
<u>Health Canada</u> <u>Policy on</u> <u>Manufacturing and</u> <u>Compounding Drug</u> <u>Products in Canada</u> <u>s5.1(j)</u>	Product should be produced from an authorized drug or Active Pharmaceutical Ingredient (API) used in an authorized drug for use in Canada or listed in a recognized Pharmacopoeia (USP, PhEur, PhF, PhI, BP, CF, NF, Codex - Schedule B Food and Drugs Act.)		