Type of Pharmacy Application for this Inspection Report

 $\square$  New Telepharmacy Community Pharmacy Licence

### **PRE-OPENING INSPECTION REPORT**

Telepharmacy (Community)

**PODSA Form 10B** 

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1. TELEPHARMACY INFORMATION					
Operating Name	External Signage Name Proposed			icensure/Completion Date	
			MMM	DD   YYYY	
Telepharmacy Address	City	Province	Postal Code	Phone Number	
		ВС			
Email Address	Website			Fax Number	

2. CENTRAL PHARMACY INFORMATION				
Operating Name				Pharmacy Licence Number
Pharmacy Address	City	Province	Postal Code	Phone Number
		ВС		
Email Address	Website			Fax Number

☐ Change of Layout (Renovation)

3. PHARMACY S	ERVICES						
ТҮРЕ	SUBTYPE	YES	NO	ТҮРЕ	YES	NO	If "YES", PROVIDE ADDITIONAL INFORMATION
OPIOID AGONIST TREATMENT	Methadone (Maintenance)			RESIDENTIAL CARE			Facility Name & Number of Beds:
	Oral Morphine			SERVICES			
Buprenorphine & Naloxone (Suboxone)							
	Injectable Opioid Agonist (iOAT)						
COMPOUNDING	Non-Sterile Preparation			CENTRALIZED PRESCRIPTION			Provide the name(s) of the pharmacy(ies) that your pharmacy
	Sterile*, Non-Hazardous			PROCESSING SERVICES			prepares/processes prescriptions/drug orders for:
	Sterile*, Hazardous			PROVIDED TO			prescriptions/ drug orders for.
OTHER	Injection & Intranasal Drug Administration			OUTSOURCED PRESCRIPTION			Provide the name(s) of the pharmacy(ies) that prepare/process
	No Public Access**		PROCESSING SERVICES			prescriptions/drug orders for your pharmacy:	
	Schedule 1A drugs On-Site			RECEIVED FROM			
	Internet Pharmacy						

<sup>\*</sup>Complete the Sterile Compounding section starting page 8. \*\*Check 'No' if you are a pharmacy that is open to the public.

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4. HOURS OF OPERATION									
ТҮРЕ	MON	TUE	WED	THU	FRI	SAT	SUN	STAT	
TELEPHARMACY									
Telepharmacy Hours #									
Pharmacy Hours <sup>  #</sup>									
Lock & Leave Hours									
CENTRAL PHARMACY									
Pharmacy Hours									
Lock & Leave Hours									

∄ When a full pharmacist at the central pharmacy is supervising pharmacy services performed at a telepharmacy through real time audio and visual observation.

 ₩When a full pharmacist is physically present on duty at the telepharmacy.

5. TELEPHA	RMACY ROSTER	*					
STAFF	REGISTRATION #	FIRST NAME/INF	ORMAL NAME	LAST NAME		REGISTRATION CLASS	
Pharmacy Manager						<ul><li>☑ Pharmacist</li><li>☑ Pharmacy Technician</li></ul>	
J						☐ Pharmacist	
Staff #1						☐ Pharmacy Technician	
Staff #2						☐ Pharmacist	
						☐ Pharmacy Technician	
Staff #3						☐ Pharmacist	
		*Include all rec	ristrant staff who may h	pe providing pharmacy services or perfo	rming inspections/aug	☐ Pharmacy Technician	
		include all reg	gisti ant stan who may t	be providing priarriacy services or perio	ining inspections/auc	arts at the telepharmacy at any time	
6. INFORM	ATION OF THE P	ERSON WHO CO	OMPLETED SEC	TION 7			
Last Name			First Name		Completion Dat	te	
Relationship t	to the Pharmacy						
☐ Pharm	nacy Manager	☐ Owner (Reg	istrant)	Owner (Non-Registrant)	☐ Colle	ege Inspector	
Email Address	s of the Person Nam	ed Above	Phone Number of	of the Person Named Above	Fax Number of	the Person Named Above	
my knowl	ledge. If any of the a	above information i	s found to be false	e accompanying digital evidence e, untrue, misleading or misrep mmittee and the telepharmacy	resenting, I am av	ware that I may be	
Signature					Date		
					MMM	DD   YYYY	
The College of Pharmacists of BC ("College") collects, uses, discloses, stores, and retains personal information in compliance with the Health Professions Act (HPA), the Pharmacy Operations and Drug Scheduling Act (PODSA), and the reedom of Information and Protection of Privacy Act (FIPPA). The personal information you provide when completing and submitting this form is being collected and will be used by the College to carry out its mandate under the HPA in he public interest. The collection of this personal information is permitted under section 26(c) and (e) of FIPPA. If you have any questions or concerns about the College's privacy practices, please contact the College's Privacy Officer: <a href="mailto:rivacy@bcpharmacists.org">rivacy@bcpharmacists.org</a> or 604.733.2440.  CPBC USE ONLY							
				Approved by:	Approved date:		

When the pharmacy is closed but the premises remains open to the public

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#### 7. PRE-OPENING/CHANGE OF LAYOUT INSPECTION

Confirm whether your new telepharmacy currently complies with each of the following requirements.

- If compliant, mark "YES" under the "Compliant" column <u>AND</u> submit digital evidence (e.g. photos/videos) using this <u>Powerpoint template</u> (<u>Telepharmacy</u>) along with this Pre-Opening Inspection Report to the Licensure Department at <u>licensure@bcpharmacists.org</u>
- If not applicable, enter "N/A" under the "Compliant" column and provide the reason in the "Comment" column.
- Digital evidence must be <u>recently produced at the current pharmacy (Change of Layout)</u>, or the new pharmacy site (New Pharmacy <u>licence or Change of Location</u>). Digital evidence previously submitted for the same location or any other location is <u>not acceptable</u>.
   If there are photos that cannot be taken at the site, explain the reasons in the Inspection Report.
- Refer to the "Pre-Opening Inspection Report and Digital Evidence" section and Appendix B in the Pharmacy Licensure Guide for
  more information (e.g. requirements and recommended content for digital evidence).

### External to Dispensary

#	Item	Compliant	Comment	CPBC Use
1a	External view of the pharmacy (street view including the external signage)			
1b	Hours of operation sign			
1c	Professional products area for schedule 3 drugs			
1d	Lock-and-Leave barriers (if the premises is open for business while the pharmacy is closed) OR N/A			
1e	Signage at 25 feet from dispensary to visually distinguish the professional products area from the remaining areas of the premises  OR N/A			
1f	"Medication Information" Sign OR N/A			
1g	Separate Injection Room for iOAT OR N/A  1. Stainless steel table 2. Chair 3. Secure container for sharps 4. Sink 5. Soap 6. Hand sanitizer 7. Antiseptic cleaning wipes 8. Paper towel in a dispenser 9. Security Camera			

## Dispensary

#	Item	Compliant	Comment	CPBC Use
2a	Dispensary area			
2b	Gate(s)/door(s) at the entrance(s) into the dispensary			
2c	Placeholder for College license			
2d	Professional service area for Schedule 2 drugs			
2e	Patient consultation area			

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#	Item	Compliant	Comment	CPBC Use
2f	Dispensing counter(s) and service counter(s)			
2g	Computer terminals for prescription processing			
2h	Shelving			
2i	Double stainless steel sink			

# Security

#	Item	Compliant	Comment	CPBC Use
3a	☐ Locked metal safe OR ☐ Safe declaration			
3b	Security camera system AND Surveillance signage			
3c	Motion sensors			
3d	Monitored alarm			
	OR N/A			
3e	Physical barriers			
	OR N/A			
3f	Locked area for sharps containers (for iOAT) OR N/A			

# **Equipment and References**

#	Item	Compliant	Comment	CPBC Use
4a	Equipment (General):  1. Telephone 2. Fax machine 3. Rx balance and calibration tools 4. Glass graduate(s) 5. Mortar 6. Pestle 7. Spatula 8. Funnel 9. Stirring rod 10. Ointment slab/ parchment paper 11. Counting tray 12. Soap in a dispenser 13. Paper towels in a dispenser 14. Plastic/metal garbage containers 15. Plastic lining			
4b	Equipment (Electronic Recordkeeping)  1. Device for inputting/creating coloured electronic records (e.g. scanner)  2. Backed up records storage area  OR N/A = Not storing prescriptions electronically			
4c	Rx filing supplies (e.g. folders/binders)			

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#	ltem	Compliant	Comment	CPBC Use
4d	Equipment (Cold Chain)  1. Refrigerator			
	2. Digital thermometer/temperature			
	monitoring system			
	3. Temperature log/record			
4e	Equipment (Methadone)			
	1. Calibrated device			
	2. Auxiliary labels			
	Containers for daily dose     A. Patient/Rx Log			
	OR N/A			
4f				
41	Equipment and Supplies (iOAT)  1. Needles for patient self-injection			
	2. Tourniquets			
	3. Alcohol swabs			
	4. Bandages			
	5. Cotton swabs			
	6. Naloxone and related supplies			
	7. Breathalyzer 8. Pulse oximeter			
	9. Blood pressure monitor			
	10. Oxygen			
	11. Bag valve mask			
	12. Disinfectant			
	13. Injectable Hydromorphone Part-Fill Accountability Log			
	OR N/A			
4g	References (CPBC)			
	1. Pharmacy legislation			
	2. CPBC Professional Practice Policies			
	3. ReadLinks			
4h	References (General)			
	1. Compendium			
	Complementary/ Alternative     Dispensatory			
	4. Drug Interactions			
	5. Non-prescription Medication (2x)			
	6. Medical Dictionary			
	7. Pregnancy and Lactation			
	8. Pediatrics 9. Therapeutics			
<u></u>	· ·			
4i	References (if applicable)			
	☐ Opioid Agonist Treatment  ○ PPP-66 Policy Guide			
	BCCSU			
	o CAMH			
	<ul> <li>Monograph</li> </ul>			
	□ Veterinary			
	☐ Psychiatric			
	☐ Geriatric☐ Compounding			
	OR N/A			
	VIIII/A			

# Prescription

#	Item	Compliant	Comment	CPBC Use
5a	Prescription hardcopy (i.e. the label/paper attached to the original prescription, which contains			

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#	Item	Compliant	Comment	CPBC Use
	prescription information generated after transmitting to PharmaNet)			
5b	Marked prescription (sample)			

# Confidentiality

#	‡ Item	Compliant	Comment	CPBC Use
6	a ☐ Shredder OR ☐ Contract with a document destruction company			
61	b Offsite storage contract OR N/A			

## **Inventory Management**

#	Item	Compliant	Comment	CPBC Use
7a	Drug receiving area			
7b	Storage area for non-usable and expired drugs			

# **Dispensed Products**

#	Item	Compliant	Comment	CPBC Use
88	Prescription product label  1. Single-entity product  2. Multiple-entity product			
81	b Filling supplies (e.g. vials and bottles including caps)			

# Pharmacy Manager's Responsibilities

#	Item	Compliant	Comment	CPBC Use
9a	Staff identification (e.g. Name tag/badge, apparel)			
9b	Policy & procedure manual			

# **Central Pharmacy**

#	Item	Reference and Requirements	Compliant	Details (Mandatory field)	CPBC Use
10a	Tool/technology	PODSA Bylaws s.31.1(1)(a)  A telepharmacy must not remain open and prescriptions must not be		Name of tool/technology:	
	supervision on dispensary activities directs	dispensed without a full pharmacist physically present 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 Telepharmacy Standards of Practice.		Describe in detail how compliance is met:	
		PODSA Bylaws Definitions			
		"direct supervision" means real time audio and 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).			
	a full pharmacist employed at the central pharmacy resp providing direct supervision of pharmacy services in a tel	HPA Bylaws Schedule F Part 6 s.3			
		"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.  HPA Bylaws Schedule F Part 6 s.4(3)			

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#	Item	Reference and Requirements	Compliant	Details (Mandatory field)	CPBC Use
		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.			
10b	Tool/technology used for transmitting prescription and personal health information between sites	HPA Bylaws Schedule F Part 6 s.6(2)  Each telepharmacy and central pharmacy must maintain a secure connection to the central pharmacy for transmission of prescription and personal health information		Name of tool/technology:  Describe in detail how compliance is met:	
10c	Tool/technology used for processing prescriptions at the central pharmacy for prescriptions received at the telepharmacy	PODSA Bylaws s.31.1(9)  All transactions in PharmaNet must be distinguishable between the central pharmacy and telepharmacy.  HPA Bylaws Schedule F Part 6 s.6(1)  All prescription processing must occur at the central pharmacy unless a full pharmacist is physically present on duty at the telepharmacy.		Name of tool/technology:  Describe in detail how compliance is met:	
10d	Tool/technology enabling direct supervision on product final check	A telepharmacy must not remain open and prescriptions must not be dispensed without a full pharmacist physically present 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 Telepharmacy Standards of Practice.  HPA Bylaws Schedule F Part 6 s.3  "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, or (c) a full pharmacist who is physically present on duty at the telepharmacy.  HPA Bylaws Schedule F Part 6 s.4(2)(a)  A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide direction and support to persons performing pharmacy services at the telepharmacy.  HPA Bylaws Schedule F Part 6 s.4(4)  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.  HPA Bylaws Schedule F Part 6 s.4(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.		Name of tool/technology:  Describe in detail how compliance is met:	
10e	Tool/technology enabling direct pharmacist/patient consultation	HPA Bylaws Schedule F Part 6 s.3  "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.  HPA Bylaws Schedule F Part 6 s.4(2)(b)  A supervising pharmacist must be readily available at all times when a telepharmacy is open to provide pharmacist/patient consultation.  HPA Bylaws Schedule F Part 6 s.7  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 Health Professions Act Bylaws.		Name of tool/technology:  Describe in detail how compliance is met:	

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### Complete the section below if your pharmacy compounds sterile preparations

# Sterile Compounding (Hazardous/Non-Hazardous)

### ANTEROOM

#	Item	Compliant	Comment	CPBC Use
C1a	Functional Parameters			
	<ol> <li>□ Non-Hazardous only,</li> </ol>			
	2. 🔲 Hazardous only, and/or			
	3. 🛛 Shared Anteroom			
C1b	Room Temperature Control/Monitoring Device			
C1c	Demarcation Line			

### ANTEROOM - EQUIPMENT AND SUPPLIES

#	ltem	Compliant	Comment	CPBC Use
C2a	For Gowning and Garbing  1. Personal Protective Equipment (PPE)  a) shoe covers  b) hair cover  c) beard covers (if applicable)  d) surgical mask  e) non-shedding protective gown			
	f) non-powdered sterile gloves g) Dedicated apparel (e.g. Uniform/clean room scrubs) 2. Mirror, or other means to verify garbing			
C2b	For Hand Hygiene Cleansing  1. Hands-free sink  2. Soap dispenser  3. Nail picks  4. Alcohol-based hand rub (ABHR)  5. Hand-drying system: ☐ Lint free towels in a dispenser or ☐ air hand dryer designed for use in controlled areas  6. Clock  7. Eyewash station (in/nearby anteroom)			
C2c	For Cleaning  1. Cleaning equipment and supplies  2. Disinfectant  a) Germicidal detergent  b) Sterile disinfectant (70% isopropyl alcohol), AND  c) Sporicidal agent  3. Waste container and plastic bags  4. Material Safety Data Sheets			
C2d	Cold-chain equipment  1. Refrigerator  2. Freezer OR □ N/A  3. □Digital thermometer and Temperature log, or □ continuous temperature recorder  OR □ N/A			
C2e	For transferring products  1. Pass-through OR □ N/A  2. Cart OR □ N/A  3. Bin or tray			

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### **CLEAN ROOM**

#	Item	Compliant	Comment	CPBC Use
СЗа	Functional Parameters: Non-Hazardous Only, OR ☐ N/A			
C3b	Functional Parameters: Hazardous Only, OR ☐ N/A			
C3c	Primary Engineering Control (PEC): Non-Hazardous			
	<ol> <li>□ LAFW, and/or</li> </ol>			
	2. □ CAI			
	OR □ N/A			
C3d	Primary Engineering Control (PEC): Hazardous			
	<ol> <li>Class II or Class III BSC, and/or</li> </ol>			
	2. □ CACI			
	OR □ N/A			
C3e	Cold-chain equipment			
	1. Refrigerator			
	2. Freezer OR □ N/A			
	3.			
	log, or ☐ continuous temperature			
	recorder			
	OR □ N/A			

#### **OTHER AREAS**

#	ltem	Compliant	Comment	CPBC Use
C4a	Segregated area(s): Non-Hazardous  1. □ LAFW, and/or  2. □ CAI  OR □ N/A			
C4a	Segregated area(s): Hazardous  1. □ Class II or Class III BSC, and/or  2. □ CACI  OR □ N/A			
C4c	Storage area for hazardous drugs  1. □ dedicated room, and/or  2. □ in clean room  OR □ N/A			
C4d	Storage area for cleaning equipment and supplies			
C4e	Cold-chain equipment in storage area  1. Refrigerator  2. Freezer OR □ N/A  3. □ Digital thermometer and Temperature log, or □ continuous temperature recorder  OR □ N/A			
C4f	☐ Incubator, or ☐ Report from a certified external laboratory			
C4g	Signage			

### HAZARDOUS STERILE COMPOUNDING – ADDITIONAL SUPPLIES, OR ☐ N/A

#	Item	Compliant	Comment	CPBC Use
C5a	Personal Protective Equipment 1. Gloves (D-6978-05 ASTM) 2. Gown			

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#	Item	Compliant	Comment	CPBC Use
	<ol> <li>Masks (N95 or N100, NIOSH-approved)</li> <li>Goggles and face shield, OR full facepiece respirator</li> </ol>			
C5b	Spill kit including chemical cartridge respirator with pre-filter			
C5c	Cytotoxic waste container			
C5d	Surface decontamination and deactivation agents			

#### **DOCUMENTATION**

#	Item	Compliant	Comment	CPBC Use
C6a	Compounded product label			
C6b	Compounded Sterile Preparation Log			
	<ol> <li>Individual, OR □ N/A</li> </ol>			
	2. Batch, OR □ N/A			
C6c	Policies and Procedures for Compounding			
	<ol> <li>Non-Hazardous Sterile Preparation,</li> </ol>	OR		
	□ N/A			
	2. Hazardous Sterile Preparation, OR	□ N/A		
C6d	General Maintenance Log			
	1. PEC maintenance and certification			
	2. Maintenance of devices, instrument accessories	ts and		
	3. Calibration of temperature probes			
	4. Calibration of incubator OR   N/A			
	5. Forms or schedules to document			
	cleaning and disinfecting activities a	is per		
	established policy			