

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

- Failure to complete this form by July 1, 2024, <u>and</u> within 15 days of becoming PIC, may result in disciplinary action (<u>OAR 855-115-0210(1)(h)</u>).
- In order to be a PIC, a pharmacist must have:
 - Completed at least one year of pharmacy practice; or
 - Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and
 - Be employed by the outlet. (OAR 855-115-0205(1)(a)(b))
- Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years. (OAR 855-115-0205(2))

Requirements: Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the board immediately upon request at the time of inspection and retained in compliance with <u>OAR 855-104-0055</u>.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

Internal Use: Following completion of the self-inspection form, ensure it is signed and dated by the PIC, reviewed with all pharmacy staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

Agency Use: During an inspection, Compliance Officers use the self-inspection form as a general guide to assess pharmacy compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and locate any auxiliary documents referenced within at the time of inspection.

Email all compliance-related questions to: pharmacy.compliance@bop.oregon.gov.

2024 PHARMACY PRESCRIPTION LOCKER (PPL) **SELF-INSPECTION FORM**

A PIC must complete and sign this inspection becoming PIC and by 7/1/2024 (as required b		lable for inspection <u>within 15 days of</u>
Date PIC completed Self-Inspection:/		
PIC Name:		PIC License #:
PIC Work E-mail:		
Pharmacy Prescription Locker (PPL) Name:		
PPL Retail Outlet Registration #:		EXP://
Address:		
City:	State:	Zip Code:
Affiliated Pharmacy Name:		
Affiliated Pharmacy Retail Outlet Registration #:		EXP://
Address:		
City:	State:	Zip Code:
Telephone: ()		Fax: ()

Please list where the following items are specifically located inside the Affiliated Pharmacy (e.g., which cabinet, binder, etc.). Records are required to be kept at the Affiliated Pharmacy per OAR 855-143-0550(2).

Policies, Procedures, and General Records

- Current written Drug Outlet Policies and Procedures (to include Cold Drug Storage) 0
- Continuous Quality Improvement Plan 0
- Written document designating who is authorized to access the PPL 0
- Pharmacist physical inspection of PPL (in-person, every 28 days) 0
- **RPh Counseling Records** 0

Board notification of drug loss or suspected theft 0

Training Documents

Training program on proper use of PPL 0

Cold Drug Storage Records

- Drug storage monitoring plan 0
- Emergency action plan 0
- Excursion Documentation (including the event date, name of persons(s) involved in excursion responses, action(s) 0 taken, including decision to guarantine drug for destruction, or determination that drug is safe for continued use, and the details of the information source used to make this decision.)
- Temperature logs 0
- Quarterly validations \cap

When mentioned herein, the term "pharmacist," or "Pharmacist," means Oregon-licensed pharmacist, and the term "Affiliated Pharmacy" means Pharmacy Prescription Locker Affiliated Pharmacy:

- OAR 855-006-0005(37) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.
- OAR 855-143-0005(1) "Pharmacy Prescription Locker Affiliated Pharmacy" or "PPL Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy **Prescription Locker.**

Is the PPL located in Oregon and registered with the board? OAR 855-143-0010(1)(3) 1 Does the PPL have an Oregon-registered Affiliated Pharmacy with OAR 855-143-0010(1)(3) 2 an Oregon-licensed PIC? Is the PPL's registration displayed at both the PPL and its Affiliated OAR 855-143-0010(10) 3 \square Pharmacy? Does the PPL store controlled substances? OAR 855-143-0010(2) 4 \square \square OAR 855-143-0225 Note: A PPL may not store controlled substances, unless the DEA issues a DEA license for the PPL. Is the PPL aware that a change of location or ownership of the PPL OAR 855-143-0010 5 П OAR 855-143-0015 or Affiliated Pharmacy requires submission of a new application? OAR 855-143-0020 **Note:** A PPL must not operate until a certificate of registration has OAR 855-143-0025 been issued by the board. OAR 855-143-0025 Is the PPL aware that the board must be notified by the Affiliated 6 Pharmacy a minimum of 15 days prior to discontinuing operations?

General Requirements

Yes No

Yes	NO			Rule Reference
		7	Have all Pharmacists, Interns, Certified Oregon Pharmacy Technicians (COPT) and Pharmacy Technicians (PT) completed a training program on the proper use of the PPL?	OAR 855-143-0050(2)
		8	Are the prescription and non-prescription drugs, devices, and related supplies placed in the PPL sourced ONLY from the Affiliated Pharmacy?	OAR 855-143-0120
		9	Does the Affiliated Pharmacy ensure that each prescription is correctly dispensed by the PPL accurately, in accordance with the prescribing practitioner's authorization, and to the correct party?	OAR 855-143-0345(1),(2)
		10	Does the PPL and its Affiliated Pharmacy ensure disasters, accidents and emergencies which may affect the strength, purity or labeling of drugs or devices are reported to the board immediately?	OAR 855-143-0130(1)
		11	Does the PPL and its Affiliated Pharmacy ensure that confirmed significant drug loss, or any loss related to suspected drug theft, is reported to the DEA, and the Board within one business day?	OAR 855-143-0130(2)
		12	Does the PPL and its Affiliated Pharmacy ensure the PPL is kept clean?	OAR 855-143-0150
		13	Are the Affiliated Pharmacy and PIC aware they are responsible for all operations and enforcing all policies and procedures of the PPL?	OAR 855-143-0200(1)
		14	Is the PPL less than 120 miles from its Affiliated Pharmacy?	OAR 855-143-0200(3)
		15	 Does the PPL and its Affiliated Pharmacy comply with the following? Have the same owner; or have a written contract that specifies: The services to be provided by each licensee and registrant; The responsibilities of each licensee and registrant; and The accountabilities of each licensee and registrant; Ensure each prescription and non-prescription drug, device, and related supplies are dispensed in compliance with OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-041, and OAR 855-113; OAR 855-120, OAR 855-125, OAR 855-041, and OAR 855-143; Ensure that the Affiliated Pharmacy prevents duplicate dispensing of a prescription; Comply with all applicable federal and state laws and rules; Ensure that there is a PIC who is responsible for all operations and enforcing all policies and procedures of the PPL; Designate in writing the pharmacists, Interns, COPT, and PT authorized to access the PPL; Utilize complete chain of custody tracking; Train the Oregon licensed Pharmacists, Interns, COPT, PT in the operation of the PPL and document the training; Develop, implement, and enforce a continuous quality improvement program for dispensing services from a PPL designed to objectively and systematically: Monitor, evaluate, and document the quality and appropriateness of patient care; Improve patient care; and Identify, resolve, and establish the root cause of dispensing and DUR errors and prevent their reoccurrence; 	<u>OAR 855-143-0200(4)</u>

Yes No

Yes	No		Rule Reference
		 Provide a telephone number that a patient, patient's agent, or prescriber may use to contact the Oregon licensed Pharmacist from the PPL Affiliated Pharmacy; and Develop, implement, and enforce a process for an inperson physical inspection of the PPL by an Oregon-licensed Pharmacist at least once every 28 days (or more frequently as deemed necessary by the Oregon licensed PIC of the PPL Affiliated Pharmacy); the inspection must utilize the PPL self-inspection form, be documented, and retained. 	

Minimum Equipment, Policy and Procedures and Records

Yes	No			Rule Reference
		16	Does each PPL have appropriate equipment and supplies based on services offered by the PPL, as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP)?	<u>OAR 855-143-0155(1)</u>
		17	Are Drug Outlet Policies & Procedures compliant with Oregon laws and rules, reflect the current practice at the outlet, and do they address the following? • Security • Operation, testing, and maintenance of the telepharmacy and PPL systems • Sanitation and cleaning • Storage of drugs • Stocking and destocking • Dispensing (to include preventing duplications) • Pharmacist supervision, direction, and control of licensed personnel and of accessing of the PPL • Documenting the identity, function, location, date and time of licensees engaging in telepharmacy and licensed personnel accessing the PPL • Utilization of Pharmacist (i.e. Counseling) • Drug and/or device procurement, receiving, and delivery • Recordkeeping • Patient confidentiality • On-site inspection by a Pharmacist • Continuous quality improvements • Plan for discontinuing and recovering services if PPL disruption occurs • Training: initial and ongoing • Interpretation, translation, and prescription reader services Date reviewed with PPL Affiliated Pharmacy staff:	<u>OAR 855-143-0200</u>
-	-		•	·

Yes	No			Rule Reference
		18	 Does the PPL contain all required signage in a location that is easily seen by the public, including but not limited to: Stating "The (insert name of PPL Affiliated Pharmacy) may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on this sign must be in block letters not less than one inch in height; Providing notification in each of the languages required in OAR 855-141-0410 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescription Locker, supervised by an Oregon licensed Pharmacist from (insert name of Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and Providing notification of accurate hours of operation at the PPL 	<u>OAR 855-143-0155(1)(c)</u>
		19	 Does the Affiliated Pharmacy retain the following records for the PPL? Date, time, and identification of each individual and activity or function performed on the PPL; Oregon licensed Pharmacist physical inspection of the PPL; Audiovisual communication system testing; Licensee training on the proper use of the PPL; Still image capture and store and forward images must be retained according to OAR 855-143-0550(1); Data and surveillance system data must be retained for 30 days except when an Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the Affiliated Pharmacy must retain the data related to that incident for 6 months from the date of review; and Any errors or irregularities identified by the quality improvement program. 	<u>OAR 855-143-0550(3)</u>
		20	 Does the Affiliated Pharmacy retain the following dispensing records for the PPL? Physical location of the PPL; Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies; A digital image of the individual to whom the prescription was dispensed. Date and time of transaction; Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity; 	

Yes	No
100	110

Rule Reference

	 Each non-prescription drug and supply name, UPC or NDC number, and quantity; and Name of Oregon licensed pharmacist or Oregon licensed Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled. 	
21	 Does the Affiliated Pharmacy retain the following for stocking and destocking records for the PPL?: Date and time; Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity; Each non-prescription drug and supply name, UPC or NDC number, and quantity; Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs, and supplies from the system; and Identity of the Oregon licensed Pharmacist who verifies that the system has been accurately stocked or destocked. 	<u>OAR 855-143-0550(5)</u>

<u>Technology</u>

Yes No

-	-	-	
	22	Does the PPL and the Affiliated Pharmacy utilize a shared computer system and have appropriate technology or interface to allow access to information required to dispense prescription and non-prescription drugs, devices, and related supplies, and counsel the patient or patient's agent?	<u>OAR 855-143-0205(1)</u>
	23	Do the PPL and its Affiliated Pharmacy utilize barcodes, radio- frequency identification, or quick response code technology <u>for</u> <u>stocking, destocking, and dispensing</u> at the PPL?	OAR 855-143-0205(2)
	24	Does the PPL and the Affiliated Pharmacy test the PPL and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescription and non-prescription drugs, devices, and related supplies and after an upgrade or change is made to the system? Note: The Affiliated Pharmacy must make the results of such testing available to the board upon request	<u>OAR 855-143-0205(3)</u>
	25	Have the PPL and its Affiliated Pharmacy developed, implemented, and enforced a plan for routine maintenance of PPL?	OAR 855-143-0205(4)
	26	Have the PPL and its Affiliated Pharmacy developed, implemented, and enforced a plan for responding to and recovering from an interruption of service where the PPL is not fully operational and functioning?	<u>OAR 855-143-0205(5)</u>

Security

No

Yes

	27	Are the PPL, Affiliated Pharmacy, PIC of the Affiliated Pharmacy, and each Oregon-licensed Pharmacist supervising the PPL aware they are each responsible for the security of the PPL, including provisions for adequate safeguards against <u>loss</u> , <u>theft</u> or <u>diversion</u> of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices, and related supplies?	<u>OAR 855-143-0100(1)</u>
	28	Is the PPL in a secure, indoor location that is climate controlled, protected from the elements, and securely fastened to a permanent structure?	OAR 855-143-0100(2)(a)(b)
	29	Does the PPL utilize an alarm system that sends real-time notifications to a Pharmacist if unauthorized access occurs?	OAR 855-143-0100(7)(a)
		Note: Per <u>OAR 855-006-0005(2)</u> , an "Alarm system" means a device or series of devices, which emit or transmit an audible or remote visual or electronic alarm signal, which is intended to summon a response.	
	30	 Does the PPL utilize an electronic entry system that is controlled by a Pharmacist and records the following? ID of Pharmacist authorizing each access and securing the PPL ID of Pharmacist, Intern, or technicians accessing and securing the PPL Date and time of each activity 	<u>OAR 855-143-0100</u> (7)(b)(A)(B)
	31	Does the PPL have a surveillance system that utilizes continuously accessible and recorded video between the Affiliated Pharmacy?	OAR 855-143-0100(7)(C)(c)
		Is the camera view clear, providing view of the entire PPL (including access points)?	
		Note: Per <u>OAR 855-006-0005(53)</u> , a "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance	
	32	Are Interns, COPTs and PTs only accessing the PPL when authorized in real-time by the Pharmacist supervising them?	OAR 855-143-0100(5)
	33	Are all unlicensed personnel (e.g., machine repair technicians) able to access the PPL only when escorted and continually observed by a licensee who is authorized by the Pharmacist who is supervising and authorizing access to the PPL in real-time?	<u>OAR 855-143-0100(6)</u>
	34	 Is the PPL secured to prevent access when: there is no Pharmacist supervising and authorizing access in real-time? there are no licensed personnel being supervised by a Pharmacist at the PPL? any component of the PPL is not functioning? 	<u>OAR 855-143-0100(3)</u>
	35	Is there a record with the name and Oregon license number for each person permitted to access the PPL?	OAR 855-143-0100(4)
	36	Are the following security methods utilized?	OAR 855-143-0100(7)

|--|

Outlet Supervision

Yes No

Rule Reference

	37	Are prescription and non-prescription drugs, devices, and related supplies only dispensed if a Pharmacist is available for patient consultation and the PPL is fully operational?	OAR 855-143-0210(1)
	38	Is the stocking and destocking of prescription and non-prescription drugs, devices, and related supplies completed under the supervision, direction, and control of a Pharmacist?	OAR 855-143-0210(2)
	39	 Is a Pharmacist verifying and documenting the following? All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL All prescription and non-prescription drugs, devices, and related supplies destocked from the PPL were returned to the Affiliated Pharmacy Proper storage conditions were maintained during transfer from Affiliated Pharmacy to PPL per OAR 855-141-0125; and Records are maintained per OAR 855-141-0550 	<u>OAR 855-143-0210(3)</u>
	40	Do the PPL and its Affiliated Pharmacy ensure drugs and devices destocked from a PPL satisfy the requirements of the regulations before returning to stock at the PPL Affiliated Pharmacy?	OAR 855-143-0210(4)

Pharmacists

Yes No

	41	 Do the PPL and its Affiliated Pharmacy ensure that a prescription drug or device is not released from the PPL until the Pharmacist or Intern as permitted by the supervising pharmacist has completed the following? Provided counseling when required under OAR 855-115-0145 or when requested by the patient or patient's agent? Documented the interaction? 	OAR 855-143-0215
	42	Does the Pharmacist verify all prescription and nonprescription drugs, devices, and related supplies prior to placing in the PPL?	OAR 855-143-0210 OAR 855-143-0220

Drug Storage

Yes	No			Rule Reference
		43	 Does the PPL maintain proper storage of all drugs? This includes, but is not limited to, the following: Storage according to the published manufacturer's or USP guidelines Appropriate storage in terms of temperature, light, humidity, sanitation, ventilation, and space Appropriate storage conditions during transfers between facilities and to patients Quarantine of outdated, adulterated, misbranded or suspect drugs 	<u>OAR 855-143-0125(1)</u>
		44	Do the PPL's cold drug storage systems ensure that the refrigerated products are stored between 2 to 8 °C (35.6 to 46.4°F) and frozen products between -25 to -10 °C (-13 to 14 °F), or as specified by the manufacturer?	OAR 855-143-0125(2)
		45	Do the PPL's cold drug storage systems utilize a centrally-placed, accurate and calibrated thermometer?	OAR 855-143-0125(2)(B)
		46	 Is the temperature for each of the PPL's cold drug storage systems measured continuously, and documented either: <u>manually</u>, twice a day, to include minimum, maximum and current temperatures? <u>automatically</u>, with a system capable of creating a producible history of temperature reading? 	<u>OAR 855-143-0125(2)(D)</u>
		47	 Does the PPL and its Affiliated Pharmacy adhere to the following monitoring plan? Documentation of training of all personnel Maintain manufacturer recommended calibration of thermometers Maintain of records of temperature logs for a minimum of three years; Document each excursion in detail of excursion detail, including, but not limited to, Event date and name of persons(s) involved in excursion responses; Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by Pharmacist that it is safe for continued use. This documentation must include details of the information source; A written emergency action plan; Roouine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and Documentation and review of temperature recordings at least once every 28 days by the Pharmacist at the time of in person physical inspection 	<u>OAR 855-143-0125(2)(b)</u>
		48	Does the Affiliated Pharmacy quarantine drugs from the PPL that are outdated, damaged, deteriorated, misbranded, adulterated, or suspect and physically separate them from other drugs until they are destroyed or returned to their supplier?	<u>OAR 855-041-1025</u> OAR 855-041-1036(1)(d)

Prohibited Practices

Yes	No			Rule Reference
		49	Do unlicensed personnel or technicians ask questions of a patient or patient's agent which screen and/or limit interaction with a Pharmacist?	OAR 855-143-0600(1)
		50	Does the PPL utilize a person to dispense or deliver a prescription and non-prescription drugs, devices, and related supplies directly to the patient?	OAR 855-143-0600(2)
		51	Are drugs that require further manipulation prior to administration or dispensing (e.g. reconstitution, compounding, vaccines) placed in the PPL?	OAR 855-143-0600(3)
		52	Are controlled substances stored or dispensed in/from a PPL?	OAR 855-143-0600(4)
		53	Is the PPL aware that a licensee or registrant of the board MAY NOT DISCLOSE patient information to a third party without the consent of the patient, except as provided in (a)-(e) of this rule? Is the pharmacy aware that a licensee or registrant of the board MAY NOT ACCESS OR OBTAIN patient information unless it is for the purpose of patient care, except as provided in (1)(a)-(e) of this rule?	OAR 855-143-0602

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, that written policies and procedures reflect current practices, that I have documented training of staff, and that the answers marked on this form are true and correct.

Date: ____ / ____ / ____

Signature of PIC: _____

Printed Name of PIC: _____