



2023
PHARMACY PRESCRIPTION LOCKER (PPL)
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Oregon law states the pharmacist-in-charge (PIC) and all pharmacists on duty are responsible for ensuring the pharmacy is in compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this form by February 1, 2023, and within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.

The primary objective of this form and your self-inspection is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (Note: Neither the self-inspection nor a Board inspection evaluates compliance with all laws and rules of the practice of pharmacy.) The inspection form also serves as a necessary document used by Board Compliance Officers during an inspection to evaluate a pharmacy's level of compliance.

Following your self-inspection and completion of the form, please review it with staff pharmacists, technicians, and interns, correct any deficiencies noted, sign and date the form and file it in a readily retrievable manner. **DO NOT SEND** the form to the Board office. You are responsible for ensuring the completed form is available at the time of inspection.

Board inspections are not scheduled; therefore, it is common for the PIC to be absent or unavailable at the time of the inspection. For this reason, you are asked to provide a list of the locations of required documents. Having all required documents and records maintained in a well-organized and readily retrievable manner (a binder is recommended) increases compliance and may improve the efficiency of the inspection.

Do not assume that you are in compliance. Please review Board regulations and take the time to personally verify that compliance exists. Email all Compliance related questions to: pharmacy.compliance@bop.oregon.gov.

By answering the questions and referencing the appropriate laws and rules provided, you can determine whether the pharmacy is compliant with many of the rules and regulations. If you have corrected any deficiencies, please write corrected and the date of correction by the appropriate question.

The Board offers a PIC training course. Check the Board website for more information.

Following an inspection, the Compliance Officer may provide a list of observations in the inspection report. An observation is any potential regulatory violations found during the routine inspection.

The Inspection Report will be emailed to the PIC's work email address in 2 to 4 weeks. It should be reviewed, and a copy should be retained with the Self Inspection Report for 3 years as part of the outlet's records.

If in the inspection results in a Deficiency Notification (DN) or a Non-Compliance Notification (NCN), the Compliance Officer will include instructions.

**2023
PHARMACY PRESCRIPTION LOCKER
SELF-INSPECTION FORM**

All PIC's must complete and sign this inspection form and have it available for inspection within 15 days of becoming PIC and by 2/1/2023 (as required by OAR 855-019-0300).

Date PIC Inspection was performed:

PIC Name & License #:

PIC work e-mail:

Pharmacy Prescription Locker (PPL) Name:

Address:

City: State: Zip Code:

PPL Retail Outlet Registration #:

Telephone #: Fax #:

Address:

City: State: Zip Code:

DEA #: Exp:

PPL Affiliated Pharmacy Name:

PPL Affiliated Pharmacy Retail Outlet Registration #:

Please list where the following items are located inside the PPL Affiliated Pharmacy. Be as specific as possible as there can be many filing cabinets and binders. (Records are required to be kept at the PPL Affiliated Pharmacy per [OAR 855-143-0550\(2\)](#))

PIC Self Inspection Reports (Last 3 years):

RPH Counseling Records:

Policies and Procedures

Continuous Quality Improvement Plan:

Current written Drug Outlet Policy Procedures:

Written document designating who is authorized to access the PPL:

In person physical inspection of PPL by pharmacist (Every 28 days):

Training Documents

PPL training program on proper use of PPL:

Board notification of drug loss or suspected theft:

Cold Drug Storage Records

Policies and Procedures:

Temperature logs:

Quarterly validation records:

Drug storage monitoring plan:

Emergency action plan:

The term Pharmacist means Oregon licensed pharmacist

General Requirements

Yes	No		Rule Reference
		1	Is the PPL located in Oregon and registered with the board? OAR 855-143-0010(1)(3)
		2	Does the PPL have an Oregon registered Affiliated Pharmacy and an Oregon licensed PIC? OAR 855-143-0010(1)(3)
		3	Is the PPL's registration displayed at both the PPL and the PPL Affiliated Pharmacy? OAR 855-143-0010(10)
		4	Does the PPL store controlled substances? Note: PPL may not store controlled substances OAR 855-143-0010(2) OAR 855-143-0225
		5	Is the PPL aware that a change of location, ownership, or closure of the PPL or Affiliated Pharmacy requires submission of a new application and board approval? OAR 855-143-0010 OAR 855-143-0015 OAR 855-014-0020 OAR 855-143-0025
		6	Is the PPL aware that the board must be notified by the PPL Affiliated Pharmacy a minimum of 15 days prior to discontinuing operations? OAR 855-143-0025
		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 only prescription, non-prescription drugs, devices, and related supplies <u>from the PPL Affiliated Pharmacy</u> placed in the PPL? OAR 855-143-0120
		9	Does the PPL Affiliated Pharmacy ensure each prescription, prescription refill and drug order is correctly dispensed by the PPL in accordance with the prescribing practitioner's authorization? OAR 855-143-0345(1)
		10	Does the PPL and PPL Affiliated Pharmacy ensure the PPL dispenses prescriptions accurately and to the correct party? OAR 855-143-0345(2)
		11	Does the PPL and PPL Affiliated Pharmacy ensure disasters, accidents and emergencies which may affect the strength, purity OAR 855-143-0130(1)

Yes	No		Rule Reference
		or labeling of drugs or devices are reported to the board immediately?	
		12 Does the PPL and PPL Affiliated Pharmacy ensure that confirmed significant drug loss or any loss related to suspected drug theft is reported to the board within one business day?	OAR 855-143-0130(2)
		13 Does the PPL and PPL Affiliated Pharmacy ensure the PPL is kept clean?	OAR 855-143-0150
		14 Are the PPL 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)
		15 Is the PPL less than 120 miles from PPL Affiliated Pharmacy?	OAR 855-143-0200(3)
		16 Does the PPL and the PPL Affiliated Pharmacy comply with the following? <ul style="list-style-type: none"> • 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 855-019, OAR 855-025, OAR 855-031, OAR 855-041, and OAR 855-143; • Ensure that the PPL Affiliated Pharmacy prevents duplicate dispensing of a prescription; • Comply with all applicable federal and state laws and rules; • Ensure that PPL Affiliated Pharmacy has received and documented consent by the patient or patient's agent for the patient's prescription and non-prescription drugs, devices, and related supplies to be placed in the PPL; • Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all policies and procedures of the PPL; • Designate in writing the Oregon licensed 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, 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; 	OAR 855-143-0200(4)

Yes	No			Rule Reference
			<ul style="list-style-type: none"> • 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 in person 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 records retained. 	

Minimum Equipment, Policy and Procedures and Records

Yes	No			Rule Reference
		17	Does each PPL have appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the PPL outlet?	OAR 855-143-0155(1)
		18	<p>Are Drug Outlet Policies & Procedures compliant with Oregon laws and rules and do they reflect the current practice at the outlet, and do they address the following?</p> <ul style="list-style-type: none"> • Security • Operation, testing, and maintenance of the PPL • Sanitations and cleaning • Storage of drugs • Stocking and destocking • Dispensing • Preventing duplicate dispensing • Oregon licensed Pharmacist supervision, direction, and control of licensed personnel and of accessing of the PPL • Documentation of the identity, function, location, date, and time of licensed personnel accessing the PPL • Utilization of Oregon licensed Pharmacist (i.e. Counseling) • Recordkeeping • Patient consent and confidentiality • On-site inspection by an Oregon licensed Pharmacist • Continuous quality improvements • Plan for discontinuing and recovering services if PPL disruption occurs • Training: initial and ongoing • Interpretation, translation, and prescription reader services <p>Date reviewed with PPL Affiliated Pharmacy staff:</p> <p>* Note this must be completed every 12 months</p>	OAR 855-0143-0200
		19	Does the PPL have appropriate equipment to maintain the proper storage of drugs (e.g., cold drug storage monitoring, ambient temperature monitoring)?	OAR 855-143-0155(1)(b)

Yes	No		Rule Reference
	20	Does the PPL 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?	OAR 855-041-1025 OAR 855-041-1036(1)(d)
	21	<p>Does the PPL contain all required signage in a location that is easily seen by the public, including but not limited to:</p> <ul style="list-style-type: none"> • 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 855-143-0410 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 prescriptions for a patient's self-administration; • Stating "This location is a Pharmacy Prescription Locker, supervised by an Oregon licensed Pharmacist from (insert name of PPL 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 <p>Note: As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPL may display the information required above.</p>	OAR 855-143-0155(1)(c)
	22	Are all required records for the PPL maintained by the PPL Affiliated Pharmacy?	OAR 855-143-0550(2)
	23	<p>Does the PPL Affiliated Pharmacy retain the following records for the PPL?</p> <ul style="list-style-type: none"> • 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 a PPL Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the PPL 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. 	OAR 855-143-0550(3)
	24	Does the PPL Affiliated Pharmacy retain the following dispensing records for the PPL?	OAR 855-143-0550(4)

Yes	No			Rule Reference
			<ul style="list-style-type: none"> 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; 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. 	
		25	<p>Does the PPL Affiliated Pharmacy retain the following for stocking and destocking records for the PPL?:</p> <ul style="list-style-type: none"> 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. 	OAR 855-143-0550(5)

Technology

Yes	No			Rule Reference
		26	Does the PPL and the PPL 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?	OAR 855-143-0205(1)
		27	Does the PPL and the PPL Affiliated Pharmacy utilize barcode, radio-frequency identification or quick response code technology for stocking, destocking, and dispensing at the PPL?	OAR 855-143-0205(2)
		28	<p>Does the PPL and the PPL 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?</p> <p>Note: The PPL Affiliated Pharmacy must make the results of such testing available to the board upon request</p>	OAR 855-143-0205(3)
		29	Has the PPL and the PPL Affiliated Pharmacy developed and implemented a plan for routine maintenance of the PPL?	OAR 855-143-0205(4)

			Are the PPL and the PPL Affiliated Pharmacy enforcing this plan?	
	<input type="checkbox"/>	30	Has the PPL and the PPL Affiliated Pharmacy developed and implemented a plan for responding to and recovering from an interruption of service where the PPL is not fully operational and functioning? Are the PPL and the PPL Affiliated Pharmacy enforcing this plan?	OAR 855-143-0205(5)

Security

Yes		No		Rule Reference
		31	Is the PPL Affiliated Pharmacy, the PPL, Oregon licensed PIC of the PPL 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 loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices, and related supplies?	OAR 855-143-0100(1)
		32	Is the PPL placed in a secure indoor location that is climate controlled and protected from the elements and securely fastened to a permanent structure?	OAR 855-143-0100(2)(a)(b)
		33	Does the PPL utilize a real time alarm system notification system to a Pharmacist when unauthorized access occurs? Note: Per OAR 855-006-0005(2), and "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.	OAR 855-143-0100(7)(a)
		34	Does the PPL utilize an electronic entry system that is controlled by a Pharmacist and includes the following: <ul style="list-style-type: none"> • ID of Pharmacist permitting access • ID of Pharmacist, Intern, or technicians accessing PPL and • Date and time of each activity? 	OAR 855-143-0100(7)(b)(A)(B)
		35	Does the PPL have a surveillance system that utilizes continuously accessible and recorded video between the PPL Affiliated Pharmacy? Is the camera view clear and provides a view of the entire PPL including access points? Note: Per OAR 855-006-0005(51), a "Surveillance system" means a system of video cameras, monitors, recorders, and other equipment used for surveillance	OAR 855-143-0100(7)(C)(c)
		36	Is the PPL only accessed when authorized by Pharmacist in real time?	OAR 855-143-0100(5)
		37	Are Interns, COPTs and PTs only accessing the PPL when authorized in real-time by the Pharmacist supervising them?	OAR 855-143-0100(5)

		38	Are all unlicensed personnel (e.g., machine repair) only able to access the PPL when escorted and continually observed by a licensee who is supervised by a Pharmacist who has authorized access in real-time?	OAR 855-143-0100(6)
		39	Is the PPL secured to prevent access during the following? <ul style="list-style-type: none"> When there is no Oregon licensed 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 	OAR 855-143-0100(3)
		40	Is there a record with the name and Oregon license number for each person permitted to access the PPL?	OAR 855-0143-0100(4)
		41	Are the following security methods utilized? <ul style="list-style-type: none"> PPL has an alarm system with real-time notification to an Oregon licensed Pharmacist of the PPL Affiliated Pharmacy if unauthorized access occurs? Electronic entry system controlled by an Oregon licensed Pharmacist? Electronic entry system records the <ul style="list-style-type: none"> Identification of the Oregon licensed Pharmacist authorizing access and securing the PPL; Identification of the Pharmacist, Intern, COPT, or PT accessing and securing the PPL; and Date and time of each activity; and Surveillance system with continuously accessible and recorded video between the PPL Affiliated Pharmacy and the PPL (The system must provide a clear view of the entire PPL including its access points)? 	OAR 855-0143-0100(7)

Outlet Supervision

					Yes	No	Rule Reference
		42	Are prescription and non-prescription drugs, devices, and related supplies only dispensed if an Oregon licensed Pharmacist is available for patient consultation and the PPL is fully operational?				OAR 855-143-0210(1)
		43	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)
		44	Is an Oregon licensed Pharmacist verifying and documenting the following? <ul style="list-style-type: none"> All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPL Proper storage conditions were maintained during transfer from PPL Affiliated Pharmacy to PPL per OAR 855-143-0125; and Records are maintained per OAR 855-143-0550 				OAR 855-143-0210(3)
		45	Does the PPL and its PPL Affiliated Pharmacy ensure drugs and devices destocked from a PPL that satisfy the requirements of this section may be returned to stock at the PPL Affiliated Pharmacy?				OAR 855-143-0210(4)

Pharmacist

Yes	No		Rule Reference	
		46	Does the PPL and its PPL Affiliated Pharmacy ensure that a prescription drug or device is not released from the PPL until the Oregon licensed Pharmacist or Intern has: <ul style="list-style-type: none">• Provided counseling when required under OAR 855-019-0230 or when requested by the patient or patient's agent; and• Documented the interaction?	OAR 855-143-0215
		47	Does the Pharmacist verify all nonprescription drugs and related supplies prior to placing in the PPL?	OAR 855-143-0220

Drug Storage

Yes	No		Rule Reference	
		48	Does the PPL maintain proper storage of all drugs, including but not limited to the following? <ul style="list-style-type: none">• Are drugs stored according to manufactures published or USP guidelines?• Are drugs stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space?• Are drugs maintained in appropriate storage condition during transfers between facilities and to patients?	OAR 855-143-0125(1)
		49	Does the PPL's drug refrigeration system ensure that the products are maintained 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)
		50	Does the PPL drug refrigeration system utilize a centrally placed, accurate and calibrated thermometer?	OAR 855-143-0125(2)(B)
		51	Is the PPL drug refrigeration system temperature measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature reading?	OAR 855-143-0125(2)(D)

Yes	No		Rule Reference	
		52	<p>Does the PPL and its Affiliated Pharmacy adhere to the following monitoring plan?</p> <ul style="list-style-type: none"> • 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, <ul style="list-style-type: none"> ○ 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; • Routine 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 	OAR 855-143-0125(2)(b)

Prohibited Practices

Yes	No		Rule Reference	
		53	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)
		54	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)
		55	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)
		56	Are controlled substances stored or dispensed in/from a PPL?	OAR 855-143-0600(4)
		57	Are licensees or registrants of the board, who access or interact with the PPL, allowed to disclose patient information to a third party without the consent of the patient except as provided in (2) of this rule?	OAR 855-143-0602(1)
		58	Are licensees or registrants of the board, who access or interact with the PPL, allowed to access patient information other than for the purpose of patient care?	OAR 855-143-0602(3)

I hereby certify that I have verified this outlet is in compliance with all laws and rules, have read and verified that written policies and procedures reflect current practices, have documented training of staff and the answers marked on this form are true and correct.

Signature of PIC:

Printed Name of PIC:

PIC License #:

Date: