

2024 NON-RESIDENT RETAIL DRUG OUTLET SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

- Failure to complete this form by July 1, 2024, and within 15 days of becoming PIC, may result in disciplinary action (OAR 855-115-0210(1)(h)).
- 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)(c)).
- Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years. (OAR 855-115-0205(3)).

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 upon request 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.

Agency Use: 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 if requested by a Compliance Officer.

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

2024 NON-RESIDENT PHARMACY SELF-INSPECTION FORM

A PIC must complete and sign this inspection form and have it avail <u>PIC and by 7/1/2024</u> (as required by <u>OAR 855-115-0210</u>).	able for inspection <u>within 15 days of becoming</u>
Date PIC completed Self-Inspection: / /	
PIC Name:	PIC OR License #:
PIC Work E-mail:	
Pharmacy Name:	
Address:	
City: State:	Zip Code:
Telephone: ()	Fax: ()
State License #: Exp: / / /	
DEA #: Exp: / /	-
OR Retail Drug Outlet Registration #:	Exp: / /
OR Nonprescription Drug Outlet Registration #:	_ Exp: / /
OR Institutional Drug Outlet Registration #:	_ Exp: / /

Hours of operation:

Please note that non-resident pharmacies have a legal obligation to understand and follow Oregon laws and rules when providing medications and/or pharmaceutical care to Oregon patients.

The Board's position is that the Board's regulations apply when a non-resident registrant is providing pharmacy services to patients within Oregon.

Pharmacist:

- Per <u>ORS 689</u>.005(25), "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or to engage in the practice of clinical pharmacy.
- Per <u>OAR 855-115-0001(3)</u>, a pharmacist who is located in another state and who engages in the practice of pharmacy for a patient, drug outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, <u>except that a pharmacist working for an out-of-state pharmacy</u>, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).

Technician:

- Per <u>ORS 689</u>.005(27), "Pharmacy technician" means a person licensed by the board who assists in the practice of
 pharmacy pursuant to rules of the board.
- Per <u>OAR 855-041-3110</u>, an Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:
 - (9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies, and write the date of correction, if applicable.

General Requirements

Rule Reference Yes No OAR 855-104-0010 Are all licensees aware that they must report: 1. Theft or significant loss of a controlled substance to the Board and OAR 855-041-1030 DEA within 1 business day? 21 CFR 1301.76(b) Felony arrests OR convictions, misdemeanor convictions, and . suspected or known violations of state pharmacy laws and rules to the Board within 10 days? Changes in legal name, name used when in pharmacy, preferred email address, personal phone number, physical address, mailing address, and employer within 15 days? (Visit mylicense/eGov to update) Is the PIC/pharmacy aware that when a Board licensee is terminated, OAR 855-041-1010(4) 2. or allowed to resign in lieu of termination, it must be reported to the Board within 10 working days? Note: The report must include the name of licensee, license number, the date, and the reason for the termination. Is the Oregon PIC responsible for all pharmacy services provided to OAR 855-041-1060(4) 3. residents in Oregon including the supervision and control of the pharmacy? Is the Oregon PIC normally present in the pharmacy for a minimum of OAR 855-041-1060(4)(b) 4. 20 hours per week? Is the pharmacy aware that when there is a change in the Oregon PIC OAR 855-041-1060(6) 5. the pharmacy must notify the Board within 10 days and provide the identity of the contact person or new Oregon PIC. Does the pharmacy have a developed, implemented and enforced OAR 855-041-1018(6) 6. continuous quality improvement program for dispensing services that include the following: 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? Does the pharmacy store all records and documents as required by OAR 855-041-1160 7. ORS 475, ORS 689, and OAR 855?

Minimum Equipment, Procedures and Records

Rule Reference Yes No Are drug outlet procedures compliant with Oregon laws and rules OAR 855-041-1040 8. for pharmacy services provided to residents in Oregon? Is the pharmacy aware of the requirement to provide the Board OAR 855-041-1092(4)) 9. written notice of the permanent closing of the pharmacy within 30 calendar days? **Pharmacy Closure Forms** Is the pharmacy clean (refrigerator, sink, reconstitution equipment, OAR 855-041-1015(2) 10. ventilation ducts. etc.)? Does the pharmacy guarantine ALL outdated, damaged. OAR 855-041-1025 11. deteriorated, adulterated, misbranded and suspect product? OAR 855-041-1036(1)(d) 21 USC 351 21 USC 352 Is the pharmacy aware that pseudoephedrine and ephedrine are OAR 855-080-0026 12. Schedule V Controlled Substances in Oregon? How does the pharmacy notify each person in Oregon to whom a OAR 855-041-1131 13. prescription drug is dispensed that a prescription reader is available ORS 689.561 to the person upon request? How does the pharmacy make prescription readers available for visually impaired patients in Oregon at the time of their request? Is the pharmacy using the PDMP Notice by Pharmacies to Patients OAR 333-023-0815 14. language provided by the OHA to notify each patient receiving a controlled substance about the PDMP before, or when, the controlled substance is dispensed to the patient? Note: The notification must include that the prescription will be entered into the PDMP. Is the pharmacy aware that a licensee or registrant of the board who OAR 855-041-1055(1)(2) 15. obtains any patient information MAY NOT disclose that information to a third party without the consent of the patient in Oregon except as provided in (1)(a)-(e) of this rule? A licensee may disclose patient information: (a) To the board: (b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by an Oregon licensed Pharmacist who reasonably

		believes that disclosure is necessary to protect the patient's health or wellbeing; or (c) To a third party when disclosure is authorized or required by law; or (d) As permitted pursuant to federal and state patient confidentiality laws; or (e) To the patient or to persons as authorized by the patient. Is the pharmacy aware that a licensee or registrant of the board <u>MAY</u> <u>NOT access or obtain</u> any patient information unless it is accessed or obtained for the purpose of patient care except as provided in (1)(a)- (e) of this rule?	
	16.	Does the pharmacy follow all DEA requirements for controlled substances?	21 CFR 1300 to end
	17.	 Does the pharmacy ensure that proper storage is maintained for all drugs dispensed to patients in Oregon? This includes, but is not limited to the following: All drugs must be stored according to manufacturer's published or USP standards. All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space. Appropriate storage conditions must be provided for, including during transfers between facilities and to patients. A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Note: A pharmacy must store all drugs at the proper temperature according to manufacturer's published standards (pursuant to FDA label or USP standards).	<u>OAR 855-041-1036</u>

Dispensing

Yes

No

Yes No

Rule Reference

Rule Reference

	18.	Does the pharmacy ensure that prescriptions, prescription refills, and drug orders for patients in Oregon are correctly dispensed in accordance with the prescribing practitioner's authorization?	OAR 855-041-1105(1)
	19.	Does the pharmacy ensure that all prescriptions received for patients in Oregon meet the requirements for a valid and completed prescription per OAR 855-041-1105, OAR 855-041-0115, OAR 855- 115-0130, and ORS 689.525?	OAR 855-041-1105 OAR 855-041-1115 OAR 855-115-0130 ORS 689.525
	20.	Is the pharmacy aware that prescriptions for non-controlled substances are only valid for one year from the date of issue for patients in Oregon?	OAR 855-041-1125
	21.	Is the pharmacy aware that a prescription must not be refilled out of context with the approximate dosage schedule unless specifically authorized by the prescriber for patients in Oregon?	OAR 855-041-1125

Labeling

Yes	No			Rule Reference
		22.	 Do all prescription labels dispensed to patients in Oregon contain the following information: Name, address and telephone number of the pharmacy; Date of fill; Identifying number; Name of patient; Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;; Directions for use by the patient; Name of practitioner; Required precautionary information regarding controlled substances; Cautionary information as required for patient safety; Physical Description of Drug, including any identification code that appears on the tablet or capsule. (This is not required drugs dispensed in for unit of does or unit of use packaging); AND An expiration dates on prescriptions must not exceed: That on the manufacturer's container if dispensed in the manufacturer's container; or The earliest date of either: One year from the date the drug was repackaged and dispensed. 	<u>OAR 855-041-1130</u>
		23.	If the pharmacy is dispensing customized medication packages (patient med pak) to patients in Oregon, does the pharmacy ensure that the expiration date does not exceed 60 days?	OAR 855-041-1140
		24.	For patients in Oregon, are prescription labels available in all 14 languages required by rule and are they made available to the patient if requested by the prescribing practitioner, patient or patient's agent? What is the outlet's process to ensure that these labels are available at the time of request? Note: The prescription must bear a label in both English and the language requested.	<u>OAR 855-041-1132</u> <u>ORS 689.564</u>

Interpretation Services

Yes	No			Rule Reference
		25.	Is the pharmacy aware that for patients in Oregon, a pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Pharmacist is proficient in the preferred language of the person with limited English proficiency? Note: The pharmacist or drug outlet may not charge for these services.	<u>OAR 855-041-1133</u>
		26.	 Is the pharmacy aware that a pharmacist or intern may work with a health care interpreter who is not listed on the health care interpreter registry only if the following apply? Verify that the pharmacist or intern has made a good faith effort needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558 and has found that none are available to provide interpretation; or The patient was offered services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter. 	<u>OAR 855-041-1133</u>
		27.	 Is the pharmacy retaining the following documentation? Each patient encounter in which the pharmacist or intern worked with a health care interpreter from the health care interpreter registry; or Each good faith effort to utilize a health care interpreter from the health care registry for each patient encounter in which the Pharmacist or Intern worked with an interpreter not on the health care interpreter registry and met one of the exceptions in (2) of this rule. Note: These records must include, the full name of the health care interpreter, the health care interpreter, as applicable, and the language interpreted. 	<u>OAR 855-041-1133</u>

Practice of Pharmacy: Pharmacy Services

Yes No Rule Reference Image: Description of the system of the

Rule Reference

	29.	Are pharmacy staff aware that only a pharmacist may perform the	OAR 855-125-0150
	20.	following for patients located in Oregon?Counsel patient or patient agent or provide information to a	<u>ORS 689</u>
		healthcare professional that requires judgment.Perform a drug utilization review,	
		Evaluate and interpret a prescription;	
		 Advise on therapeutic values, content, hazards and use of drugs and devices; 	
		 Interpret the clinical data in a patient record system or patient chart; 	
		 Conduct Medication Therapy Management. 	
	30.	Does the pharmacist make a reasonable effort to obtain, record, and maintain in the patient record the elements required in OAR 855-041-	OAR 855-115-0130(1)(d) OAR 855-041-1165
		1165 including but not limited to patient demographics, preferred	0/11/000/041/11/00
		language for communication, allergies and chronic medical conditions for both new and existing patients in Oregon?	
	31.	How does the pharmacist denote that a new, or refilled, prescription	OAR 855-115-0145
	01.	requires the offer or provision of counseling?	
	32.	Does counseling include all information necessary to promote safe use of the medication or device?	OAR 855-115-0145
		Note: Using their professional judgment, only a pharmacist can determine the manner and amount of counseling that is reasonable	
		and necessary.	
	33.	Are counseling activities (offer, and provision or declination) documented in real-time, including identity of the licensee involved	OAR 855-115-0145(8)
		and the function they provided (provided counseling vs. accepted	
		declination)? Is the outlet aware that a pharmacist who is located in another state	ORS 689.005(28)(29)
	34.	and who engages in the practice of pharmacy for a patient, drug	ORS 689.225
		outlet or healthcare facility in Oregon, must be licensed by the Board in accordance with the following rules, except that a pharmacist	OAR 855-115-0001(3) OAR 855-020
		working for an out-of-state pharmacy, who only performs the	OAR 855-115
		professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in	
		Oregon, is not required to be licensed by the Board unless they are the pharmacist-in-charge (PIC).	
		Note: Activities that require an Oregon pharmacist license include but is not limited to:	
		Collaborative Drug Therapy Management (CDTM),	
		 Medication Therapy management (MTM), Prescribing 	
		Consultation services (except when providing counseling on a	
		prescription that is dispensed by their pharmacy)?	

Yes	No			Rule Reference
		35.	Does the pharmacy comply with the requirement in Division 45 when providing compounded medications to Oregon?	OAR 855-045
			□ N/A	
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.				
Printed	Printed Name of PIC:			

Date: _____ / _____ / _____

Note: Additional <u>Self-Inspection Forms</u> may be required. If the pharmacy is an Affiliated Pharmacy for a:

- Remote Dispensing Site Pharmacy (RDSP) located in Oregon, completion of the RDSP Self-Inspection Form is required.
- Pharmacy Prescription Locker (PPL) located in Oregon, completion of the PPL Self-Inspection From is required.
- Pharmacy Prescription Kiosks (PPK) located in Oregon, completion of the PPK Self-Inspection Form is required.