



2023
NON-RESIDENT RETAIL DRUG OUTLET
SELF-INSPECTION FORM-UPDATE 7/2023

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

This Self- Inspection Form has been updated to reflect rule changes that were adopted at the December 2022, February 2023, April 2023 and June 2023 Board Meetings. Completion of this version (v. 7.2023) is only required with a PIC change.

Per OAR 855-019-0300: Duties of a Pharmacist-in-Charge

(4) The PIC must perform the following duties and responsibilities:

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC

(5) The PIC is responsible for ensuring that the following activities are correctly completed:

(c) Conducting an annual self-inspection of the pharmacy using the annual Self-Inspection Form provided by the board, by July 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion.*

***Please note this rule becomes effective 8/1/2023.** Required completion of the PIC Non-Resident Retail Drug Outlet Self-Inspection Form by July 1 starts in 2024. The Self-Inspection Form due by July 1, 2024 will be released in May of 2024 (v. 5.2024), allowing PICs to complete this form by the annual deadline.

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.)

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 drug outlet 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.

**2023
NON-RESIDENT RETAIL DRUG OUTLET
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 7/1/2024 (as required by OAR 855-019-0300).

Date PIC completed Self-Inspection:

PIC Name:

PIC License #:

PIC **Work** E-mail:

Pharmacy Name:

Address:

City: State: Zip Code:

Telephone: Fax:

DEA #: Exp:

Retail Drug Outlet Registration #:

Nonprescription Drug Outlet Registration #:

Hours of operation:

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 ORS 689.005 (27)** "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 OAR 855-019-0100(4)** 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, except that a pharmacist working in an out-of-state pharmacy, 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 ORS 689.005 (29)** "Pharmacy technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the board.
- **Per OAR 855-041-3110 Remote Processing - General Requirements**
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 or not the drug outlet is compliant. If a response is “No” the PIC must resolve all deficiencies and write the date of correction if applicable.

General Requirements

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	1. Are all pharmacy staff trained appropriately for the practice site and trained prior to engaging in the practice or assistance? Note: This training should include an annual review of the PIC Self-Inspection Report	OAR 855-019-0300(5)(f) OAR 855-041-1018
<input type="checkbox"/>	<input type="checkbox"/>	2. Are all Oregon licensed pharmacists, interns and technicians aware that they must report felony arrests, felony, or misdemeanor convictions and suspected and known violations to the Board within 10 days and suspected or known drug theft within 1 business day? Note: Any theft or significant loss of drug must be reported by the outlet to the Board and DEA within 1 business day. Note: It is the responsibility of the licensee to report any change in email, employment location and home/ mailing address to the Board within 15 days. Visit mylicense/eGov to update.	OAR 855-019-0205 OAR 855-025-0020 OAR 855-031-0020 OAR 855-041-1030 21 CFR 1301.76(b)
<input type="checkbox"/>	<input type="checkbox"/>	3. Is the Oregon PIC responsible for all pharmacy services provided to residents in Oregon including the supervision and control of the pharmacy?	OAR 855-041-1060(4)
<input type="checkbox"/>	<input type="checkbox"/>	4. Is the Oregon PIC normally present in the pharmacy for a minimum of 20 hours per week?	OAR 855-041-1060(4)(b)
<input type="checkbox"/>	<input type="checkbox"/>	5. Is the pharmacy aware that when there is a change in the Oregon PIC the pharmacy must notify the board within 10 days and provide the identity of the contact person or new Oregon PIC.	OAR 855-041-1060(6)
<input type="checkbox"/>	<input type="checkbox"/>	6. Does the pharmacy have a developed, implemented and enforced continuous quality improvement program for dispensing services that include the following: <ul style="list-style-type: none"> • 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 855-041-1018(6)
		7. Does the pharmacy store all records and documents as required by ORS 475, ORS 689, and OAR 855?	OAR 855-041-1160

Minimum Equipment, Procedures and Records

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	8. Are Drug Outlet Procedures compliant with Oregon laws and rules for pharmacy services provided to residents in Oregon?	OAR 855-041-1040
<input type="checkbox"/>	<input type="checkbox"/>	9. Is the pharmacy ensuring accurate hours of operation are on each telephone greeting and pharmacy-operated internet (e.g. website, social media, mobile applications)?	OAR 855-041-1035(1)(h)
<input type="checkbox"/>	<input type="checkbox"/>	10. Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)
<input type="checkbox"/>	<input type="checkbox"/>	11. Does the pharmacy quarantine ALL outdated, damaged, deteriorated, adulterated, misbranded and suspect product?	OAR 855-041-1025 OAR 855-041-1036(1)(d) 21 USC 351 21 USC 352
<input type="checkbox"/>	<input type="checkbox"/>	12. Is the pharmacy aware that pseudoephedrine and ephedrine are Schedule V Controlled Substances in Oregon?	OAR 855-080-0026
		13. How does the pharmacy notify each person in Oregon to whom a prescription drug is dispensed that a prescription reader is available 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?	OAR 855-041-1131 ORS 689.561
<input type="checkbox"/>	<input type="checkbox"/>	14. Is the pharmacy, using language provided by the Oregon Health Authority, notifying each patient in Oregon receiving a controlled substance about the PDMP before or when the controlled substance is dispensed to the patient? Note: The notification shall include that the prescription will be entered into the system.	OAR 333-023-0815
<input type="checkbox"/>	<input type="checkbox"/>	15. Is the pharmacy aware that a licensee or registrant of the board who 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 (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	OAR 855-041-1055(1)(2)

Yes	No			Rule Reference
			<p>(c) To a third party when disclosure is authorized or required by law; or</p> <p>(d) As permitted pursuant to federal and state patient confidentiality laws; or</p> <p>(e) To the patient or to persons as authorized by the patient.</p> <p>Is the pharmacy aware that a licensee or registrant of the board MAY NOT access or obtain any patient information unless it is accessed or obtained for the purpose of patient care except as provided above in (a)-(e) of this rule?</p>	
<input type="checkbox"/>	<input type="checkbox"/>	16.	Does the pharmacy follow all DEA requirements for controlled substances?	21 CFR 1300 to end
<input type="checkbox"/>	<input type="checkbox"/>	17.	<p>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:</p> <ul style="list-style-type: none"> 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. <p>Note: A pharmacy must store all drugs at the proper temperature according to manufacturer's published standards (pursuant to FDA label or USP standards).</p>	OAR 855-041-1036

Dispensing

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	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)
<input type="checkbox"/>	<input type="checkbox"/>	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 855-019-0210, and ORS 689.525?	OAR 855-041-1105 OAR 855-019-0210 OAR 855-041-1115 ORS 689.525
<input type="checkbox"/>	<input type="checkbox"/>	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
<input type="checkbox"/>	<input type="checkbox"/>	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
<input type="checkbox"/>	<input type="checkbox"/>	<p>22. Do all prescription labels dispensed to patients in Oregon contain the following information:</p> <ul style="list-style-type: none"> • 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 date after which the patient should not use the drug or medicine? <p>NOTE: Expiration dates on prescriptions must not exceed:</p> <ul style="list-style-type: none"> • That on the manufacturer's container if dispensed in the manufacturer's container; or • The earliest date of either: <ul style="list-style-type: none"> ○ The manufacturer's expiration date; or ○ One year from the date the drug was repackaged and dispensed. <p>Any drug expiring before the expected length of time for the course of therapy must not be dispensed.</p>	OAR 855-041-1130
		<p>23. Is the pharmacy dispensing customized patient medication packages to patients in Oregon?</p> <p>Note: A pharmacist may, with the consent of a patient or patient caregiver, dispense medication in a patient med pak, which contains two or more prescribed solid oral dosage forms.</p>	OAR 855-041-1140
		<p>24. If the pharmacy is dispensing customized medication packages (patient med pak) to patients in Oregon, does the pharmacy label in compliance with OAR 855-041-1140?</p>	OAR 855-041-1140

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<p>25. 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?</p> <p>What is the outlet's process to ensure that these labels are available at the time of request?</p> <p>Note: The prescription must bear a label in both English and the language requested.</p>	OAR 855-041-1132 ORS 689.564

Interpretation Services

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<p>26. 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?</p> <p>Note: The Pharmacist or drug outlet may not charge for these services.</p>	OAR 855-041-1133
<input type="checkbox"/>	<input type="checkbox"/>	<p>27. 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?</p> <ul style="list-style-type: none"> • 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. 	OAR 855-041-1133
<input type="checkbox"/>	<input type="checkbox"/>	<p>28. Is the pharmacy retaining the following documentation?</p> <ul style="list-style-type: none"> • 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. <p>Note: These records must include, the full name of the health care interpreter, the health care interpreter's registry number, as applicable, and the language interpreted.</p>	OAR 855-041-1133

Practice of Pharmacy: Pharmacy Services

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	29. For patients in Oregon, does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration?	OAR 855-019-0220(3)
<input type="checkbox"/>	<input type="checkbox"/>	30. Are pharmacy staff aware that only a pharmacist may perform the following for patients located in Oregon? <ul style="list-style-type: none"> • Counsel, make the offer to counsel on a new prescription and any changes in therapy, accept a request to not be counseled, release a prescription which requires counseling prior to a pharmacist or intern offering counseling, or document the counseling interaction. • Perform a DUR or any task that requires the professional judgement of a pharmacist • Communicate with patients about their medication in terms of drug class or indicate/use/diagnosis (e.g. when a patient asks for a refill of their “diabetes medication) • Include info about new oral prescriptions and transfers? • Engage in the practice of pharmacy as defined in ORS 689 	OAR 855-025-0040(3)(e) OAR 855-019-0200(2)(3) OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	31. Does the pharmacy capture and maintain allergies and chronic medical conditions for new and existing patients in Oregon?	OAR 855-019-0220(1) OAR 855-041-1165
<input type="checkbox"/>	<input type="checkbox"/>	32. For patients in Oregon, is a pharmacist or intern orally counseling on new and refill prescriptions requiring counseling and including information necessary to promote the safe use of the medication?	OAR 855-019-0230(1)(a) OAR 855-019-0230(2)
		33. For patients in Oregon, how is a new prescription identified as requiring counseling?	OAR 855-019-0230
		34. For patients in Oregon, how does a pharmacist identify a prescription refill as requiring counseling? Note: Using their professional judgment, only a pharmacist can determine if a prescription renewal requires counseling.	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	35. Is the pharmacist/intern personally documenting whether counseling is provided or declined on prescriptions that require counseling at the time of the counseling for patients in Oregon?	OAR 855-019-0230(1)(c)
<input type="checkbox"/>	<input type="checkbox"/>	36. Are pharmacists that provide the following services to patients in Oregon licensed in Oregon: <ul style="list-style-type: none"> • Collaborative Drug Therapy Management (CDTM), • Medication Therapy management (MTM), • Prescribe Naloxone • Consultation services (except when providing counseling on a prescription that is dispensed by their pharmacy)? 	ORS 689.005 (30)(31) ORS 689.225 OAR 855-019-0250 OAR 855-019-0260 OAR 855-020 OAR 855-019-0230

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:

License #:

Date:

If the pharmacy performs any drug compounding for patients in Oregon, you are also required to complete the Compounding Pharmacy Self-Inspection form located on the Board website.

If the pharmacy is an Affiliated Pharmacy for a:

- **Remote Dispensing Site Pharmacy (RDSP) located in Oregon please complete the RDSP Self-Inspection form located on the Board Website.**
- **Pharmacy Prescription Locker (PPL) located in Oregon please complete the PPL Self-Inspection form located on the Board Website.**
- **Pharmacy Prescription Kiosks (PPK) located in Oregon please complete the PPK Self-Inspection form located on the Board Website.**