



2022
NON-RESIDENT PHARMACY
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Please complete this report by February 1, 2022. Failure to complete this form by February 1, 2022, may result in disciplinary action (OAR 855-041-1060(4)(c)).

The PIC must perform an annual inspection of this outlet and document it by completing this report. Following your self-inspection and completion of the form, please review it with your staff, sign, and date the report, and file it in a readily retrievable manner. Do not mail to the Board office unless you are asked to do so.

The primary objective of this form, and your self-inspection, is to provide an opportunity to identify and correct areas to ensure compliance with federal and state law. (Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy.) The Board understands that regulations may sometimes appear confusing and open to different interpretations.

Do not assume that you are in compliance. Please review Board regulations and take the time to personally verify that compliance exists. If you have any questions, please **email** your question(s) to pharmacy.compliance@bop.oregon.gov. (Note: The Board does not provide individualized legal advice on how the law applies to practice in the field. You may also want to contact a qualified attorney.)

By answering the questions and referencing the appropriate laws and rules provided, you can determine whether you are 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.

**2022
NON-RESIDENT PHARMACY
SELF-INSPECTION FORM**

All PICs of non-resident pharmacies MUST complete and sign this inspection form and have it available for inspection within 15 days of becoming the Oregon PIC and by 2/1/2022 (as required by OAR 855-019-0300 and OAR 855-041-1060(4)(c)).

Date PIC Inspection was performed: _____

PIC Name & Oregon License #: _____

PIC e-mail: _____

Pharmacy: _____

Telephone: _____ Fax: _____ Address: _____

DEA #: _____ Exp: _____ Institutional Outlet Registration #: _____

Retail Outlet Registration #: _____ Nonprescription Drug Outlet Registration #: _____

State license #: _____ NABP #: _____

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.

Yes	No	N/A		Rule Reference	
			1	How many prescriptions did this pharmacy send to Oregon patients during the last calendar year?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2	Is the pharmacy compliant with the Oregon requirements for counseling and documentation of counseling?	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3	Is the pharmacy compliant with the Oregon requirements to have final verification of medications performed by a pharmacist? How is this performed at the pharmacy?	OAR 855-019-0200(2) OAR 855-006-0005(32)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4	Does the pharmacy have access to the Oregon Board of Pharmacy's laws and rules, and a minimum of three years of the Oregon Board of Pharmacy/NABP quarterly newsletters?	OAR 855-041-1035(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5	Does the pharmacy dispense medications to patients with the required Product Identification Label?	OAR 855-041-1130(1)(k)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6	Is the pharmacy aware that pseudoephedrine and ephedrine has moved from a Schedule III to a Schedule V Controlled Substance?	OAR 855-080-0026
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7	Is the pharmacy providing nonprescription pseudoephedrine and ephedrine to patients over the counter?	OAR 855-080-0026

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>If yes, are the following requirements met:</p> <ul style="list-style-type: none"> • Store all pseudoephedrine and ephedrine behind the pharmacy counter (inaccessible to the public) • Utilize an electronic system meeting the requirements specified in <u>2021 HB 2648</u> • Train staff on the requirements of the: <ul style="list-style-type: none"> ○ Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, <u>P.L. 109-177</u>), ○ Combat Methamphetamine Enhancement Act of 2010, <u>P.L. 111-268</u>, an ○ Use of the electronic system as described in 2021 HB 2648 • Ensure only a pharmacist or pharmacy technician participates in the sale • Ensure that all requirements of sale are met: <ul style="list-style-type: none"> ○ Verify purchaser is 18 years or older ○ Verify identity of purchaser with valid government issued ID ○ Confirm the purchase is permitted via the electronic system ○ Document the purchase with required information • All sales are subject to quantity limit restrictions: <ul style="list-style-type: none"> ○ No more than 3.6 grams in 24-hour period and 9 grams in a 30-day period <p>Note: Interns and clerks may not sell nonprescription pseudoephedrine and ephedrine</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>8 Does the pharmacy participate in the Oregon Prescription Drug Monitoring Program (PDMP) and upload all controlled substance dispensing data to the program? Update: effective 1/1/2020-gabapentin and naloxone dispensing must be reported to PDMP.</p> <p>Is the pharmacy, using language provided by the OHA, notifying each Oregon patient receiving a controlled substance about the PDMP before or when the controlled substance is dispensed to the patient? The notification shall include that the prescription will be entered into the system.</p>	<p>ORS 431A.860</p> <p>OAR 333-023-0810</p> <p>OAR 333-023-0815</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>9 When no pharmacist is physically present in the pharmacy or institutional facility, is the pharmacy/prescription area (including pharmacy records and computers) secured to prevent entry?</p>	<p>ORS 689.486</p> <p>OAR 855-041-1020</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>10 Do technicians process/receive prescriptions before a pharmacist arrives or after the pharmacist leaves?</p> <p><i>Note: This is not permitted.</i></p>	<p>ORS 689.486(6)</p> <p>OAR 855-006-0005(29)</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>11 How does the pharmacy maintain the security of controlled substances and follow state and federal regulations for inventory requirements?</p>	<p>OAR 855-080-0065</p> <p>OAR 855-080-0070</p>

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12	Are staff members performing only the duties they are trained and licensed to perform?	OAR 855-019-0300(5)(f) OAR 855-041-1040(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13	Is the PIC normally present at least 20 hours per week? <i>Note: This is an Oregon requirement.</i>	OAR 855-041-1060(4)(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14	Does the pharmacy provide prescription readers for visually impaired patients? Are prescription readers available and appropriate to address a person's visual impairment?	OAR 855-041-1131 ORS 689.561
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15	Are directions for use on prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent? If not, anticipated date of compliance?	OAR 855-041-1132 ORS 689.564
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16	Does the pharmacy perform any drug compounding? If yes, PIC must also complete the Compounding Self-Inspection form located on the Board website.	OAR 855-019-0300
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17	Does the pharmacy use marketers or third-party companies to direct prescriptions to this pharmacy? Do prescriptions come directly to the pharmacy from the prescriber or are they routed from a third party?	ORS 475.188
			18	List of all outlets that the pharmacy receives drug from:	

Telework

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19	Do pharmacy staff (Pharmacists, Interns or COPT) work on Oregon patients from a location physically outside of the pharmacy (i.e. their home)? Note: This is considered telework at a telework site by the board. <ul style="list-style-type: none"> If the answer is No, please proceed to the signature portion of the document. 	OAR 855-041-3205
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20	Does the pharmacy ensure that? <ul style="list-style-type: none"> Only OR licensed Pharmacists, Interns, and COPTs (with at least one year of experience) are providing pharmacy services to Oregon patients All licensees comply with applicable federal and state laws and rules; and NO DRUGS or DEVICES are permitted at a telework site 	OAR 855-041-3215 OAR 855-041-3235

Yes No N/A

Rule Reference

			21	How does the PIC and Pharmacists ensure the supervision, direction, and control of COPTs?	OAR 855-041-3215 OAR 855-041-3220
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22	Does the pharmacy have a written agreement that includes all condition, duties and policies governing the licensee engaged in telework activities?	OAR 855-041-3215 OAR 855-041-3245
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23	Does the pharmacy maintain a continuously updated list of all licensees engaged in telework and the Telework Sites that includes all of the following: <ul style="list-style-type: none"> • Address and phone number where telework is performed for each Telework Site? • Functions being performed by licensees engaged in telework? • The Pharmacist providing supervision, direction, and control for each non-pharmacist licensee? 	OAR 855-041-3215 OAR 855-041-3250
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24	Are all of the following supervision requirements met when providing pharmacy services for Oregon patients? <ul style="list-style-type: none"> • Utilize technology that enables real-time audio and visual connections and interface to allow access to information required to complete assigned duties • Ensure telephone audio is recorded, reviewed, and stored, for all patient interactions completed by each Intern and COPT • Ensure a pharmacist is supervising, directing, and controlling each Intern and COPT and that the continuous audio/visual connection is fully operational • Ensure that a Pharmacist using professional judgment, determines the frequency of "checkins" for each licensee being supervised via the real-time audio and visual connection with a minimum of at least once per work shift, and documents the interaction • Ensure a pharmacist is readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and • Ensure the Intern or COPT knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction, and control at all times • Provide adequate staff to allow the pharmacist to complete required technician reviews 	OAR 855-041-3220
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25	Are all of the following supervision requirements met by the Pharmacist when providing pharmacy services for Oregon patients? <ul style="list-style-type: none"> • Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed • Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request • Document the following within 48 hours of the review in 	OAR 855-041-3220

				<ul style="list-style-type: none"> ○ Number of each licensee's patient interactions; ○ Number of each licensee's patient interactions pharmacist is reviewing; ○ Date and time of licensee patient interaction pharmacist is reviewing; ○ Date and time of pharmacist review of licensee's patient interaction; and ○ Pharmacist notes of each interaction reviewed; and ● Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 48 hours of discovery and to the board within 10 days 	
			26	<p>How does the pharmacy ensure patient confidentiality?</p> <p>Note: All computer equipment used at the Telework Site must:</p> <ul style="list-style-type: none"> ● Establish and maintain a secure connection to the pharmacy and patient information; ● Utilize equipment that prevents unauthorized access to the pharmacy and patient information; ● Be configured so that the pharmacy and patient information is not accessible when <ul style="list-style-type: none"> ○ There is no Pharmacist actively supervising ○ There is no licensee at the telework site ○ When any component of the real-time audio-visual connection is not functioning ● Comply with security and confidentiality requirements 	OAR 855-041-3225 OAR 855-041-3240
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27	Is a COPT or Intern able to access the pharmacy and patient information when a pharmacist is not actively supervising?	OAR 855-041-3240
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28	<p>Are the following technology requirements met when providing pharmacy services for Oregon patients?</p> <ul style="list-style-type: none"> ● Test the continuous audio and visual connection and document that it operates properly before engaging in telework. ● Develop, implement, and enforce a plan for responding to and recovering from an interruption of service which prevents a pharmacist from supervising, directing, and controlling the Intern and COPT at the Telework Site ● Ensure access to: <ul style="list-style-type: none"> ○ Appropriate and current pharmaceutical references based on the services offered; and ○ Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters. ● Train the Pharmacists, Interns and COPT in the operation of continuous audio and visual connection 	OAR 855-041-3230

Yes No N/A

Rule Reference

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29	<p>If a pharmacist is performing verification via telework, are all of the following requirements met when providing pharmacy services for Oregon patients?</p> <ul style="list-style-type: none">• Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each<ul style="list-style-type: none">○ Source container including manufacturer, name, strength, lot, and expiration date;○ Dispensed product including the imprint and physical characteristics;○ Completed prescription container including the label; and○ Ancillary document provided to patient at the time of dispensing	OAR 855-041-3230(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30	<p>Does each Pharmacist determine and document how many licensed individuals they are capable of supervising, directing, and controlling?</p> <p>Note: When supervising an Intern or CPT working at a Telework Site, the Pharmacist may supervise no more than four licensees among all locations, including the Pharmacy.</p>	OAR 855-041-3235
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31	<p>Are all records maintained with in the requirements of OAR 855-041-3250?</p>	OAR 855-041-3250

Print PIC name: _____

Signature of the PIC _____ Date: _____