



**2023
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 the 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 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.) 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 completion of the self-inspection 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.

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 statutes and rules. 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. Please review the report. If observations are documented on the report, you will be provided with further instructions. Retain a copy of the inspection report for 3 years.

**2023
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:

Please specifically list where the following items are located inside the pharmacy. [OAR 855-001-0040](#) states all records are required to be stored on-site and **MUST be provided to the board immediately upon request at the time of inspection.**

PIC Inspection Reports for the last 3 years:

Quarterly PIC Compliance Audit Forms (if applicable):

CDTM Agreements:

Policies and Procedures

Current Drug Outlet Procedures:

CDTM:

Diversion; Prevention and Supporting Drug Security Documentation:

Drug Take Back Kiosk:

Interpretation Services:

Label Translation (LEP) Services:

Prescription Reader Services:

Telework:

Training Documents

Drug Storage Training Documents:

Initial and annual technician training documents:

Telework:

Controlled Substances

Current written annual controlled substance inventory:

Schedule II invoices for the last 3 years:

Schedule III-V invoices for the last 3 years:

Completed CII order forms (DEA form 222) for last 3 years:

Quarterly CII reconciliations with detailed explanations of all variances:

Immunization Records

Vaccine administration records:

Vaccine Adverse Event Protocol and dedicated supplies:

Current CPR Cards & Immunization Certification documents:

Cold Drug Storage Records

Policies and Procedures:

Temperature logs:

Quarterly validation records:

Drug storage monitoring plan:

Emergency action plan:

Telework Records

Telework written agreement:

Telephone Audio Recordings:

Documentation of patient interactions reviewed:

Still image captures or store and forward prescription information:

Prescriptive Authority

Policies and procedures:

Pharmacist prescribing records:

Training documentation:

****Compounding documentation records are requested on the Compounding Self-Inspection form that must be completed if the pharmacy is performing compounding****

You are required to confirm whether or not the outlet is compliant and mark the appropriate box to the left of each item. 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? Note: This training should include an annual review of the PIC Self-Inspection Report	OAR 855-019-0300(5)(f)
<input type="checkbox"/>	<input type="checkbox"/>	2.	Are all pharmacy staff aware that Compliance Officers must be permitted to perform the following: <ul style="list-style-type: none">Inspecting conditions, structures, equipment, materials, and methods for compliance;Inspecting all drugs and devices;Taking photographs, recording video and audio; andReviewing, verifying, and making copies of records and documents. Note: <ul style="list-style-type: none">All records must be stored as required by ORS 475, ORS 689, and OAR 855.Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection.May be stored in a secured off-site location after 12 months of on-site storage, must be provided to the board upon request within three business days.	OAR 855-001-0040

Yes	No		Rule Reference
		3. How many pharmacies is the PIC the PIC for? Note: A pharmacist may not be designated PIC of more than three pharmacies without prior written approval by the board. This does not include a Pharmacy Prescription Locker (PPL) or a Pharmacy Prescription Kiosk (PPK).	OAR 855-019-0300(3)
<input type="checkbox"/>	<input type="checkbox"/>	4. Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615
<input type="checkbox"/>	<input type="checkbox"/>	5. Are pharmacists, technicians, and interns 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 and 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"/>	6. Is the PIC/pharmacy aware that a resident pharmacy that terminates or allows a Board licensee to resign in lieu of termination must report the termination or resignation to the Board within 10 working days?	OAR 855-041-1010(2)

Minimum Equipment, Procedures and Records

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	7. Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet? Items to be addressed: <ul style="list-style-type: none"> • Security; • Operation, testing and maintenance of pharmacy systems and equipment; • Sanitation; • Storage of drugs • Dispensing; • Pharmacist supervision, direction, and control of non-Pharmacists; • Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process; • Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians; • Certified Oregon Pharmacy Technician or Pharmacy Technician 	OAR 855-041-1040

Yes	No		Rule Reference
		final verification, if utilized; <ul style="list-style-type: none"> • Drug and/or device procurement • Receiving of drugs and/or devices; • Delivery of drugs and/or devices; • Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling); • Recordkeeping; • Patient confidentiality; • Continuous quality improvement; <ul style="list-style-type: none"> • Plan for discontinuing and recovering services in the event of closure; • Training: initial and ongoing, and • Interpretation, translation, labeling and prescription reader services 	
<input type="checkbox"/>	<input type="checkbox"/>	8. Does the PIC prepare and maintain written procedures that describe the tasks that may be performed by technicians, including the methods of verification and documentation of work performed by technicians?	OAR 855-025-0025(5)
<input type="checkbox"/>	<input type="checkbox"/>	Does the PIC review the written procedures annually?	
<input type="checkbox"/>	<input type="checkbox"/>	9. Is the pharmacy providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100?	OAR 855-041-1035(1)(g)(C)
<input type="checkbox"/>	<input type="checkbox"/>	10. Is the pharmacy providing notification of accurate hours of operation at each pharmacy entrance?	OAR 855-041-1035(1)(g)(E)
<input type="checkbox"/>	<input type="checkbox"/>	11. 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"/>	12. Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)
<input type="checkbox"/>	<input type="checkbox"/>	13. Does the pharmacy quarantine ALL outdated, damaged, deteriorated, adulterated, misbranded and suspect product? Where are drugs quarantined?	OAR 855-041-1025 OAR 855-041-1036(1)(d) 21 USC 351 21 USC 352
<input type="checkbox"/>	<input type="checkbox"/>	14. Is the pharmacy aware that a Drug Take Back Box may be requested free of charge?	https://www.oregon.gov/deq/Hazards-and-Cleanup/hw/Pages/drugtakeback.aspx
<input type="checkbox"/>	<input type="checkbox"/>	15. Is the pharmacy registered with the DEA as an authorized collector for drug take back disposal?	OAR 855-041-1046

			<p>If yes, are the following requirements met?</p> <ul style="list-style-type: none"> • Notify BOP within 30 days of initiating or terminating program • Receptacle stored in secured location, which is accessible to the public, inside the retail drug outlet, and within the view of the pharmacy counter but NOT behind the pharmacy counter • Adequate security measures for proper installation and maintenance of the collection receptacle, tracking of liner, documentation, and key accountability maintained • Appropriate training and accountability provided to all parties involved in maintaining the drug take back disposal box 	21 CFR1317
<input type="checkbox"/>	<input type="checkbox"/>	16.	<p>Is the pharmacy aware that pseudoephedrine and ephedrine is a Schedule V Controlled Substance?</p>	OAR 855-080-0026
<input type="checkbox"/>	<input type="checkbox"/>	17.	<p>Is the pharmacy providing non-prescription pseudoephedrine and ephedrine to patients over the counter?</p> <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 ORS 475.230 • 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, P.L. 109-177), ○ Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and ○ Use of the electronic system as described in ORS 475.230. ○ Ensure only a pharmacist, intern or 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 ○ Maintain an electronic log for at least three years from the date of the transaction that documents the following elements: <ul style="list-style-type: none"> ▪ (A) Date and time of the purchase; ▪ (B) Name, address, and date of birth of the purchaser; ▪ (C) Form of government-issued photo identification and the identification number used to verify the identity of the purchaser; ▪ (D) Name of the government agency that issued the photo identification in (C); ▪ (E) Name of product purchased; ▪ (F) Quantity in grams of product purchased; ▪ (G) Name or initials of Pharmacist, Intern, Certified Oregon Pharmacy Technician or 	OAR 855-080-0026 2022 HB 4034 Section 1 ORS 475.230

Yes No

Rule Reference

			<p>Pharmacy Technician who provides the drug; and</p> <ul style="list-style-type: none"> ▪ (H) Signature of the purchaser. The signature of the purchaser may be recorded on a written log that also contains the transaction ID generated by the electronic system. <ul style="list-style-type: none"> • All sales of pseudoephedrine or ephedrine 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 • Only licensed personnel (i.e. Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician) may sell non-prescription pseudoephedrine or ephedrine to the purchaser <p>Note: Non-licensed personnel may not sell nonprescription pseudoephedrine and ephedrine</p>	
<input type="checkbox"/>	<input type="checkbox"/>	18.	<p>Are prescription labels available, if requested by a patient or patient's agent, in the required 14 languages?</p> <p>Note: The prescription must bear a label in both English and the language requested.</p>	<p>OAR 855-041-1132 ORS 689.564</p>
<input type="checkbox"/>	<input type="checkbox"/>	19.	<p>Does the pharmacy have signage easily seen by the public which provides patient notification in each language required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels?</p> <p>Dual Language Labeling Sign for Pharmacies</p>	<p>OAR 855-041-1035 (1)(e)(B) OAR 855-041-1133</p>
		20.	<p>How does the pharmacy notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request?</p>	<p>OAR 855-041-1131 ORS 689.561</p>
<input type="checkbox"/>	<input type="checkbox"/>	21.	<p>Is the pharmacy using language provided by the OHA to notify each patient receiving a controlled substance about the PDMP before or when a controlled substance is dispensed to the patient?</p> <p>Note: The notification shall include that the prescription will be entered into the system.</p>	<p>OAR 333-023-0815</p>
<input type="checkbox"/>	<input type="checkbox"/>	22.	<p>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 except as provided in (a)-(e) of this rule?</p> <p>A licensee may disclose patient information:</p> <p>(a) To the board;</p>	<p>OAR 855-041-1055(1)(2)</p>

Yes	No		Rule Reference
		<p>(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</p> <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>	

Pharmacy Closures: Temporary and Permanent

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<p>23. Is the pharmacy aware of and following the requirements to post notification of closure on each pharmacy entrance, telephone greeting and pharmacy operated internet (e.g., website, social media, mobile applications) as soon as possible for a temporary pharmacy closure?</p>	OAR 855-041-1092(1)
<input type="checkbox"/>	<input type="checkbox"/>	<p>24. Is the pharmacy aware and following the requirements to notify the board and public of permanent closures?</p> <ul style="list-style-type: none"> • Prior to closing, the pharmacy must: <ul style="list-style-type: none"> ○ Provide notification to each patient who has filled a prescription within the previous 12 months. ○ Notify DEA of any controlled substances being transferred to another registrant as specified in 21 CFR 1301.52 (04/01/2021). • On the date of closing or up to 24 hours after the permanent closure begins, the PIC must: <ul style="list-style-type: none"> ○ Complete and document an inventory of all controlled substances. ○ If the pharmacy dispenses prescriptions: <ul style="list-style-type: none"> ▪ Transfer the prescription drug order files and patient medication records to a licensed pharmacy or to an Oregon licensed Pharmacist who will serve as the custodian of records; ▪ Update the pharmacy operating status with each electronic prescribing vendor; and ▪ Remove all signs and symbols indicating the presence of the pharmacy. • After closing. Within 30 calendar days after the closing of the pharmacy, the PIC must complete the requirements in OAR 	OAR 855-041-1092(2)

Yes	No	Rule Reference
		855-041-1092 and provide the board a written notice of the closing on the board prescribed form.

Interpretation Services

Yes	No	Rule Reference	
		<p>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?</p> <p>Note: The Pharmacist or drug outlet may not charge for these services.</p>	OAR 855-041-1133
		<p>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?</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
		<p>27. 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

Controlled Substances

Yes	No	Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	28. Is the pharmacy identifying and CLEARLY DOCUMENTING AND EXPLAINING ALL VARIANCES on CII reconciliations?	OAR 855-019-0300(5)(e)(h)

Yes	No		Rule Reference
		<p>Note: The Board considers a reconciliation to be an accurate <u>accounting</u> of the outlet's true inventory, performed at least quarterly.</p> <p>If these records are maintained electronically, they must be accessible and producible at the time of inspection (audit, variances, and explanations or documentation showing that no discrepancies were identified).</p> <p>Note: Providing the count at the time of the reconciliation is not sufficient to meet this requirement. Working copies or documentation showing the audit and all variance explanations for all CII's must be kept and will be requested for review at time of inspection.</p>	
<input type="checkbox"/>	<input type="checkbox"/>	29.	<p>Is the PIC/pharmacy reporting the theft or significant loss of a controlled substance to the Board and DEA within 1 business day?</p> <p>OAR 855-019-0205(6) OAR 855-041-1030 21 CFR 1306.76(b)</p>
<input type="checkbox"/>	<input type="checkbox"/>	30.	<p>Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory?</p> <p>Date of last annual CII-V inventory:</p> <p>Note:</p> <ul style="list-style-type: none"> • Inventory includes drugs in LTC e-kits, drugs used for compounding, items in the refrigerator, automated dispensing machines, outdated controlled substances. • 24-hour pharmacies must indicate the time frame in which the inventory was completed. Non 24-hour pharmacies must indicate if the inventory was completed before opening or after closing. <p>OAR 855-080-0070</p>
<input type="checkbox"/>	<input type="checkbox"/>	31.	<p>Is the annual CII inventory filed separately from the CIII-CV inventory and are CII invoices and prescriptions filed separately from other prescriptions and invoices?</p> <p>21 CFR 1304.04</p>
		32.	<p>How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?</p> <p>OAR 855-041-1020</p>

Security

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	33.	<p>When there is no pharmacist present, is the pharmacy secured to prevent entry?</p> <p>Note: <u>Computers, records and medications must be properly secured to prevent entry and access to records by non-pharmacist employees.</u></p> <p>OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1)</p>

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	34.	Is the pharmacy only operated when a pharmacist licensed to practice in this state is present? Note: Non-pharmacist staff may not process/receive prescriptions or access records before a pharmacist arrives or after the pharmacist leaves.	OAR 855-041-1020(3) OAR 855-041-1015(1)
<input type="checkbox"/>	<input type="checkbox"/>	35.	Does the pharmacist ensure the security of the pharmacy area including: <ul style="list-style-type: none"> • Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs; • Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules; • Ensuring that only a Pharmacist has access to the pharmacy when the pharmacy is closed. 	OAR 855-019-0200(4)(i)

Support Personnel

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	36.	Are pharmacists, interns and technicians clearly identified as such to the public?	OAR 855-025-0025(3)
<input type="checkbox"/>	<input type="checkbox"/>	37.	Are technicians completing initial training that includes on-the-job and related education that is commensurate with the tasks that the technician will perform, prior to the performance of those tasks? Is the outlet providing initial and ongoing technician training to ensure the continuing competency of Certified Oregon Pharmacy Technicians and Pharmacy Technicians?	OAR 855-025-0025(6)
<input type="checkbox"/>	<input type="checkbox"/>	38.	Does each technician know at all times the pharmacist that is supervising, directing, and controlling them?	ORS 689.486 OAR 855-025-0023(2)(c)
<input type="checkbox"/>	<input type="checkbox"/>	39.	Is pharmacy staff aware that technicians and non-licensed personnel are not permitted to perform the following: <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) • 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"/>	40.	Is all work performed by a technician that requires judgment verified by a pharmacist? How is the pharmacist's verification of a technician's work documented?	OAR 855-025-0025(4) OAR 855-019-0200

Pharmacists

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	41.	Is each pharmacist aware they are required to control each aspect of the practice of pharmacy? OAR 855-019-0200(4)(b)
<input type="checkbox"/>	<input type="checkbox"/>	42.	Does each pharmacist know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction, and control at all times? OAR 855-019-0200(4)(e)
<input type="checkbox"/>	<input type="checkbox"/>	43.	Does each pharmacist ensure that the supervision of non-Pharmacist personnel does not exceed their capacity to supervise based on the workload and services being provided? OAR 855-019-0200(4)(f)
<input type="checkbox"/>	<input type="checkbox"/>	44.	Is the pharmacy aware that only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require reasonable professional judgment of a Pharmacist include but are not limited to: <ul style="list-style-type: none"> • Drug Utilization Review; • Counseling; • Drug Regimen Review; • Medication Therapy Management; • Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement; • Practice pursuant to State Drug Therapy Management Protocols; • Prescribing a drug or device, as authorized by statute; • Ordering, interpreting, and monitoring of a laboratory test; • Oral receipt or transfer of a prescription; and • Verification of the work performed by those under their supervision OAR 855-019-0200(3)
<input type="checkbox"/>	<input type="checkbox"/>	45.	Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration? How is this DUR documented? OAR 855-019-0220(3)
<input type="checkbox"/>	<input type="checkbox"/>	46.	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients? OAR 855-019-0220(1) OAR 855-041-1165
<input type="checkbox"/>	<input type="checkbox"/>	47.	Does the PIC verify that policies and procedures are followed to ensure that prescriptions are correctly dispensed? OAR 855-041-1105 OAR 855-019-0210(1)
<input type="checkbox"/>	<input type="checkbox"/>	48.	When pharmacists or interns receive a telephone prescription, are they documenting their name, the date and the name of the person transmitting the prescription? OAR 855-019-0210 OAR 855-041-1105
<input type="checkbox"/>	<input type="checkbox"/>	49.	Does the pharmacist and pharmacy ensure each prescription is correctly dispensed and in accordance with the prescribing practitioner's authorization? OAR 855-041-1105

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	50.	<p>Is a pharmacist ensuring each prescription is dispensed with a correct expiration date?</p> <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(10)(11) OAR 855-019-0210
<input type="checkbox"/>	<input type="checkbox"/>	51.	<p>Are all dispensed prescription medication, other than those in unit dose or unit of use packaging, labeled with its physical description, including any identification code that may appear on tablets and capsules?</p>	OAR 855-041-1130(12)
<input type="checkbox"/>	<input type="checkbox"/>	52.	<p>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?</p>	OAR 855-019-0230(1)(a) OAR 855-019-0230(2)
		53.	<p>How is a new prescription identified as requiring counseling?</p>	OAR 855-019-0230
		54.	<p>How does a pharmacist identify a prescription refill as requiring counseling?</p> <p>Note: Using their professional judgment, only a pharmacist can determine if a prescription renewal requires counseling.</p>	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	55.	<p>Is the pharmacist/intern documenting whether counseling is provided or declined on prescriptions that require counseling at the time of the counseling?</p>	OAR 855-019-0230(1)(c)

Drug Storage

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	56.	<p>Does each active cold storage system maintain the temperature of refrigerated products between 2-8°C (35-46°F) and frozen products between -25 to -10°C (-13 to 14°F) <u>or as specified by the manufacturer?</u></p> <p>Note: A temperature excursion occurs when any temperature reading is outside the recommended range for a drug as defined by the manufacturer.</p>	OAR 855-041-1036 (2)(a)(A)

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	57.	<p>Are the thermometers/probes centrally placed, accurate and calibrated?</p> <p>When is the next <u>calibration due</u> (to ensure temperature readings are correct)?</p>	OAR 855-041-1036(2)
<input type="checkbox"/>	<input type="checkbox"/>	58.	Is there documented training for ALL pharmacy personnel related to the drug storage monitoring plan?	OAR 855-041-1036(2)
<input type="checkbox"/>	<input type="checkbox"/>	59.	<p>Do all explanations and documentation of ALL drug storage excursions include at least all the following?:</p> <ul style="list-style-type: none"> • The event date & time frame; • The name of person(s) involved in response; • Pharmacist review of duration and variance; • Action(s) taken <ul style="list-style-type: none"> ○ The decision to quarantine product for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; ○ This documentation must include details of the information source • Which pharmacist made the final decision 	OAR 855-041-1036(2)(b)(D-E)

Vaccine Drug Storage N/A

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	60.	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator?	OAR 855-041-1036(3) (a)(A)
<input type="checkbox"/>	<input type="checkbox"/>	61.	Does each active vaccine storage unit utilize a system of <i>continuous</i> temperature monitoring with automated data logging?	OAR 855-041-1036(3)(d)
<input type="checkbox"/>	<input type="checkbox"/>	62.	<p>Does the pharmacy conduct quarterly validations of EACH <u>vaccine</u> storage unit and their monitoring equipment?</p> <p>When is the next validation due?</p> <p>Note: Quarterly validations are not the same as the thermometer calibrations</p>	OAR 855-041-1036(3) (a)(D)

Vaccine Administration N/A
Prescriptive Authority is per OHA vaccine protocol

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	63.	Do all immunizing pharmacists/interns have a current CPR card intended for healthcare providers that contains a hands-on training component and is valid for not more than three years?	OAR 855-019-0270 OAR 855-019-0290(3)

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	64.	Does the pharmacy have the required equipment and supplies for managing adverse events? Note: Please see OHA Oregon Pharmacy Protocols for Immunization for current Guidelines for managing adverse events.	OAR 855-019-0270
<input type="checkbox"/>	<input type="checkbox"/>	65.	Does each pharmacist check ALERT as required by OHA Immunizations protocols?	OAR 855-019-0290
<input type="checkbox"/>	<input type="checkbox"/>	66.	Is the pharmacist/intern who administers any vaccine recording and maintaining the following information: <ul style="list-style-type: none"> Name, address, gender, date of birth of the patient and phone number when available; Date of administration; Injection site; Vaccine name, dose, manufacturer, lot number and expiration date; Identity of administering pharmacist; The date of the publication of the VIS; and the date the VIS was provided? 	OAR 855-019-0290

Final Verification N/A

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	67.	Are the pharmacy and staff aware that “final verification” means, after prescription information is entered into a pharmacy’s electronic system and reviewed by a pharmacist for accuracy, a physical verification that the drug and drug dosage, device or product selected from a pharmacy’s inventory pursuant to the electronic system entry <u>is the prescribed drug and drug dosage, device, or product.</u>	ORS 689.005 OAR 855-005-0006(18) OAR 855-019-0200(5)(6) OAR 855-025-0023(4)
<input type="checkbox"/>	<input type="checkbox"/>	68.	If the pharmacist chooses to delegate final verification to a technician, has the pharmacist used their reasonable professional judgment in making this determination? Note: <ul style="list-style-type: none"> Only the PHARMACIST may delegate “final verification” “Reasonable professional judgment” means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion. 	OAR 855-005-0006(43) OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
<input type="checkbox"/>	<input type="checkbox"/>	69.	Does the pharmacist supervise the technician that they have delegated “final verification” to? How does the pharmacist supervise technicians performing “final verification”?	OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	70.	Does the supervising pharmacist ensure that the technician performs a physical (i.e. in person) "final verification"? OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
<input type="checkbox"/>	<input type="checkbox"/>	71.	If a technician performs final verification on the drug and dosage, is a pharmacist performing verification on the remaining items such as prescription label accuracy, appropriate auxiliary labels, expiration date, quantity? OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
<input type="checkbox"/>	<input type="checkbox"/>	72.	Is the supervising pharmacist aware that a technician may not use discretion when performing "final verification"? How does each supervising pharmacist ensure that technicians do not use discretion when performing "final verification"? OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005

Collaborative Drug Therapy Management (CDTM) N/A

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	73.	Do pharmacists participate in Collaborative Drug Therapy Management (CDTM)? Examples: Diabetes management, anticoagulation, hypertension. OAR 855-019-0260
<input type="checkbox"/>	<input type="checkbox"/>	74.	Does the written CDTM agreement contain the following: <ul style="list-style-type: none"> • Identification of the participating pharmacist(s) and practitioner(s) • The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement • The types of decisions that the pharmacist is allowed to make and when the pharmacist should initiate communications with the practitioner OAR 855-019-0260 (2)(a)-(g) and (3)
<input type="checkbox"/>	<input type="checkbox"/>	75.	Are CDTM agreements being reviewed and updated at least every two years? OAR 855-019-0260(2)(h)
<input type="checkbox"/>	<input type="checkbox"/>	76.	Are the practitioner and pharmacist identified on each prescription order? Note: The practitioner is the individual who referred the patient for treatment under the CDTM agreement. For a prescription ordered by a pharmacist under CDTM to be valid, the practitioner must be identified as the prescriber. OAR 855-019-0260(2)(a-b)

Pharmacist Prescriptive Authority: Naloxone N/A

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	77.	Do pharmacists at this location prescribe naloxone to individuals or entities? OAR 855-019-0460 OAR 855-041-2340

Telework N/A

Yes	No	Rule Reference		
<input type="checkbox"/>	<input type="checkbox"/>	83.	<p>Does pharmacy staff (Intern or technician) work on behalf of the drug outlet pharmacy from a location physically outside of the pharmacy (i.e. their home)?</p> <p>Note: This is considered telework at a telework site by the board. This is not applicable to pharmacists not working on behalf of a board registered drug outlet and the technicians who are assisting those pharmacists.</p> <ul style="list-style-type: none"> If the answer is No to this question, please proceed to the next set of questions. 	OAR 855-041-3205
		84.	<p>How does the PIC and the supervising Pharmacist ensure the supervision, direction, and control of each technician and supervision of an Intern?</p>	OAR 855-041-3215 OAR 855-041-3220
<input type="checkbox"/>	<input type="checkbox"/>	85	<p>Are all of the following supervision requirements met?</p> <ul style="list-style-type: none"> Utilize audio-communications system and have appropriate technology or interface to allow access to information required to complete assigned duties Ensure telephone audio is recorded and stored for all patient interactions completed by each Intern and technicians Ensure a Pharmacist is supervising, directing, and controlling each Intern and technician and that the continuous audio/visual connection is fully operational Ensure that a Pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the real-time audiovisual communication system 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 technician 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

Long Term Care (LTC) / Community Based Care (CBC) Services N/A

Yes	No	Rule Reference		
<input type="checkbox"/>	<input type="checkbox"/>	86.	<p>Is the pharmacy or Pharmacists assisting in the establishment and supervision of the policies & procedures for the safe storage, distribution, administration, & disposal of drugs and for professional advice/medication counseling of patients and/or caregivers?</p>	OAR 855-041-7060(1)

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	87.	<p>Are emergency drug kits provided to any facilities?</p> <p>Does each facility's license allow them to have an emergency drug kit?</p> <p>If yes, how does a pharmacist verify and document verification of the kit?</p>	OAR 855-041-7060(2)
<input type="checkbox"/>	<input type="checkbox"/>	88.	<p>Is the pharmacy ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-6310 AND that there is a practitioner's order to authorize the removal of medications?</p> <p>How is this being ensured?</p>	OAR 855-041-7060(2)(b) OAR 855-041-7060(5)
<input type="checkbox"/>	<input type="checkbox"/>	89.	<p>If the pharmacy accepts the return of previously dispensed prescriptions, is the facility in compliance with OAR 855-041-1045?</p>	OAR 855-041-1045
<input type="checkbox"/>	<input type="checkbox"/>	90.	<p>Does the pharmacy dispense medications that have been previously dispensed and returned?</p> <p>If so, under what circumstances?</p>	OAR 855-041-1045(3)
<input type="checkbox"/>	<input type="checkbox"/>	91.	<p>Are prescriptions provided to patients in a Skilled Nursing Facility (SNF) and/or Immediate Care Facility (ICF)?</p> <p>If yes, what is the outlet's Institutional Drug Outlet Registration #?</p> <p>Registration #:</p>	OAR 855-041-5005 OAR 855-041-5015 OAR 855-041-7050
<input type="checkbox"/>	<input type="checkbox"/>	92.	<p>Are all partially dispensed CII prescriptions (Note: Valid for up to a maximum of 60 days from the date written) documented with the following?</p> <ul style="list-style-type: none"> • "LTCF patient" or "terminally ill" • Date of partial fill • Quantity dispensed 	21 CFR 1306.13

Yes No

Rule Reference

			<ul style="list-style-type: none"> • Remaining quantity authorized to be dispensed • Identification of the dispensing pharmacist for each partial fill 	
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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, 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) please complete the RDSP Self-Inspection form located on the Board Website.**
- **Pharmacy Prescription Locker (PPL) please complete the PPL Self-Inspection form located on the Board Website.**
- **Pharmacy Prescription Kiosks (PPK) please complete the PPK Self-Inspection form located on the Board Website.**

