



**2024**  
**INSTITUTIONAL 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\(2\)](#))

**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 immediately upon request at the time of inspection and retained in compliance with [OAR 855-104-0055](#).

**Scope:** The primary objective of completing the self-inspection is to ensure compliance and 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 Board of Pharmacy office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

**Board of Pharmacy Use:** During an inspection, 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 at the time of inspection.

Email all compliance-related questions to: [pharmacy.compliance@bop.oregon.gov](mailto:pharmacy.compliance@bop.oregon.gov).

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INSTITUTIONAL DRUG OUTLET  
SELF-INSPECTION FORM**

**The PIC 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 855-115-0210](#)).**

Date PIC completed Self-Inspection: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

PIC Name: \_\_\_\_\_ PIC License #: \_\_\_\_\_

PIC **Work** E-mail: \_\_\_\_\_

Pharmacy Name: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Telephone: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_ Fax: (\_\_\_\_\_) \_\_\_\_\_ - \_\_\_\_\_

DEA #: \_\_\_\_\_ Exp: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Institutional Drug Outlet Registration #: \_\_\_\_\_ Exp: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Retail Drug Outlet Registration #: \_\_\_\_\_ Exp: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Wholesaler Drug Outlet Registration#: \_\_\_\_\_ Exp: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Nonprescription Drug Outlet Registration #: \_\_\_\_\_ Exp: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Hours of operation:

**Please list where the following items are specifically located inside the pharmacy. Once located, ensure each is compliant, and reflects current practices within the outlet (if an item is not applicable, indicate with N/A). Unless otherwise specified, documents are to be retained for 3 years (the first year must be on site) and must be provided to the Board upon request, as outlined in [OAR 855-104-0055](#).**

**Policies, Procedures, and Protocols (list # and/or location):**

- Diversion Prevention and Drug Security
- Language Services (to include Prescription Reader, Label Translation, and Interpreter Services)
- Pseudoephedrine / Ephedrine Sales
- Destruction or Return of Adulterated/Outdated Controlled Substances

- Managing Adverse Reactions (for vaccinations)
- Collaborative Practice Agreements / Collaborative Drug Therapy Management (CPA / CDTM)
- Telework (to include agreements, prescriptions, etc.)

### **Trainings/ Certifications**

- Initial and ongoing Technician Training
- Immunization Training and CPR Certification
- Aseptic Manipulation Skills Testing
- Nonsterile Compounding Training

### **Controlled Substance Records (for the last 3 years)**

- Annual Controlled Substance Inventories / Reconciliations
- C-II Monthly Reconciliations and Perpetual Inventory Log
- C-II Random Sampling Documentation (must be completed at least quarterly)
- Completed C-II Order Forms (DEA 222/CSOS)
- C-II Invoices
- C-III through C-V Invoices
- DEA Form 106
- Invoices for Controlled Substance Returns (to include executed DEA 222 Forms for reverse distribution)

### **Cold Drug Storage**

- Policies and Procedures (to include storage, monitoring, and emergency action plan)
- Temperature Monitoring Data

- Excursion Documentation (including the event date, name of persons(s) involved in excursion responses, action(s) taken, including decision to quarantine drug for destruction, or determination that drug is safe for continued use, and the details of the information source used to make this decision)
- Calibration Certificates
- Quarterly Validations (for all vaccine storage units)

**Prescriptive Authority (to include policies and procedures, training, and prescribing records)**

- Short-acting opioid antagonists (e.g., naloxone, nalmefene)
- Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) (including statewide drug therapy management protocols and formulary)

**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**

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	1	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?  <a href="#">OAR 855-041-1015(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	2	Are the following current, and conspicuously posted? (check box) <ul style="list-style-type: none"> <li><input type="checkbox"/> Pharmacy registration(s)</li> <li><input type="checkbox"/> DEA registration</li> <li><input type="checkbox"/> Pharmacist license(s)</li> <li><input type="checkbox"/> Preceptor license(s)</li> <li><input type="checkbox"/> Intern license(s)</li> <li><input type="checkbox"/> Technician license(s)</li> <li><input type="checkbox"/> Laboratory license (if applicable)</li> </ul> <a href="#">ORS 689.615</a> <a href="#">OAR 855-041-1190(2)(a)</a> <a href="#">OAR 855-115-0105(11)</a> <a href="#">OAR 855-120-0105(3)(i)</a> <a href="#">OAR 855-120-1070(3)(a)</a> <a href="#">OAR 855-125-0105(3)(j)</a>
<input type="checkbox"/>	<input type="checkbox"/>	3	Is the hospital accredited?  If yes, by whom?  Date(s) of the last accreditation survey:  <b><i>*Please attach all pharmacy observations &amp; recommendations*</i></b>
<input type="checkbox"/>	<input type="checkbox"/>	4	Are all pharmacy staff aware that Compliance Officers must be permitted to perform the following? <ul style="list-style-type: none"> <li>• Inspecting conditions, structures, equipment, materials, and methods for compliance</li> <li>• Inspecting all drugs and devices</li> <li>• Taking photographs, recording video and audio; and</li> </ul> <a href="#">OAR 855-104-0055</a> <a href="#">OAR 855-104-0115</a>

Yes	No		Rule Reference
		<ul style="list-style-type: none"> <li>Reviewing, verifying, and making copies of records and documents</li> </ul>	
<input type="checkbox"/>	<input type="checkbox"/>	<p>5 Are all licensees aware that they must report:</p> <ul style="list-style-type: none"> <li>Theft or significant loss of a controlled substance to the Board and DEA <b><u>within 1 business day?</u></b></li> <li>Felony arrests OR convictions, misdemeanor convictions, and suspected or known violations of state pharmacy laws and rules to the Board <b><u>within 10 days?</u></b></li> <li>Changes in legal name, name used when in pharmacy, preferred email address, personal phone number, physical address, mailing address, and employer <b><u>within 15 days?</u></b></li> </ul> <p>(Visit <a href="#">mylicense/eGov</a> to update your information)</p>	<a href="#">OAR 855-104-0010</a> <a href="#">OAR 855-041-1030</a> <a href="#">21 CFR 1301.76(b)</a>
<input type="checkbox"/>	<input type="checkbox"/>	<p>6 Is the PIC/pharmacy aware that when a Board licensee is terminated, or allowed to resign in lieu of termination, the outlet must report it to the Board <b><u>within 10 working days?</u></b></p>	<a href="#">OAR 855-041-1010(4)</a>
<input type="checkbox"/>	<input type="checkbox"/>	<p>7 Is the PIC responsible for more than 1 location? If so, list additional sites below:</p> <ol style="list-style-type: none"> <li></li> <li></li> <li></li> </ol> <p><b>Note:</b> A pharmacist may not be designated PIC of more than three pharmacies (this does not include a Pharmacy Prescription Kiosk (PPK) or Pharmacy Prescription Locker (PPL) Affiliated Pharmacy).</p>	<a href="#">OAR 855-115-0205(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	<p>8 Are policies and procedures for the following items current, and compliant with federal and state regulations? (check once verified)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Security</li> <li><input type="checkbox"/> Operation, testing and maintenance of pharmacy systems and equipment</li> <li><input type="checkbox"/> Sanitation</li> <li><input type="checkbox"/> Storage of drugs</li> <li><input type="checkbox"/> Dispensing</li> <li><input type="checkbox"/> Pharmacist supervision, direction, and control of non-Pharmacists</li> <li><input type="checkbox"/> 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</li> <li><input type="checkbox"/> Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians</li> <li><input type="checkbox"/> Certified Oregon Pharmacy Technician or Pharmacy Technician final verification and/or vaccination, if utilized</li> <li><input type="checkbox"/> Drug and/or device procurement</li> <li><input type="checkbox"/> Receiving of drugs and/or devices</li> <li><input type="checkbox"/> Disposal of drugs and/or devices including hazardous and pharmaceutical waste</li> <li><input type="checkbox"/> Delivery of drugs and/or devices</li> <li><input type="checkbox"/> Utilization of Oregon licensed Pharmacist (i.e. Drug Utilization Review (DUR), Counseling)</li> </ul>	<a href="#">OAR 855-041-1040</a>

Yes	No			Rule Reference
			<input type="checkbox"/> Recordkeeping <input type="checkbox"/> Patient confidentiality <input type="checkbox"/> Continuous quality improvement <input type="checkbox"/> Plan for discontinuing and recovering services in the event of a pharmacy closure <input type="checkbox"/> Training: initial and ongoing for all licensees <input type="checkbox"/> Interpretation, translation, and prescription reader services	

**Personnel (Non-licensed, Technicians, Certified Oregon Pharmacy Technicians, Interns, and Pharmacists)**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	9	Are <b>all pharmacy staff</b> clearly identified in all interactions and communications (e.g., nametag, phone interactions, chart notations)?	<a href="#">OAR 855-115-0105(10)</a> <a href="#">OAR 855-120-0105(3)(h)</a> <a href="#">OAR 855-125-0105(3)(i)</a>
<input type="checkbox"/>	<input type="checkbox"/>	10	Are <b>all pharmacy staff</b> trained appropriately prior to performance of tasks and with each policy/procedure update for the practice site?  <b>Note:</b> This training should include an <u>annual review</u> of the PIC Self-Inspection Form.	<a href="#">OAR 855-115-0120(1)(i)</a> <a href="#">OAR 855-120-0105(3)(e)</a> <a href="#">OAR 855-125-0105(2)(k)</a>
<input type="checkbox"/>	<input type="checkbox"/>	11	At all times, during any given shift, do <b>ALL</b> : <input type="checkbox"/> <b>Pharmacists</b> know the identity of each Intern under their supervision, and Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction, and control? <input type="checkbox"/> <b>Interns</b> know their supervising Pharmacist or Preceptor? <input type="checkbox"/> <b>Technicians</b> know the Pharmacist that is supervising, directing, and controlling them?	<a href="#">ORS 689.486</a> <a href="#">OAR 855-115-0120(1)(d)</a> <a href="#">OAR 855-120-0105(3)(d)</a> <a href="#">OAR 855-125-0105(3)(b)(c)</a>
<input type="checkbox"/>	<input type="checkbox"/>	12	Are <b>technicians</b> completing initial and ongoing 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 and with each update to the written policies and procedures?	<a href="#">OAR 855-125-0105(3)(k)</a>
<input type="checkbox"/>	<input type="checkbox"/>	13	Does the PIC prepare and maintain written procedures that describe the tasks that may be performed by <b>technicians</b> , including the methods of verification and documentation of work performed by technicians?  <input type="checkbox"/> Does the PIC review the written procedures annually?	<a href="#">OAR 855-125-0135(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	14	Do <b>technicians</b> know they cannot use judgment without verification by a pharmacist? Examples of this include, but are not limited to: <ul style="list-style-type: none"> <li>Communicating with a patient about a drug's class, indication, or use (such as a patient asking for refills on their "diabetes" medication)</li> <li>Preparing the proper amount of water to use when reconstituting a medication.</li> </ul> How is pharmacist verification of technician work documented?	<a href="#">OAR 855-125-0135(2)</a>

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	15	Do <b>technicians</b> know they can only <u>assist</u> in the practice of pharmacy as permitted by the Pharmacist who is supervising, directing, and controlling their work, and cannot <u>perform</u> any act that constitutes the practice of pharmacy as defined in ORS 689, except as permitted in OAR 855-125-0105(4)? This includes, but is not limited to, the following: <ul style="list-style-type: none"> <li>• Counseling</li> <li>• DUR</li> <li>• Conducting MTM</li> <li>• Recommending or forecasting vaccinations</li> <li>• Prescribing</li> </ul>	<a href="#">ORS 689.005(28)(29)</a> <a href="#">OAR 855-125-0150(1)(3)</a>
<input type="checkbox"/>	<input type="checkbox"/>	16	Do <b>interns</b> know that they: <ul style="list-style-type: none"> <li>• cannot practice pharmacy except as permitted by the Pharmacist or Healthcare Preceptor who is supervising them?</li> <li>• cannot engage in patient care services when the supervising Pharmacist is not trained and qualified to perform the service?</li> <li>• may only observe DUR, DRR, counseling, advising, MTM, engaging in a CPA/CDTM or statewide protocol, prescribing or performing verification during their first academic year?</li> </ul>	<a href="#">OAR 855-120-0150</a>

### Pharmacists

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	17	Does the pharmacist ensure that each prescription order contains all of the required elements?	<a href="#">OAR 855-115-0130(1)(c)</a> <a href="#">OAR 855-041-1105</a>
<input type="checkbox"/>	<input type="checkbox"/>	18	Does the pharmacist ensure that when a verbal prescription is received, the identity of the licensee (name, initials, or electronic identifier) and name of the person transmitting the prescription is documented?	<a href="#">OAR 855-041-1105(3)</a>
<input type="checkbox"/>	<input type="checkbox"/>	19	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	<a href="#">OAR 855-115-0130(1)(d)</a> <a href="#">OAR 855-041-1165</a>
<input type="checkbox"/>	<input type="checkbox"/>	20	Does the pharmacist follow policies and procedures to ensure that prescriptions are accurately dispensed to the correct party, pursuant to a valid prescription and patient-practitioner relationship, and for a legitimate medical purpose?	<a href="#">OAR 855-115-0130(1)(e)</a> <a href="#">OAR 855-115-0210(1)(d)</a> <a href="#">OAR 855-041-1105</a>
<input type="checkbox"/>	<input type="checkbox"/>	21	Does the pharmacist perform a DUR for ALL prescriptions prior to dispensing, or preparing for administration?  At which point in the prescription process does a pharmacist perform a DUR?	<a href="#">OAR 855-115-0140</a>

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>		<p>Does this vary depending on the type of fill (new vs refill)? If so, please explain.</p> <p>If an intervention is required, how is it carried out and documented?</p> <p><b>Note:</b> A pharmacist must personally perform a DUR on each fill even if there are no computer-generated alerts.</p>	
	<input type="checkbox"/>	22	<p>Does the pharmacist ensure that each prescription is assigned a correct expiration date, not to exceed the following?</p> <ul style="list-style-type: none"> <li>• That on the manufacturer's container, if dispensed in the manufacturer's container, <b>or</b></li> <li>• The earliest date of either: <ul style="list-style-type: none"> <li>○ the manufacturer's expiration date, <b>or</b></li> <li>○ one year from the date that the drug was repackaged.</li> </ul> </li> </ul> <p><b>Note:</b> Any drug expiring before the course of therapy is expected to finish, must not be dispensed.</p>	<a href="#">OAR 855-115-0105</a> <a href="#">OAR 855-041-1130(10)(11)</a>
<input type="checkbox"/>	<input type="checkbox"/>	23	<p>Does the label on each prescription medication (excluding unit dose or unit of use packaging) contain its physical description, including any identification codes that may appear on tablets or capsules?</p>	<a href="#">OAR 855-041-1130(12)</a>

### Labeling

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	24	<p>Do labels on each drug dispensed to an inpatient contain the following information?</p> <ul style="list-style-type: none"> <li>• Patient name and location</li> <li>• Drug name and strength</li> <li>• Route of administration (when necessary for clarification)</li> <li>• Manufacturer and lot number (or internal pharmacy code)</li> <li>• Auxiliary labels (if needed)</li> <li>• Expiration date</li> </ul> <p><b>Note:</b> A drug that is provided for outpatient use must be dispensed by a retail drug outlet.</p>	<a href="#">OAR 855-041-6270(3)</a>
<input type="checkbox"/>	<input type="checkbox"/>	25	<p>Does the pharmacy add a barcode or an electronic label to any drug?</p> <p><b>Note:</b> If so, a pharmacist <b>must verify and document</b> accuracy prior to distribution.</p>	<a href="#">OAR 855-041-6270(5)</a>



Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	26	Are repackaged unit-dose drugs labeled with the following? <ul style="list-style-type: none"> <li>• Name, strength, and expiration date</li> <li>• Manufacturer and lot number (or internal pharmacy code which references manufacturer and lot number)</li> </ul> <p><b>Note:</b> This includes labeling individual oral syringes.</p>	<a href="#">OAR 855-041-6270(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	27	Does the pharmacy document all pharmacy personnel involved in repackaging, including the pharmacist who verified the repackaged drug?	<a href="#">OAR 855-041-6270(1)</a>

**Absence of a Pharmacist**     N/A

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	28	Does the hospital use a night cabinet or allow after-hours access to the pharmacy?	<a href="#">OAR 855-041-6300</a>
<input type="checkbox"/>	<input type="checkbox"/>	29	Is access to night cabinet or pharmacy limited to <b>one authorized registered nurse</b> on a shift?  Where is the authorized nurse's identity designated in writing with documentation of the nurse(s) training in the proper procedure for access, removal of drugs and recordkeeping?	<a href="#">OAR 855-041-6305</a> <a href="#">OAR 855-041-6310</a>
<input type="checkbox"/>	<input type="checkbox"/>	30	For each drug removed after hours, does a pharmacist confirm the following? <ul style="list-style-type: none"> <li>• The nurse was appropriately trained</li> <li>• The nurse's initials were documented</li> <li>• A copy of the practitioner's order was left for verification</li> <li>• Either the container from which the drug was removed, or an identical unit dose, was left for accuracy verification</li> </ul>	<a href="#">OAR 855-041-6310(2)</a>

**Security of Records and Drugs**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	31	Does the PIC/pharmacist know they are responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.	<a href="#">OAR 855-041-1020</a>
		32	What are the procedures for the pharmacist to maintain supervision of the pharmacy?  Who is permitted to access the pharmacy and under what conditions?	<a href="#">OAR 855-041-1020(3)</a> <a href="#">OAR 855-041-2100</a> <a href="#">OAR 855-041-1015(1)</a> <a href="#">OAR 855-041-6200</a>

<input type="checkbox"/>	<input type="checkbox"/>	33	Can prescriptions be processed, or records accessed, when a pharmacist is not on duty? If so, please explain:	<a href="#">OAR 855-041-1020(3)</a>
<input type="checkbox"/>	<input type="checkbox"/>	34	Is the PIC/pharmacy aware that a licensee or registrant of the board <b>MAY NOT DISCLOSE</b> patient information to a third party without the consent of the patient, except as provided in OAR 855-041-1055(1)(a)-(e)?	<a href="#">OAR 855-041-1055(1)(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>		Is the PIC/pharmacy aware that a licensee or registrant of the board <b>MAY NOT ACCESS OR OBTAIN</b> patient information unless it is for the purpose of patient care, except as provided in OAR 855-041-1055(1)(a)-(e)?	
<input type="checkbox"/>	<input type="checkbox"/>	35	Where does the pharmacy quarantine product that is unfit for distribution (e.g., product that is recalled, outdated, damaged, deteriorated, misbranded, adulterated, counterfeit or suspect, etc.)?	<a href="#">OAR 855-041-1025</a> <a href="#">OAR 855-041-1036(1)(d)</a> <a href="#">21 U.S.C. 351</a> <a href="#">21 U.S.C. 352</a>
		36	How does the Pharmacist/pharmacy maintain the security of <b>controlled substances</b> that have been quarantined?	<a href="#">OAR 855-041-1020</a> <a href="#">OAR 855-041-6200</a> <a href="#">OAR 855-115-0125(5)</a>

### Controlled Substances

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	37	Is the pharmacy aware that pseudoephedrine and ephedrine are Schedule-V Controlled Substances in Oregon?	<a href="#">OAR 855-080-0026</a>
<input type="checkbox"/>	<input type="checkbox"/>	38	Are on-hand quantity changes of controlled substances reviewed?  If so, how often, and by whom?  Who is permitted to make on-hand changes?	
<input type="checkbox"/>	<input type="checkbox"/>	39	Is the pharmacist/pharmacy reporting suspected theft, or confirmed significant loss, of a controlled substance to the Board and DEA within 1 business day?  Submit by email to <a href="mailto:pharmacy.druglossreporting@bop.oregon.gov">pharmacy.druglossreporting@bop.oregon.gov</a> , with " <u>Controlled Substance Loss Notification</u> " in the subject line.	<a href="#">OAR 855-115-0115</a> <a href="#">OAR 855-041-1030</a> <a href="#">CFR 1306.76(b)</a>
<input type="checkbox"/>	<input type="checkbox"/>	40	Is the PIC ensuring that the ALL VARIANCES on MONTHLY C-II reconciliations are DOCUMENTED, and CLEARLY EXPLAINED? If recorded electronically, it MUST be made available at time of inspection.	<a href="#">OAR 855-115-0210(1)(i)</a>

Yes No

Rule Reference

			<p><b>Note: Providing an on-hand count is not sufficient to meet this requirement.</b> The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least every 31 days in an Institutional Drug Outlet Pharmacy.</p> <p>If it is determined that no discrepancies are found for any CII, provide documentation to show this (i.e., screenshot of computer report that says this or report with expected value vs. actual value).</p>	
<input type="checkbox"/>	<input type="checkbox"/>	41	<p>Was the annual controlled substance inventory (C-II through C-V) performed on one day, within 12 months (367 days) of the previous inventory?</p> <p><b>Dates of the last two controlled substance inventories:</b></p> <p style="text-align: center;"><b>and</b></p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Inventory includes drugs in the refrigerator, automated dispensing machines, outdated controlled substances, etc.</li> <li>• 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 <b>before opening or after closing</b>.</li> </ul>	<p><a href="#">OAR 855-080-0070</a>  <a href="#">OAR 855-115-0210(1)(i)</a></p>
<input type="checkbox"/>	<input type="checkbox"/>	42	<p>Are CII records (prescriptions, inventories/reconciliations, invoices, etc.) filed separately from those in all other classes?</p>	<p><a href="#">21 CFR 1304.04</a></p>
<input type="checkbox"/>	<input type="checkbox"/>	43	<p>Does the pharmacy maintain a perpetual CII inventory system documenting drugs received, stored, and distributed by the pharmacy that is reconciled with an actual inventory <b>at least monthly</b>?</p> <p><input type="checkbox"/> <input type="checkbox"/> Are quarantined controlled substances included in the monthly inventory?</p>	<p><a href="#">OAR 855-041-6610(1)(a)</a></p>
<input type="checkbox"/>	<input type="checkbox"/>	44	<p>Is there a quality assurance procedure for the random sampling of the CII inventory performed at least quarterly, which includes auditing of dose-by-dose administration?</p>	<p><a href="#">OAR 855-041-6610(1)(c)</a></p>
<input type="checkbox"/>	<input type="checkbox"/>	45	<p>Is the hospital following established procedures to account for all controlled substances?</p>	<p><a href="#">OAR 855-041-6600</a></p>
<input type="checkbox"/>	<input type="checkbox"/>	46	<p>Does the pharmacy utilize electronic surveillance or analytics to assist with this (e.g., monitoring drugs removed from stock, administered, and wasted)?</p>	<p><a href="#">OAR 855-041-6600</a></p>
		47	<p>What is the pharmacy's process for reconciling the quantity of controlled substances received on invoice with the quantity added to inventory?</p>	<p><a href="#">OAR 855-041-6600</a>  <a href="#">OAR 855-041-6200(3)(c)</a></p>

**Cold Drug Storage**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	48	Is there documented training for ALL pharmacy personnel related to the cold drug storage monitoring plan (to include vaccine drug storage)?	<a href="#">OAR 855-041-1036(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	49	Are the thermometers/probes centrally placed?	<a href="#">OAR 855-041-1036(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	50	Are thermometers/probes routinely calibrated to ensure accuracy?  When was the last calibration performed?  When is the next calibration due?  How does the hospital ensure <b>calibrations</b> of the thermometers are conducted as specified by the manufacturer?	<a href="#">OAR 855-041-1036(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	51	Does each active cold storage system maintain the temperature of refrigerated products between 2 to 8°C (35 to 46°F) and frozen products between -25 to -10°C (-13 to 14°F), <u>or as specified by the manufacturer?</u>  <b>Note:</b> ANY temperature outside of these parameters for ANY amount of time IS CONSIDERED AN EXCURSION and should be researched appropriately with documentation maintained.	<a href="#">OAR 855-041-1036(2)(a)(A)</a>
<input type="checkbox"/>	<input type="checkbox"/>	52	Are <u>ALL</u> excursions documented to include the following? <ul style="list-style-type: none"> <li>• Event date &amp; time frame</li> <li>• Name of person(s) involved</li> <li>• Pharmacist's review of duration and magnitude</li> <li>• Action(s) taken, whether to <u>quarantine</u> product for destruction/return, or <u>keep</u> product if deemed safe for continued use</li> <li>• Source of information used</li> <li>• Identity of pharmacist who made final decision</li> </ul>	<a href="#">OAR 855-041-1036(2)(b)(D-E)</a>

**Vaccine Drug Storage**       N/A

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	53	Does the pharmacy store vaccines in the temperature-stable sections of the refrigerator?	<a href="#">OAR 855-041-1036(3)(a)(A)</a>
<input type="checkbox"/>	<input type="checkbox"/>	54	Does each active vaccine storage unit utilize a system of <i>continuous</i> temperature monitoring with automated data logging?	<a href="#">OAR 855-041-1036(3)(d)</a>

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	56	<p>Are quarterly validations conducted for <b>EACH</b> vaccine storage unit and its monitoring equipment?</p> <p>Date last validation was performed:</p> <p>Date next validation is due:</p> <p><b>Note:</b> Quarterly validations are not the same as the thermometer calibrations.</p>	<a href="#">OAR 855-041-1036(3)(a)(D)</a>

**Emergency Kit and Code Cart**

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	56	<p>Does a pharmacist verify and document the contents of all emergency kits?</p> <p><b>Note:</b> Emergency kits consist of those drugs which may be required to meet the immediate therapeutic needs of inpatients and are not available from any other authorized source in sufficient time to prevent risk of harm to patients. Examples include: Malignant Hyperthermia Kit, Stroke Kit, RSI Kit, Maternal Hemorrhage Kit, etc.</p>	<a href="#">OAR 855-041-6420(2)</a>
<input type="checkbox"/>	<input type="checkbox"/>	57	<p>Is each kit/code cart locked and <b>externally labeled</b> with name, strength, quantity, and expiration date?</p> <p><b>Note:</b> Putting the list of drugs on the exterior of the tray that is then locked inside a cart does not meet this requirement. The drug list must be able to be accessed without breaking the primary cart or kit's lock.</p> <p>The expiration date of the kit/cart should be the expiration date of the first drug to expire in the kit/cart.</p>	<a href="#">OAR 855-041-6420(6)(7)</a>

**Automated Distribution Cabinets (ADC), Floor Stock, Non-emergency Trays and Kits**  N/A

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	58	<p>Does the outlet have policies and procedures for inspection of drug storage areas (at least every 2 months) that includes verification and documentation of proper storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, temperature monitoring and integrity of emergency drug supply?</p> <p>Who is responsible for supervising the inspection and any follow-up needed if the inspection is performed by a technician?</p>	<a href="#">OAR 855-041-6200(3)(d)</a>

Yes	No			Rule Reference
		59	Who does the PIC permit to access each ADC and how does the PIC determine who to permit accesses and how or when to revoke it?  <b>Note:</b> A nurse or technician <u>is not</u> permitted to return a drug to an ADC after removing it, except to place in a designated return bin.	<a href="#">OAR 855-041-6540(4)</a>
		60	How does the pharmacy ensure that all returned drugs from ADCs are reviewed by a pharmacist prior to returning them to the pharmacy inventory?	<a href="#">OAR 855-041-6540(7)</a>
<input type="checkbox"/>	<input type="checkbox"/>	61	Is a count confirmation (or "blind count") performed <b>every</b> time a controlled substance bin is accessed (loaded, unloaded, removed, and inventoried) in an ADC?  <b>Note:</b> Discrepancies reconciliation must be documented, and supervised by a pharmacist.	<a href="#">OAR 855-041-6540(8)</a>

**Medication History Reconciliation**

N/A

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	62	Is the pharmacy involved in obtaining medication histories and performing medication reconciliations?  If yes, what is the pharmacist's role?	
		63	Who is permitted to obtain the medication history for medication reconciliations?	<a href="#">855-115-0120 (1)(f)</a> <a href="#">855-125-0135</a>
		64	If a technician is involved, how are they supervised, directed, and controlled?  How and when is the technician's work verified by a pharmacist?	<a href="#">ORS 689.486(6)</a> <a href="#">OAR 855-025-0025(6)(1)</a> <a href="#">855-125-0135</a>

Yes	No			Rule Reference
			** Please provide technician training specific to this task for all technicians involved. **	

### **Additional Services**

#### **Final Verification**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	65	Do pharmacists at this location allow technicians to participate in “Final Verification” (that is, 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 is the prescribed drug and drug dosage, device, or product)?  If yes, please print, complete, and attach the <i>Additional Services Self-Inspection Supplement</i> .	<a href="#">ORS 689.005</a> <a href="#">OAR 855-005-0006(18)</a> <a href="#">OAR 855-115-0130(3)</a> <a href="#">OAR 855-125-0105(4)</a>

#### **Collaborative Drug Therapy Management (CDTM)**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	66	Do pharmacists at this location participate in <b><u>CDTM</u></b> ?  <b>Examples:</b> Vancomycin-dosing and anticoagulation-dosing.  If yes, please print, complete, and attach the <i>Additional Services Self-Inspection Supplement</i> .	<a href="#">OAR 855-115-0315</a>

#### **Telework**

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	67	Does pharmacy staff (Intern or Technician) work on behalf of the drug outlet pharmacy from a location physically outside of the pharmacy (e.g., their home)?  <b>Note:</b> 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.  If yes, please print, complete, and attach the <i>Additional Services Self-Inspection Supplement</i> .	<a href="#">OAR 855-041-3205</a>

**\*\* If the pharmacy performs any drug compounding, you are also required to complete the Compounding Self-Inspection form located on the Board website. \*\***

If the outlet has a Retail Drug Outlet Registration, but provides limited retail services, completion of the following abbreviated *INSTITUTIONAL DRUG OUTLET with RETAIL DRUG OUTLET SELF-INSPECTION FORM* is required. Alternately, a *RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY SELF-INSPECTION FORM* must be completed if the outlet has a traditional retail pharmacy and dispenses prescriptions to the public beyond dispensing ED prepacks from the emergency department .

N/A

**2024  
INSTITUTIONAL DRUG OUTLET with RETAIL DRUG OUTLET  
SELF-INSPECTION FORM**

**General Requirements**

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	1. Are the outlet's policies and procedures for the following items current, and compliant with federal and state regulations? <ul style="list-style-type: none"> <li>• Security</li> <li>• Operation, testing and maintenance of pharmacy systems and equipment</li> <li>• Sanitation</li> <li>• Storage of drugs</li> <li>• Dispensing</li> <li>• Pharmacist supervision, direction, and control of non-Pharmacists</li> <li>• 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</li> <li>• Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians</li> <li>• Drug and/or device procurement</li> <li>• Receiving of drugs and/or devices</li> <li>• Delivery of drugs and/or devices</li> <li>• Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling)</li> <li>• Recordkeeping</li> <li>• Patient confidentiality</li> <li>• Continuous quality improvement</li> <li>• Plan for discontinuing and recovering services in the event of a pharmacy closure</li> <li>• Training: initial and ongoing</li> <li>• Interpretation, translation, and prescription reader services</li> </ul>	<a href="#">OAR 855-041-1040</a>

**Outpatient Medications (including ED pre-packs)**

Yes	No		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	2. Do labels for each patient specific prescription dispensed to a patient contain the following information? <ul style="list-style-type: none"> <li>• Name, address and telephone number of the pharmacy</li> <li>• Date of Fill</li> <li>• Identifying Number</li> <li>• Patient Name</li> </ul>	<a href="#">OAR 855-041-1130</a>



Yes No

Rule Reference

			<ul style="list-style-type: none"> <li>• Drug name and strength, quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor</li> <li>• Directions for use by the patient</li> <li>• Name of the practitioner</li> <li>• Required precautionary information</li> <li>• Expiration date</li> <li>• Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules.</li> </ul>	
<input type="checkbox"/>	<input type="checkbox"/>	3.	<p>Is the amount of medication contained in each ED prepack limited to a 48-hour supply, unless otherwise allowed in Board rule?</p> <p>Does your outlet have policies and procedures that place limitations on prepack medications? If so, please explain:</p>	<a href="#">OAR 855-041-6410(3)</a>
<input type="checkbox"/>	<input type="checkbox"/>			
		4.	<p>Do labels for each ED prepack contain the following information:</p> <ul style="list-style-type: none"> <li>• Name of drug, strength, and number of units. When a generic is used, the label must also contain the identifier of the manufacturer or distributor;</li> <li>• Accessory cautionary information as required for patient safety;</li> <li>• Product identification label if the drug is not in unit-of-use packaging;</li> <li>• An expiration date after which the patient should not use the drug; and</li> <li>• Name, address and phone number of the outlet pharmacy.</li> </ul>	<a href="#">OAR 855-041-06410(1)(d)</a>
		5.	<p>Does the outlet ensure that the practitioner or nurse adds the following information to the drug container before dispensing to the patient?</p> <ul style="list-style-type: none"> <li>• Name of patient;</li> <li>• Directions for use by the patient;</li> <li>• Date of issue;</li> <li>• Unique identifying number as determined by policy and procedure;</li> <li>• Name of prescribing practitioner; and</li> <li>• Initials of the dispensing nurse or practitioner.</li> </ul> <p>Note:</p> <ul style="list-style-type: none"> <li>• A label is not required as described in SB 450 (2023)</li> <li>• A controlled substance may only be distributed or dispensed by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined.</li> </ul>	<a href="#">OAR 855-041-6410(1)(e)(2)</a>
		6.	<p>Does the practitioner or nurse ensure that the following information is maintained in the dispensing record:</p>	<a href="#">OAR 855-041-6410(1)(f)</a>

Yes	No			Rule Reference
			<ul style="list-style-type: none"> <li>• Name of patient;</li> <li>• Date of issuance;</li> <li>• Drug name and strength distributed;</li> <li>• Units issued;</li> <li>• Name of practitioner;</li> <li>• Initials of the dispensing nurse or practitioner; and</li> <li>• Instructions given to the patient as labeled.</li> </ul>	
<input type="checkbox"/>	<input type="checkbox"/>	7.	<p>Are all prescription dispensing records verified by a pharmacist within 24 hours of dispensing an ED pre-pack, to include the following?</p> <ul style="list-style-type: none"> <li>• Verification of drug name, strength, and quantity</li> <li>• Performing and documenting a DUR</li> </ul> <p><b>Note:</b> If the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open (not to exceed 72 hours following the dispensing).</p>	<a href="#">OAR 855-041-6410(1)(h)</a>
<input type="checkbox"/>	<input type="checkbox"/>	8.	<p>Are dual language prescription labels available in each of the 14 required languages, and provided upon request by the patient or patient's agent?</p> <p><b>Note:</b> The prescription must bear a label in <b>both</b> English and the language requested.</p>	<a href="#">OAR 855-041-1132</a> <a href="#">ORS 689.564</a>
<input type="checkbox"/>	<input type="checkbox"/>	9.	<p>Does the pharmacy provide prescription readers upon request for visually impaired patients that are appropriate for their specific type of visual impairment?</p>	<a href="#">OAR 855-041-1131</a> <a href="#">ORS 689.561</a>
<input type="checkbox"/>	<input type="checkbox"/>	10.	<p>Does the pharmacy have signage easily seen by the public which provides notification of the right to free, competent oral interpretation and translation services (including translated prescription labels) in each of the 14 required languages?</p> <p><a href="#">Dual Language Labeling Sign for Pharmacies</a></p>	<a href="#">OAR 855-041-1035</a> <a href="#">OAR 855-041-1131</a>

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, that written policies and procedures reflect current practices, that I have documented training of staff, and that the answers marked on this form are true and correct.

Date:

Signature of PIC: \_\_\_\_\_

Printed Name of PIC:

License # RPH:

**PHARMACY PERSONNEL – KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED**

Have each licensee review this inspection form, corresponding documents and procedures, and be prepared to assist in locating information during an inspection.

<b>NAME</b>	<b>FULL OREGON LICENSE NUMBER</b>	<b>OREGON LICENSE EXPIRATION DATE</b>



**LOCATION OF TECHNICIANS**

Please use this page to list where technicians are located. What are they doing at each location? How are they supervised, directed, and controlled?

<b><u>LOCATION</u></b>	<b><u>TASKS/DUTIES</u></b>	<b><u>SUPERVISION, DIRECTION AND CONTROL</u></b>
<i>Example: Inpatient Pharmacy and Multiple floors</i>	<i>Refilling ADCs</i>	<i>Supervised, directed, and controlled by staff inpatient RPH. In patient pharmacist to answer technician questions, verify technician work, and provide direction of what tasks may be performed.</i>