

# 2025 INSTITUTIONAL DRUG OUTLET SELF-INSPECTION FORM

#### **ATTENTION: PHARMACIST-IN-CHARGE (PIC)**

Failure to complete this form by July 1, 2025, 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 (OAR 855-115-0205(1)(a)(b)(c)):

- 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.

Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years (OAR 855-115-0200(3)).

**Requirements:** Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the Compliance Officer immediately upon request at the time of inspection and retained in compliance with <u>OAR 855-104-0055</u>.

**Scope:** The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, and laws and rules may 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.

**Agency 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

# 2025 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 7/1/2025 (as required by OAR 855-115-0210).

Date PIC completed Self-Inspection:	//	_
PIC Name:		RPH 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. 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 policy # and location):

- Diversion Prevention and Drug Security
- Language Services (to include Prescription Reader, Label Translation, and Interpreter Services)
- Destruction or Return of Adulterated/Outdated Controlled Substances
- Collaborative Drug Therapy Management (CDTM)

o Telework (to include agreements, prescriptions, etc.)

#### **Trainings/ Certifications**

- o Initial and Ongoing Technician Training
- o Medication Reconciliation Training
- Drug Take-Back Box Training

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

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

#### **Cold Drug Storage**

- o 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)

 Public Health and Pharmacy Formulary Advisory Committee (PHPFAC) (including statewide drug therapy management protocols and formulary)

#### **INSTRUCTIONS:**

Verify compliance of each section by marking the corresponding box. Should any non-compliance be identified, rectify the deficiencies and record the correction date

#### **General Requirements**

res	NO			Rule Reference
		1.	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)
		2.	Are the following current, and conspicuously posted? (check box)  Pharmacy registration(s)  DEA registration  Pharmacist license(s)  Preceptor license(s)  Intern license(s)  Technician license(s)  Laboratory license (if applicable)	ORS 689.615 OAR 855-041-1190(2)(a) OAR 855-115-0105(11) OAR 855-120-0105(3)(i) OAR 855-120-1070(3)(a) OAR 855-125-0105(3)(j)
		3.	Is the hospital accredited?  If yes, by whom?	
		4.	Are all pharmacy staff aware that Compliance Officers must be permitted to perform the following?  Inspect conditions, structures, equipment, materials, and methods for compliance  Inspect all drugs and devices  Take photographs, recording video and audio; and  Review, verify, and make copies of records and documents	OAR 855-104-0055 OAR 855-104-0115

	5.	Are all licensees aware that they must report:	OAR 855-104-0010 OAR 855-041-1030 21 CFR 1301.76(b)
		<ul> <li>Felony arrests OR convictions, misdemeanor convictions, and suspected or known violations of state pharmacy laws and rules to the Board within 10 days?</li> <li>Changes in legal name, name used when in pharmacy, preferred email address, personal phone number, physical address, mailing address, and employer within 15 days?</li> </ul>	
		Note: Visit mylicense/eGov to update	
	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 within 10 working days?	OAR 855-041-1010(4)
	7.	Is the PIC responsible for more than 1 location? If so, list additional sites and registration number below:  1	OAR 855-115-0205(2)
		Note: 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).	
	8.	Are policies and procedures for the following items current, and compliant with federal and state regulations? (check once verified)  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 final verification and/or vaccination, if utilized Drug and/or device procurement Receiving of drugs and/or devices Disposal of drugs and/or devices including hazardous and pharmaceutical waste Delivery of drugs and/or devices Utilization of Oregon licensed pharmacist (i.e. Drug Utilization Review (DUR), Counseling) Recordkeeping	OAR 855-041-1040

Yes	No			Rule Reference
			<ul> <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 for all licensees</li> <li>□ Interpretation, translation, and prescription reader services</li> </ul>	
Perso Yes	nnel (	(Non-I	licensed, Technicians, Certified Oregon Pharmacy Technicians, Inte	rns, and Pharmacists) Rule Reference
res	NO			Rule Reference
		9.	Are <u>all pharmacy staff</u> clearly identified in all interactions and communications (e.g., nametag, phone interactions, chart notations)?	OAR 855-115-0105(10) OAR 855-120-0105(3)(h) OAR 855-125-0105(3)(i)
		10.	Are <u>all pharmacy staff</u> trained appropriately prior to performance of tasks and with each policy/procedure update for the practice site?  Note: This training should include an <u>annual review</u> of the PIC Self-Inspection Form.	OAR 855-115-0120(1)(i) OAR 855-120-0105(3)(e) OAR 855-125-0105(3)(k)
		11.	At all times, during any given shift, do ALL:  Pharmacists know the identity of each intern under their supervision, and certified Oregon pharmacy technician and pharmacy technician under their supervision, direction, and control?  Interns know their supervising pharmacist or preceptor?  Technicians know the pharmacist that is supervising, directing, and controlling their work?	ORS 689.486 OAR 855-115-0120(1)(d) OAR 855-120-0105(3)(d) OAR 855-125-0105(3)(b)(c)
		12.	Are <u>technicians</u> 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?	OAR 855-125-0105(3)(k)
		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	OAR 855-125-0135(2)

technicians?

by a pharmacist?

Does the PIC review the written procedures annually?

Do technicians know they cannot use judgment without verification

How is pharmacist verification of technician work documented?

14.

OAR 855-125-0135(2)

	15.	Do technicians know they can only assist in the practice of pharmacy as permitted by the pharmacist who is supervising, directing, and controlling their work, and cannot perform 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:  Counseling DUR Conducting MTM Recommending or forecasting vaccinations Prescribing	ORS 689.005(28)(29) OAR 855-125-0150(1)(3)
	16.	<ul> <li>Do <u>interns</u> know that they:         <ul> <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 and not conduct a DUR, DRR, counseling, advising, MTM, engaging in a CPA/CDTM or statewide protocol, prescribing or performing verification during their first academic year?</li> </ul> </li> </ul>	OAR 855-120-0150

# **Pharmacists**

Yes	No			Rule Reference
		17.	Does the pharmacist ensure that each medication order contains all of the required elements?	OAR 855-115-0130(1)(c) OAR 855-041-1105
		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?	OAR 855-041-1105(3)
		19.	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	OAR 855-115-0130(1)(d) OAR 855-041-1165
		20.	Does the pharmacist follow policies and procedures to ensure that prescription orders are accurately dispensed to the correct party, pursuant to a valid prescription order and patient-practitioner relationship, and for a legitimate medical purpose?	OAR 855-115-0130(1)(e) OAR 855-115-0210(1)(d) OAR 855-041-1105
		21.	Does the pharmacist perform a DUR for ALL prescription order prior to dispensing, or preparing for administration?  If an intervention is required, how is it carried out and documented?	OAR 855-115-0140

Yes	No			Rule Reference
		22.	Does the pharmacy and pharmacist ensure that expiration dates of prescriptions are labeled with an expiration date after which the patient should not use the drug or medicine? Expiration dates on prescriptions must not exceed:  • That on the manufacturer's container if dispensed in the manufacturer's container; or  • The earliest date of either:  • The manufacturer's expiration date; or  • One year from the date the drug was repackaged and dispensed  Note: Any drug expiring before the expected length of time for the course of therapy must not be dispensed.	OAR 855-041-1130(10)(11)
<u>Labeli</u>	ing			
Yes	No			Rule Reference
		23.	Do labels on each drug dispensed to an inpatient contain the following information?  • Patient name and location  • Drug name and strength  • Route of administration (when necessary for clarification)  • Manufacturer and lot number (or internal pharmacy code)  • Auxiliary labels (if needed)  • Expiration date	OAR 855-041-6270(3)
		24.	Does the pharmacy add a barcode or an electronic label to any drug?  Note: If so, a pharmacist must verify and document accuracy prior to distribution.	OAR 855-041-6270(5)
		25.	Are repackaged unit-dose drugs labeled with the following?     Name, strength, and expiration date     Manufacturer and lot number (or internal pharmacy code which references manufacturer and lot number)  Note: This includes labeling individual oral syringes.	OAR 855-041-6270(2)
		26.	Does the pharmacy document all pharmacy personnel involved in repackaging, including the pharmacist who verified the repackaged drug?	OAR 855-041-6270(1)
Δhser	nce of	a Pha	rmacist □ N/A	
Yes	No	<u>a i 1141</u>	IIIIdolot LI IVA	Rule Reference
			Does the hospital use a night cabinet or allow after-hours	OAR 855-041-6300
		27.	access to the pharmacy?	<u>OAN 000-04 1-0000</u>

	28.	Is access to the night cabinet or pharmacy limited to <b>one</b> authorized registered nurse on a shift?	OAR 855-041-6305 OAR 855-041-6310
		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?	
	29.	For each drug removed after hours, does a pharmacist confirm the following?  The nurse was appropriately trained The nurse's initials were documented A copy of the practitioner's order was left for verification Either the container from which the drug was removed, or an identical unit dose, was left for accuracy verification	OAR 855-041-6310(2)

# **Security of Records and Drugs**

Yes	No			Rule Reference
		30.	Does the PIC/pharmacist know they are responsible for the security of the pharmacy area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.	OAR 855-041-1020
		31.	What are the procedures for the pharmacist to maintain supervision of the pharmacy and staff located in satellite locations outside the pharmacy?	OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1) OAR 855-041-6200
			Who is permitted to access the pharmacy and under what conditions?	
		32.	Can orders be processed, or records accessed, when a pharmacist is not on duty?  If so, please explain:	OAR 855-041-1020(3)
		33.	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)?	OAR 855-041- 1055(1)(2)
			Is the PIC/pharmacy aware that a licensee or registrant of the board MAY NOT ACCESS OR OBTAIN patient information unless it is for the purpose of patient care, except as provided in OAR 855-041-1055(1)(a)-(e)?	
		34.	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.)?	OAR 855-041-1025 OAR 855-041- 1036(1)(d)

			21 U.S.C. 351 21 U.S.C. 352
	35.	How does the pharmacist/pharmacy maintain the security of <b>controlled substances</b> that have been quarantined?	OAR 855-041-1020 OAR 855-041-6200 OAR 855-115-0125(5)

#### **Controlled Substances**

Yes No **Rule Reference** Is the pharmacy aware that pseudoephedrine and ephedrine are OAR 855-080-0026 36. П П Schedule-V Controlled Substances in Oregon? Are on-hand quantity changes of controlled substances reviewed? 37. If so, how often, and by whom? Who is permitted to make on-hand changes? Is the pharmacist/pharmacy reporting suspected theft, or confirmed OAR 855-115-0115 38. OAR 855-041-1030 significant loss, of a controlled substance to the Board and DEA within 1 business day? CFR 1306.76(b) Submit by email to pharmacy.druglossreporting@bop.oregon.gov, with "Controlled Substance Loss Notification" in the subject line. Are annual CII through CV controlled substance inventories (with OAR 855-080-0070 39. reconciliations) performed on one day, and within 367 days of the last OAR 855-115inventory? 0210(1)(i) OAR 855-041-Dates of the last two annual controlled substance inventories (with 1020(2) reconciliation): and \_\_\_\_/ \_\_\_\_/ Note: Ensure a complete controlled substance inventory (CII through CV) with discrepancy reconciliation is done.

		<ul> <li>Inventory includes drugs in will call or pending patient pick up, in LTC e-kits, drugs used for compounding, items in the refrigerator, automated dispensing machines, outdated controlled substances, etc.</li> <li>Non-24-hour pharmacies must indicate if the inventory was completed before opening or after closing.</li> </ul>	
	40.	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>performed at least every 31 days</b> .?	OAR 855-041- 6610(1)(a) OAR 855-115- 0210(1)(i)
		Are quarantined controlled substances included in the monthly inventory?  Note:  Providing an on-hand count is not sufficient to meet this requirement.  Electronic and written records, MUST be made available at time of inspection.	3 3 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
	41.	Is the PIC ensuring that ALL DISCREPANCIES involving a CII controlled substance are DOCUMENTED, and CLEARLY EXPLAINED?  Note:  If it is determined that no discrepancies are found, documentation to show this (i.e. written documents with investigative notes, screenshot of computer, etc.) must be provided.	OAR 855-115- 0210(1)(i) OAR 855-041- 1020(2)
	42.	Are CII records (prescriptions, inventories/reconciliations, invoices, etc.) filed separately from those in all other classes?	21 CFR 1304.04
	43.	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?  What is the pharmacies QA procedure?  How does the pharmacist review this data?	OAR 855-041- 6610(1)(c)

	45.	Does the pharmacy utilize electronic surveillance or analytics to assist with this (e.g. monitoring drugs removed from stock, administered, and wasted)?	OAR 855-041-6600
	46.	What is the pharmacy's process for reconciling the quantity of controlled substances received on invoice with the quantity added to inventory?	OAR 855-041-6600 OAR 855-041- 6200(3)(c)

# **Cold Drug Storage**

Yes	No			Rule Reference
		47.	Is there documented training for ALL pharmacy personnel related to the cold drug storage monitoring plan (to include vaccine drug storage)?	OAR 855-041-1036(2)
		48.	Are the thermometers/probes centrally placed?	OAR 855-041-1036(2)
		49.	Are thermometers/probes routinely calibrated to ensure accuracy?  Note: this is not the same as the quarterly validation requirement.  When is the next calibration due?///  Note: If units have different calibration dates please attach list of units with due dates.	OAR 855-041-1036(2)
		50.	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), or as specified by the manufacturer?  Note: ANY temperature outside of these parameters for ANY amount of time IS CONSIDERED AN EXCURSION, unless specified by the manufacturer, and should be researched appropriately with documentation maintained.	OAR 855-041-1036(2) (a)(A)
		51.	Are ALL excursions documented to include the following?     Event date & time frame     Name of person(s) involved     Pharmacist's review of duration and magnitude     Action(s) taken, whether to quarantine product for destruction/return, or keep product if deemed safe for continued use     Source of information used (e.g. package insert, contacted manufacturer, etc.)     Identity of pharmacist who made final decision	OAR 855-041- 1036(2)(b)(D-E)

# Vaccine Drug Storage ☐ N/A

Yes	No	Rule Reference

	52.	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator?	OAR 855-041-1036(3)(a)(A)
	53.	Does each active vaccine storage unit utilize a system of continuous temperature monitoring with automated data logging?	OAR 855-041-1036(3)(d)
	54.	Are quarterly validations conducted for <b>EACH</b> vaccine storage unit and its monitoring equipment?	OAR 855-041-1036(3)(a)(D)
		Date last validation was performed://	
		Date next validation is due://	
		<b>Note</b> : Quarterly validations are not the same as thermometer calibrations.	

# **Emergency Kit and Code Cart**

Yes No Rule Reference

	55.	Does a pharmacist verify and document the contents of all emergency kits?	OAR 855-041-6420(2)
		<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.	
	56.	Is each kit/code cart locked and <u>externally labeled</u> with name, strength, and quantity of each medication it contains and the expiration date of the kit (first expiring drug)?	OAR 855-041-6420(6)(7)
		<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 accessed without breaking the primary cart or kit's lock.	

Auton	utomated Distribution Cabinets (ADC), Floor Stock, Non-emergency Trays and Kits					
Yes	No			Rule Reference		
		57.	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?  Who is responsible for supervising the inspection and any follow-up needed if the inspection is performed by a technician?	OAR 855-041-6200(3)(d)		
		58.	Who does the PIC permit to access each ADC?	OAR 855-041-6540(4)		
			How does the PIC determine who to permit accesses to and when to revoke it?			
			Note: A nurse or technician is not permitted to return a drug to an ADC after removing it, except to place it in a designated return bin.			
		59.	How does the pharmacy ensure that all returned drugs from ADCs are reviewed by a pharmacist prior to returning them to the pharmacy inventory?	OAR 855-041-6540(7)		
		59.	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?  Note: Discrepancy reconciliations must be documented and	OAR 855-041-6540(8)		

supervised by a pharmacist.

ation	Histo	ory Reconciliation N/A	
No			Rule Reference
	60.	Is the pharmacy involved in obtaining medication histories and performing medication reconciliations?  If yes, what is the pharmacist's role?	
	61.	Who is permitted to obtain the medication history for medication reconciliations?	855-115-0120 (1)(f) 855-125-0135
	62.	If a technician is involved, how are they supervised, directed, and controlled by a pharmacist?	ORS 689.486(6) 855-125-0135
		How and when is the technician's work verified by a pharmacist?	
		** Please provide technician training specific to this task for all technicians involved.**	
ound	<u>ing</u>		
No			Rule Reference
	63.	Does pharmacy at this location participate in Compounding?  If yes, please print, complete, and attach the <u>Compounding Self Inspection Form</u>	OAR 855-115-0315
oorati	ve Dr	ug Therapy Management (CDTM)	1
No			Rule Reference
	64.	Do pharmacists at this location participate in CDTM? <b>Examples:</b> Vancomycin-dosing and anticoagulation-dosing.	OAR 855-115-0315
	No   Dound   No   Dorati	No	Sounding   Sounding

If yes, please print, complete, and attach the <u>Additional Services Self-Inspection Supplement.</u>	

# **Final Verification**

Yes	No			Rule Reference
		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 <a href="mailto:physical verification">physical verification</a> 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 <a href="mailto:additional Services">Additional Services</a> <a href="mailto:Self-Inspection Supplement.">Self-Inspection Supplement.</a>	ORS 689.005 OAR 855-005-0006(18) OAR 855-115-0130(3) OAR 855-125-0105(4)

# **Telework**

Yes	No			Rule Reference
		66.	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)?	OAR 855-041-3205
			<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 <u>Additional Services</u> <u>Self-Inspection Supplement.</u>	

# INSTITUTIONAL DRUG OUTLET with RETAIL DRUG OUTLET SELF-INSPECTION FORM

If the Hospital Pharmacy has a Retail Registration, but provides limited retail services, completion of the following abbreviated *HOSPITAL WITH RETAIL PHARMACY SELF-INSPECTION FORM* is required.

Alternatively, a RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY SELF-INSPECTION FORM must be completed if the hospital has a traditional retail pharmacy and dispenses prescriptions to the public beyond dispensing ED prepacks from the emergency department

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# **General Requirements**

Yes	No		Rule Reference
		<ul> <li>Are the outlet's policies and procedures for the following items current, and compliant with federal and state regulations?</li> <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>	OAR 855-041-1040

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

Yes No **Rule Reference** Do labels for each patient specific prescription dispensed to a OAR 855-041-1130 2. patient contain the following information? Name, address and telephone number of the pharmacy; Date of fill; Identifying number: Patient name; Drug name and strength, quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor; Directions for use by the patient; Name of the practitioner: Required precautionary information; Expiration date; 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. Is the amount of medication contained in each ED prepack limited OAR 855-041-6410(3) 3. to a 48-hour supply, unless otherwise allowed in Board rule? Does your outlet have policies and procedures that place П П limitations on prepack medications? If so, please explain: Do labels for each ED prepack contain the following information: OAR 855-041-06410(1)(d) П П 4. 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: Accessory cautionary information as required for patient Product identification label if the drug is not in unit-of-use packaging: An expiration date after which the patient should not use the drug; and Name, address and phone number of the hospital pharmacy. Does the pharmacy ensure that the practitioner or nurse adds the OAR 855-041-6410(1)(e)(2) 5. following information to the drug container before dispensing it to the patient? Name of patient: Directions for use by the patient; Date of issue;

		Unique identifying number as determined by policy and	
		procedure;	
		Name of prescribing practitioner; and	
		Initials of the dispensing nurse or practitioner.	
		Note: A label is not required for certain short acting opioid	
		antagonist as described in ORS 689.813	
	6.	Does the practitioner or nurse ensure that the following	OAR 855-041-6410(1)(f)
	0.	information is maintained in the dispensing record:	
		<ul><li>Name of patient;</li><li>Date of issuance;</li></ul>	
		<ul> <li>Drug name and strength distributed;</li> </ul>	
		Units issued;	
		Name of practitioner;  Initials of the diagonaina pures or practitioner; and	
		<ul> <li>Initials of the dispensing nurse or practitioner; and</li> <li>Instructions given to the patient as labeled.</li> </ul>	
		Are all prescription dispensing records verified by a pharmacist	OAR 855-041-6410(1)(h)
	7.	and is the review documented within 24 hours of dispensing an	<u> </u>
		ED pre-pack, to include the following?	
		<ul> <li>Verification of drug name, strength, and quantity</li> <li>Performing and documenting a DUR</li> </ul>	
		1 Onoming and documenting a Bott	
		<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).	
		Are dual language prescription labels available in each of the 14	OAR 855-041-1132
	8.	required languages, and provided upon request by the patient or	ORS 689.564
		patient's agent?	
		<b>Note:</b> The prescription must bear a label in <b>both</b> English and the	
		language requested.	
	9.	Does the pharmacy have signage easily seen by the public	OAR 855-041-1035
	0.	which provides notification of the right to free, competent oral interpretation and translation services (including translated	OAR 855-041-1131
		prescription labels) in each of the 14 required languages?	
		Dual Language Labeling Sign for Pharmacies	
	10.	Is the pharmacy aware that for patients in Oregon, a pharmacist or intern must work with a health care interpreter from the health	OAR 855-041-1133 ORS 413.558
		care interpreter registry administered by the Oregon Health	<u> </u>
		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?	
		Notes The phenomeniation down pullet are a set along the first	
		<b>Note:</b> The pharmacist or drug outlet may not charge for these services.	
		OHA Health Care Interpreter Registry	OAD 055 044 4400(0)
	11.	Is the pharmacy aware that a pharmacist or intern may work with a health care interpreter who is not listed on the health care	OAR 855-041-1133(2)
		interpreter registry only if the following apply?	
		1	

Yes	NO			Kule Reference
			<ul> <li>The pharmacist or intern has made a good faith effort to obtain an interpreter from the health care interpreter registry and has found that none are available to provide interpretation; or</li> <li>An interpreter from the health care interpreter registry was offered, and the patient declined/chose another interpreter.</li> </ul>	
		12.	<ul> <li>Is the pharmacy retaining the following documentation?</li> <li>Each patient encounter in which the pharmacist or intern worked with a health care interpreter from the health care interpreter registry; or</li> <li>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 – see #66 above for exceptions</li> <li>Note: These records must be retrievable at the time of inspection and include: the full name of the health care interpreter, the health care interpreter's registry number, as applicable and the language interpreted.</li> </ul>	OAR 855-041-1133
		13.		OAR 855-041-1131 ORS 689.561
Pharn	nacy I	Presci	ription Locker (PPL)	
Yes	No			Rule Reference
		14.	Is the pharmacy an Affiliated Pharmacy for a Pharmacy Prescription Locker (PPL)?	OAR 855-143
			If yes, please print, complete, and attach the <u>PPL Self-</u> Inspection Form.	
Pharn	nacy I	Presci	ription Kiosk (PPK)	
Yes	No			Rule Reference
		15.	Is the pharmacy utilizing a Kiosk?	OAR 855-141

If yes, please print, complete, and attach the *Kiosk Self-Inspection Form.* 

Date:	/	_/			
Signature of PIC:					
Drinted N	ame of PIC:				

correct.

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, and that the answers marked on this form are true and

# 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.

NAME	FULL OREGON LICENSE NUMBER	OREGON LICENSE EXPIRATION DATE

# PHARMACY PERSONNEL - KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED (cont.)

NAME	FULL OREGON LICENSE NUMBER	OREGON LICENSE EXPIRATION DATE

#### **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?

LOCATION	TASKS/DUTIES	SUPERVISION, DIRECTION AND CONTROL
Example: Inpatient Pharmacy and Multiple floors	Refilling ADCs	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.