2023
INSTITUTIONAL 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 Institutional 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 drug outlet'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 drug outlet 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.

The Inspection Report will be emailed to the PIC's work email address in 2 to 4 weeks. It should be reviewed, and a copy should be retained with the Self Inspection Report for 3 years as part of the outlet's records.

2023
INSTITUTIONAL DRUG OUTLET
SELF-INSPECTION FORM

All PICs 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:

Institutional Drug Outlet Registration #:

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 past 3 years:

Repackaging Records:

CDTM Agreements:

Policies and Procedures:

Current Drug Outlet Procedures:

CDTM:

Diversion; Prevention and Supporting Drug Security Documentation:

Interpretation Services:

Telework:

Controlled Substances

Current written annual controlled substance inventory:

Schedule II Invoices for the past 3 years:

Schedule III-V Invoices for the past 3 years:

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

Perpetual Schedule II inventory and Monthly reconciliations:

QA procedure for the random sampling of the CII inventory performed at least quarterly:

Training

Drug Storage Training Documents:

Technician Training Documents:

Aseptic manipulative skills testing:

Telework:

Cold Drug Storage Records

Policies and procedures:

Temperature logs:

Quarterly validation of cold storage equipment:

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:

****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
☐	☐	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)
☐	☐	2.	Are all pharmacy staff aware that Compliance Officers are authorized to and must be permitted to perform the following: • Inspecting conditions, structures, equipment, materials, and methods for compliance; • Inspecting all drugs and devices; Taking photographs, recording video and audio; and • Reviewing, verifying, and making copies of records and documents. Note: • 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
☐	☐	3.	Is the hospital accredited? If yes, by whom? Date(s) of the last accreditation survey: ***Please attach all pharmacy observations and recommendations.***	
☐	☐	4.	Are the current active pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615

Yes	No			Rule Reference
☐	☐	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/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 CFR 1301.76(b)
☐	☐	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
☐	☐	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: • Security; • Operation, testing and maintenance of pharmacy systems and equipment; • Sanitation; • Storage of drugs • Dispensing; • Pharmacist supervision, direction and control of technicians and supervision of Interns; • 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, if utilized; • 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; and • Training: initial and ongoing.	OAR 855-041-1040 OAR 855-019-0300(5)(f)
☐	☐	8.	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)

Yes	No			Rule Reference
		9.	What are the procedures to maintain supervision of the pharmacy? Who is permitted to access the pharmacy and under what conditions?	OAR 855-019-0200(8) OAR 855-041-1020(1) OAR 855-041-1040(1) OAR 855-041-6200
☐	☐	10.	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)
☐	☐		Does the PIC review the written procedures annually?	
☐	☐	11.	Does the pharmacy quarantine ALL outdated, damaged, deteriorated, adulterated, misbranded and suspect product? Where does the pharmacy quarantine drugs?	OAR 855-041-1025 OAR 855-041-1036(1)(d) 21 CFR
☐	☐	12.	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? A licensee may disclose patient information: (a) To the board; (b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by an Oregon licensed Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or wellbeing; or (c) To a third party when disclosure is authorized or required by law; or (d) As permitted pursuant to federal and state patient confidentiality laws; or (e) To the patient or to persons as authorized by the patient.	OAR 855-041-1055(1)(2)
☐	☐		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?	

Controlled Substances

Yes	No			Rule Reference
☐	☐	13.	Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory? Date of last annual CII-CV inventory: Note: 24-hour pharmacies need to indicate the time frame in which the inventory was completed. It is acceptable to have one report for the central pharmacy then additional reports for other areas that have floor stock, including ADCs, kits, carts, and ED pre-packs.	OAR 855-080-0070
☐	☐	14.	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?	21 CFR 1304.04
☐ ☐	☐ ☐	15.	Is the hospital following established procedures to account for all controlled substances? Does the pharmacy utilize electronic surveillance or analytics to assist with this? (i.e. monitoring drugs removed from stock, administered, and wasted)	OAR 855-041-6600
		16.	What is the pharmacy's process for reconciling the quantity of controlled substances received on invoice and the quantity added into inventory?	OAR 855-041-6600 OAR 855-041-6200(3)(c) OAR 855-019-0200(1)(2)
☐	☐	17.	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 at least monthly?	OAR 855-041-6610(1)(a)
☐	☐	18.	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?	OAR 855-041-6610(1)(c)
☐	☐	19.	How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded, and suspect product)? Are quarantined controlled substances included in the monthly inventory?	OAR 855-041-6200

Security

Yes	No			Rule Reference
☐	☐	20.	Is the pharmacy only operated when a pharmacist licensed to practice in this state is present? Note: This means that the pharmacist must be physically present in the pharmacy or institutional facility.	OAR 855-041-1015(1)
☐	☐	21.	When there is no pharmacist present, is the pharmacy secured to prevent entry? Note: Except as permitted by OAR 855-041-6310	OAR 855-041-1020(3)
☐	☐	22.	Does the pharmacist ensure the security of the pharmacy area including: • 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
☐	☐	23.	Are pharmacists, interns and technicians **clearly identified** as such to the public?	OAR 855-025-0025(3)
☐ ☐	☐ ☐	24.	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)
☐	☐	25.	Does each technician know **at all times** the pharmacist that is **supervising, directing, and controlling** them? *Please complete page 22 regarding location of technicians	ORS 689.486 OAR 855-025-0023(2)(c)
☐	☐	26.	Does each pharmacist know **at all times** who they are **supervising, directing, and controlling** during any given shift?	ORS 689.486
☐	☐	27.	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

Yes	No			Rule Reference
☐	☐	28.	Is pharmacy staff aware that technicians and non-licensed personnel are not permitted to perform the following: • Counsel, make the offer to counsel on a new prescription and any changes in therapy, accept a request to not be counseled, release a prescription which requires counseling prior to a pharmacist or intern offering counseling, or document the counseling interaction. • Perform a DUR or any task that requires the professional judgement of a pharmacist • Communicate with patients about their medication in terms of drug class or indicate/use/diagnosis (e.g. when a patient asks for a refill of their "diabetes medication) • Include info about new oral rxs and transfers? Engage in the practice of pharmacy as defined in ORS 689	OAR 855-025-0040(3)(e) OAR 855-019-0200(2)(3) OAR 855-019-0230

Pharmacists

Yes	No			Rule Reference
☐	☐	29.	Is each pharmacist aware they are required to control each aspect of the practice of pharmacy?	OAR 855-019-0200(4)(b)
☐	☐	30.	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)
☐	☐	31.	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)
☐	☐	32.	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: • 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)

Yes	No			Rule Reference
☐	☐	33.	Does the pharmacist perform a DUR for all prescription orders? How is this DUR documented?	OAR 855-019-0220(3) OAR 855-041-1040(2)(g)

Labeling

Yes	No			Rule Reference
☐	☐	34.	Does the pharmacy document all pharmacy personnel involved in repackaging, including the pharmacist who verified the repackaged drug?	OAR 855-041-6270(1)
☐	☐	35.	Are repackaged unit dose drugs labeled with the following? • Name, strength, and expiration date • Manufacturer and lot number, or an internal pharmacy code that references the manufacturer and lot number Note: This includes labeling individual oral syringes.	OAR 855-041-6270(2)
☐	☐	36.	Is each drug dispensed to an inpatient labeled with the following information: • Name and location of patient; • Name and strength of drug; • Route of administration, when necessary for clarification; • Manufacturer and lot number, or internal pharmacy code; • Auxiliary labels as needed, and • Expiration date. Note: A drug that is provided for outpatient use must be dispensed by a retail drug outlet.	OAR 855-041-6270(3)
☐	☐	37.	Does the pharmacy add a barcode or an electronic label to any drug? If yes, the pharmacist **must verify and document** the accuracy prior to distribution.	OAR 855-041-6270(5)

Drug Storage

Yes	No			Rule Reference
☐	☐	38.	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) or **as specified by the manufacturer?** **Note: An excursion is any temperature outside of these specified parameters for any amount of time.**	OAR 855-041-1036

Yes	No			Rule Reference
☐	☐	39.	Does the pharmacy have documented training for ALL pharmacy personnel related to the drug storage monitoring plan?	OAR 855-041-1036(2)
		40.	Where is the pharmacy's emergency plan for all refrigerated and frozen products located?	OAR 855-041-1036 (2)(b)(F)
☐	☐	41.	Does the pharmacy have a quality assurance plan specific to vaccine storage?	OAR 855-041-1036 (3)(a)(E)
☐	☐	42.	**Do all explanations and documentation of ALL drug storage excursions include at least all the following?:** • The event date and timeframe; • The name of person(s) involved in response; • Pharmacist review of duration and variance; • Action(s) taken o The decision to quarantine product for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; o This documentation must include details of the information source • Which **pharmacist** made the final decision	OAR 855-041-1036(2)
☐	☐	43.	Does the hospital conduct **quarterly validations** of **each active** *vaccine* storage unit and their monitoring equipment? How are quarterly validations conducted? Note – Quarterly validations are not the same as the calibration of thermometers.	OAR 855-041-1036(3)
		44.	How does the hospital ensure **calibrations** of the thermometers are conducted as specified by the manufacturer?	OAR 855-041-1036(2)(b)(B)

Vaccine Drug Storage ☐ N/A

Yes	No			Rule Reference
☐	☐	45.	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator?	OAR 855-041-1036(3) (a)(A)

Yes	No			Rule Reference
☐	☐	46.	Does each active vaccine storage unit utilize a system of *continuous* temperature monitoring with automated data logging?	OAR 855-041-1036(3)(d)
☐	☐	47.	Does the pharmacy conduct quarterly **validations** of **EACH** *vaccine* storage unit and their monitoring equipment? When is the next validation due? **Note**: Quarterly validations are not the same as the thermometer calibrations	OAR 855-041-1036(3) (a)(D)

Emergency Kit and Code Cart

Yes	No			Rule Reference
☐	☐	48.	An emergency kit consists 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 of emergency kits are a Malignant Hyperthermia Kit, Stroke Kit, RSI Kit, or Maternal Hemorrhage Kit Does a pharmacist verify and document the contents of all emergency kits?	OAR 855-041-6420(2)
☐	☐	49.	Is each kit/code cart locked and labeled with name, strength, quantity, and expiration date of the kit/cart? Note: The expiration date of the kit/cart should be the expiration date of the first drug to expire in the kit/cart. The label/list must be on the **exterior** of the kit/cart.	OAR 855-041-6420(6) and (7)

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

Yes	No			Rule Reference
☐	☐	50.	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?	OAR 855-041-6200(3)(d)

Yes	No			Rule Reference
		51.	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? Note: A nurse or technician is not permitted to return a drug to an ADC after removing it, except to place in a designated return bin.	OAR 855-041-6540(4)
		52.	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)
☐	☐	53.	Is a count confirmation (i.e. blind count) performed at all times a controlled substance is accessed (loaded, unloaded, removed, and inventoried) in an ADC? Note: Discrepancies must be documented and reconciled.	OAR 855-041-6540(8)

Final Verification ☐ N/A

Yes	No			Rule Reference
☐	☐	54.	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 is the prescribed drug and drug dosage, device, or product.	ORS 689.005 OAR 855-005-0006(18) OAR 855-019-0200(5)(6) OAR 855-025-0023(4)
☐	☐	55.	If the pharmacist chooses to delegate final verification to a technician, has the pharmacist used their reasonable professional judgment in making this determination? Note: • 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

Yes	No			Rule Reference
☐	☐	56.	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
☐	☐	57.	Does the supervising pharmacist ensure that the technician performs a physical (i.e. in person) “final verification”? How does the supervising pharmacist do this?	OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
☐	☐	58.	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

Absence of a Pharmacist ☐ N/A

Yes	No			Rule Reference
☐	☐	59.	Does the pharmacy utilize off-site or non-resident pharmacists to perform remote verification? If yes provide name and license #s: Note: This requires Oregon registration and remote processing designation.	OAR 855-019-0100
☐	☐	60.	Does the hospital use a night cabinet or allow after-hours access to the pharmacy?	OAR 855-041-6300

Yes	No			Rule Reference
☐	☐	61.	Is access to night cabinet or pharmacy limited to one authorized registered nurse 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?	OAR 855-041-6305 OAR 855-041-6310
☐	☐	62.	When a drug is removed after hours, is the pharmacist confirming that: • The nurse has been appropriately trained • The nurse's initials are documented • A copy of the practitioner's order is left for verification • Either the container from which the drug was removed, or an identical unit dose is left for accuracy verification	OAR 855-041-6310(2)

Collaborative Drug Therapy Management (CDTM) ☐ N/A

Yes	No			Rule Reference
☐	☐	63.	Does a pharmacist participate in Collaborative Drug Therapy Management (CDTM)? *Examples*: Vancomycin-dosing and anticoagulation-dosing.	OAR 855-019-0260
☐	☐	64.	Does the written CDTM agreement contain the following: • 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)
☐	☐	65.	Are CDTM agreements being reviewed and updated at least every two years?	OAR 855-019-0260(2)(h)
☐	☐	66.	Are the practitioner and pharmacist identified on each CDTM prescription order? Note: The practitioner is the individual who referred the patient for treatment under the CDTM agreement. For a prescription written by a pharmacist under CDTM to be valid, the practitioner must be identified as the prescriber.	OAR 855-019-0260 (2)(a-b)

Medication History/Reconciliation ☐ N/A

Yes	No			Rule Reference
☐	☐	67.	Is the pharmacy involved?	

Yes	No			Rule Reference
			If yes, what is the pharmacist's role?	
		68.	Who performs medication history gathering for medication reconciliation?	OAR 855-025-0025
☐	☐	69.	If a technician is involved, how are they supervised, directed, and controlled? How and when is the technician's work verified by a pharmacist? Provide technician training specific to this task.	ORS 689.486(6) OAR 855-025-0025(6)(1)

Telework ☐ N/A

Yes	No			Rule Reference
☐	☐	70.	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)? **Note:** This is considered telework at a telework site by the board. This is not applicable to pharmacists who are not working on behalf of a board-registered drug outlet and the technicians who are assisting those pharmacists. • If the answer is No to this question, please proceed to the next set of questions.	OAR 855-041-3205
		71.	How does the PIC and the supervising Pharmacist ensure the supervision, direction, and control of each technician?	OAR 855-041-3215 OAR 855-041-3220
☐	☐	72.	Are all of the following supervision requirements met? • Utilize technology that enables real-time audio and visual connections and interface to allow access to information required to complete assigned duties	OAR 855-041-3220

Yes	No			Rule Reference
			• Ensure telephone audio is recorded, reviewed, and stored, for all patient interactions completed by each Intern and technician • 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 audio and visual connection with a minimum of at least once per work shift, and documents the interaction • Ensure a pharmacist is readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and • Ensure the Intern or 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	

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

2023
INSTITUTIONAL DRUG OUTLET with RETAIL DRUG OUTLET
SELF-INSPECTION FORM

If the Hospital Pharmacy has a Retail Registration, completion of the following abbreviated *HOSPITAL WITH RETAIL PHARMACY SELF-INSPECTION FORM* is required. Alternately, 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 room.

☐ N/A

General Requirements

Yes	No			Rule Reference
☐	☐	73.	Are drug outlet procedures compliant with Oregon laws and rules and do they reflect the practice at the outlet and include the following? • 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;	OAR 855-041-1040

Yes	No			Rule Reference
			• Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians; • 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; • Plan for discontinuing and recovering services in the event of a pharmacy closure; • Training: initial and ongoing; and • Interpretation, translation, and prescription reader services.	

Outpatient Medications (including ED pre-packs)

Yes	No			Rule Reference
☐	☐	74.	Are all prescription dispensing records verified by a pharmacist within 24 hours of dispensing an ED pre-pack? If the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open, but not to exceed 72 hours following the dispensing. Note: This includes verifying name, strength, quantity of medication dispensed, directions for use, performing a DUR and documenting the review.	OAR 855-041-6410(1)(h)
☐	☐	75.	Are all outpatient prescriptions labeled with: the name, address and telephone number of the pharmacy, name of drug, strength, number of units, identifier of the manufacturer or distributor for generics without brand names, accessory cautionary information, product identification label and an **expiration date**?	OAR 855-041-1130
☐	☐	76.	Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent? Note: The prescription must bear a label **in both English and the language requested.**	OAR 855-041-1132 ORS 689.564
☐	☐	77.	Does the pharmacy provide prescription readers for visually impaired patients? Are prescription readers available and appropriate to address a person's visual impairment?	OAR 855-041-1131 ORS 689.561
☐	☐	78.	Does the pharmacy display information to patients that the pharmacy will offer language assistance to patients who need it including translated labels?	OAR 855-041-1035 OAR 855-041-1131
☐	☐	79.	Does the practitioner or nurse label the container for emergency outpatient prescriptions with the following: • Name of patient, • Directions for use, date, identifying number • Name of prescribing practitioner • Initials of the dispensing nurse?	OAR 855-041-6410 OAR 855-041-410(1)(i)

Yes	No			Rule Reference
☐	☐	80.	Is the amount of medication contained in each ED prepack limited to an emergency supply to meet the acute care needs of a patient? Are prepack medications limited by policy and procedures? Note: ED prepacks may not exceed 48-hour supply with limited exceptions permitted by Board rule.	OAR 855-041-6410(3)
☐	☐	81.	Is each patient provided instructions on the use and precautions for taking the drug?	OAR 855-041-6410(1)(c)

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 technicians and the answers marked on this form are true and correct.

Signature of PIC:

Printed Name of PIC:

License #:

Date:

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

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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.*