



2023
INSTITUTIONAL DRUG OUTLET
SELF-INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Oregon law states the pharmacist-in-charge (PIC) and all pharmacists on duty are responsible for ensuring the pharmacy is in compliance with all state and federal laws governing the practice of pharmacy. Failure to complete this form by February 1, 2023, and within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.

The primary objective of this form and your self-inspection is to provide an opportunity to identify and correct areas of non-compliance with state and federal law. (Note: Neither the self-inspection nor a Board inspection evaluates compliance with all laws and rules of the practice of pharmacy.) The inspection form also serves as a necessary document used by Board Compliance Officers during an inspection to evaluate a pharmacy's level of compliance.

Following your self-inspection and completion of the 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.

Do not assume that you are in compliance. Please review Board regulations and take the time to personally verify that compliance exists. Email all Compliance related questions to: pharmacy.compliance@bop.oregon.gov.

By answering the questions and referencing the appropriate laws and rules provided, you can determine whether the pharmacy is compliant with many of the rules and regulations. 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.

If in the inspection results in a Deficiency Notification (DN) or a Non-Compliance Notification (NCN), the Compliance Officer will include instructions.

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All PICs MUST complete and sign this inspection form and have it available for inspection within 15 days of becoming PIC and by 2/1/2023 (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:

Label Translation (LEP) Services:

Prescription Reader 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 & 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

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 any 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.

Public Health Emergency (PHE) and COVID

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	Are staff aware that Division 7 rules are ONLY in effect during a Public Health Emergency declared by the Governor or the Federal Government?	OAR 855-007
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2	Are staff familiar the COVID-19 resources on the Board of Pharmacy website (Covid Communication Update)? https://www.oregon.gov/pharmacy/Pages/COVID-19.aspx	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3	Are staff wearing masks or appropriate face coverings per current OHA requirements?	OAR 855-007-0088 OAR 333-019-1011 OAR 333-019-1025

General Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>		4	Are all pharmacy staff trained appropriately for the practice site? Note: This training should include an annual review of the PIC Self-Inspection Report	OAR 855-019-0300(5)(f)
<input type="checkbox"/>	<input type="checkbox"/>		5	Are all pharmacy staff aware that Compliance Officers are authorized to and must be permitted to perform the following: <ul style="list-style-type: none"> Inspecting conditions, structures, equipment, materials, and methods for compliance; Inspecting all drugs and devices; Taking photographs, recording video and audio; and Reviewing, verifying, and making copies of records and documents. Note: <ul style="list-style-type: none"> All records must be stored as required by ORS 475, ORS 689, and OAR 855. Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection. May be stored in a secured off-site location after 12 months of on-site storage, must be provided to the board upon request within three business days. 	OAR 855-001-0040
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6	Is the hospital accredited? If yes, by whom? Date(s) of the last accreditation survey: <i>*Please attach all pharmacy observations and recommendations.</i>	

Yes No N/A

Rule Reference

<input type="checkbox"/>	<input type="checkbox"/>		7	Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615
<input type="checkbox"/>	<input type="checkbox"/>		8	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/mailling address to the Board within 15 days. Visit https://orbop.mylicense.com/EGOV/Login.aspx to update.	OAR 855-019-0205 OAR 855-025-0020 OAR 855-031-0020 OAR 855-041-1030 CFR 1301.76(b)
<input type="checkbox"/>	<input type="checkbox"/>		9	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)
			10	What are the procedures to maintain supervision of the pharmacy? Who is permitted to access the pharmacy and under what conditions? Are there any computer terminals located outside the pharmacy that non-pharmacist staff can use to access patient information?	OAR 855-019-0200(8) OAR 855-041-1020(1) OAR 855-041-1040(1) OAR 855-041-6200
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11	Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet? Items to be addressed: <ul style="list-style-type: none"> • Security; • Operation, testing and maintenance of pharmacy systems and equipment; • Sanitation; • Storage of drugs • Dispensing; • Pharmacist supervision, direction, and control of non-Pharmacists; 	OAR 855-041-1040 OAR 855-019-0300(5)(f)

				<ul style="list-style-type: none"> • 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. 	
<input type="checkbox"/>	<input type="checkbox"/>		12	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)
<input type="checkbox"/>	<input type="checkbox"/>		13	Does each technician know at all times who is supervising, directing, and controlling them during any given shift? *Please complete page 22 regarding location of technicians	ORS 689.486
<input type="checkbox"/>	<input type="checkbox"/>		14	Does each pharmacist know at all times who they are supervising, directing, and controlling during any given shift?	ORS 689.486
<input type="checkbox"/>	<input type="checkbox"/>		15	Is all work performed by a technician that requires judgment verified by a pharmacist? How is pharmacist verification of technician work documented?	OAR 855-025-0025(4)
<input type="checkbox"/>	<input type="checkbox"/>		16	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? Does the PIC review the written procedures annually? Date of PIC review:	OAR 855-025-0025(5)
<input type="checkbox"/>	<input type="checkbox"/>		17	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

Controlled Substances

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	18	<p>Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory?</p> <p>Date of last annual CII-CV inventory:</p> <p>Note: 24-hour pharmacies need to indicate the time frame in which the inventory was completed.</p> <p>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.</p>	OAR 855-080-0070
<input type="checkbox"/>	<input type="checkbox"/>	19	<p>Is the annual CII inventory filed separately from the CIII-CV inventory and are CII invoices and prescriptions filed separately from other prescriptions and invoices?</p>	21 CFR 1304.04
<input type="checkbox"/>	<input type="checkbox"/>	20	<p>Is the hospital following established procedures to account for all controlled substances?</p> <p>Does the pharmacy utilize electronic surveillance or analytics to assist with this? (i.e. monitoring drugs removed from stock, administered, and wasted)</p>	OAR 855-041-6600
		21	<p>What is the pharmacy's process for reconciling the quantity of controlled substances received on invoice and the quantity added into inventory?</p>	OAR 855-041-6600 OAR 855-041-6200(3)(c) OAR 855-019-0200(1)(2)
<input type="checkbox"/>	<input type="checkbox"/>	22	<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 at least monthly?</p>	OAR 855-041-6610(1)(a)
<input type="checkbox"/>	<input type="checkbox"/>	23	<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>	OAR 855-041-6610(1)(c)
		24	<p>How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded, and suspect product)?</p>	OAR 855-041-6200
<input type="checkbox"/>	<input type="checkbox"/>		<p>Are quarantined controlled substances included in the monthly inventory?</p>	

Labeling

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25	Does the pharmacy document all pharmacy personnel involved in repackaging, including the pharmacist who verified the repackaged drug?	OAR 855-041-6270(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26	Are repackaged unit dose drugs labeled with the following? <ul style="list-style-type: none"> • 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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27	Does the pharmacy add a barcode or an electronic label to any drug? If yes, the pharmacist <u>must verify and document</u> the accuracy prior to distribution.	OAR 855-041-6270(5)

Drug Storage

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	28	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
<input type="checkbox"/>	<input type="checkbox"/>	29	Does the pharmacy have documented training for ALL pharmacy personnel related to the drug storage monitoring plan?	OAR 855-041-1036(2)
		30	Where is the pharmacy's emergency plan for all refrigerated and frozen products located?	OAR 855-041-1036(2)(b)(F)
<input type="checkbox"/>	<input type="checkbox"/>	31	Does the pharmacy have a quality assurance plan specific to vaccine storage?	OAR 855-041-1036(3)(a)(E)
<input type="checkbox"/>	<input type="checkbox"/>	32	Do all explanations and documentation of ALL drug storage excursions include at least all the following?: <ul style="list-style-type: none"> • The event date & time frame; • The name of person(s) involved in response; • Pharmacist review of duration and variance; • Action(s) taken <ul style="list-style-type: none"> ○ The decision to quarantine product for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; 	OAR 855-041-1036(2)

Yes	No			Rule Reference
			<ul style="list-style-type: none"> ○ This documentation must include details of the information source ● Which pharmacist made the final decision 	
		33	<p>Does the hospital conduct quarterly validations of each active vaccine storage unit and their monitoring equipment?</p> <p>How are quarterly validations conducted?</p> <p>Note – Quarterly validations are not the same as the calibration of thermometers.</p>	OAR 855-041-1036(3)
		34	<p>How does the hospital ensure calibrations of the thermometers are conducted as specified by the manufacturer?</p>	OAR 855-041-1036(2)(b)(B)

Emergency Kit and Code Cart

Yes	No			Rule Reference
		35	<p>An emergency kit consists of those drugs which may be required to meet the immediate therapeutic needs of in-patients 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</p> <p>Does a pharmacist verify and document the contents of all emergency kits?</p>	OAR 855-041-6420(2)
<input type="checkbox"/>	<input type="checkbox"/>	36	<p>Is each kit/code cart locked and labeled with name, strength, quantity, and expiration date of the kit/cart?</p> <p>Note: The expiration date of the kit/cart should be the expiration date of the first drug to expire in the kit/cart.</p> <p>The label/list must be on the exterior of the kit/cart.</p>	OAR 855-041-6420(6) and (7)

Automated Distribution Cabinets (ADC), Floor Stock, Non-emergency Trays and Kits

N/A

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	37	<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?</p>	OAR 855-041-6200(3)(d)
		38	<p>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?</p> <p>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.</p>	OAR 855-041-6540(4)
		39	<p>How does the pharmacy ensure that all returned drugs from ADCs are reviewed by a pharmacist prior to returning them to the pharmacy inventory?</p>	OAR 855-041-6540(7)
<input type="checkbox"/>	<input type="checkbox"/>	40	<p>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?</p> <p>Note: Discrepancies must be documented and reconciled.</p>	OAR 855-041-6540(8)

Final Verification N/A

Yes	No		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	41	<p>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, <u>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.</u></p>	ORS 689.005 OAR 855-005-0006(18) OAR 855-019-0200(5)(6) OAR 855-025-0023(4)
<input type="checkbox"/>	<input type="checkbox"/>	42	<p>If the pharmacist chooses to delegate final verification to a technician, has the pharmacist used their reasonable professional judgment in making this determination?</p>	OAR 855-005-0006(43) OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005

			<p>Note:</p> <ul style="list-style-type: none"> • Only the PHARMACIST may delegate “final verification” • “Reasonable professional judgment” means an objectively reasonable and impartial belief, opinion or conclusion held with confidence, and founded on appropriate professional knowledge, skills, abilities, qualifications, and competencies, after careful review, analysis and consideration of the relevant subject matter and all relevant facts and circumstances that were then known by, or reasonably available to, the person or party holding such belief, opinion, or conclusion. 	
		43	<p>Does the pharmacist supervise the technician that they have delegated “final verification” to?</p> <p>How does the pharmacist supervise technicians performing “final verification”?</p>	OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
		44	<p>Does the supervising pharmacist ensure that the technician performs a physical (i.e. in person) “final verification”?</p> <p>How does the supervising pharmacist do this?</p>	OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005
		45	<p>Is the supervising pharmacist aware that a technician may not use discretion when performing “final verification”?</p> <p>How does each supervising pharmacist ensure that technicians do not use discretion when performing “final verification”?</p>	OAR 855-019-0200(5)(6) OAR 855-025-0023(4) ORS 689.005

Absence of a Pharmacist N/A

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	46	<p>Does the pharmacy utilize off-site or non-resident pharmacists to perform remote verification?</p> <p>If yes provide name and license #s:</p> <p>Note: This requires Oregon registration and remote processing designation.</p>	OAR 855-019-0100

Yes	No			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	47	Does the hospital use a night cabinet or allow after-hours access to the pharmacy?	OAR 855-041-6300
<input type="checkbox"/>	<input type="checkbox"/>	48	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
<input type="checkbox"/>	<input type="checkbox"/>	49	When a drug is removed after hours, is the pharmacist confirming that: <ul style="list-style-type: none"> • 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
<input type="checkbox"/>	<input type="checkbox"/>	50	Does a pharmacist participate in Collaborative Drug Therapy Management (CDTM) agreements? <i>Examples: Vancomycin-dosing and anticoagulation-dosing.</i>	OAR 855-019-0260
<input type="checkbox"/>	<input type="checkbox"/>	51	Does the written CDTM agreement contain the following: <ul style="list-style-type: none"> • Identification of the participating pharmacist(s) and practitioner(s) • The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement • The types of decisions that the pharmacist is allowed to make and when the pharmacist should initiate communications with the practitioner 	OAR 855-019-0260 (2)(a-g) and (3)
<input type="checkbox"/>	<input type="checkbox"/>	52	Are CDTM agreements being reviewed and updated at least every two years?	OAR 855-019-0260(2)(h)
<input type="checkbox"/>	<input type="checkbox"/>	53	Are the practitioner and pharmacist identified on each prescription order? Note: The practitioner is the individual who referred the patient for treatment under the CDTM agreement. For a prescription 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
<input type="checkbox"/>	<input type="checkbox"/>	54	Is the pharmacy involved? If yes, what is the pharmacist's role?	
		55	Who performs medication history gathering for medication reconciliation?	OAR 855-025-0025
		56	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
<input type="checkbox"/>	<input type="checkbox"/>	57	Does pharmacy staff (Pharmacist, 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 not working on behalf of a board registered drug outlet and the technicians who are assisting those pharmacists. <ul style="list-style-type: none"> If the answer is No to this question, please proceed to the next set of questions. 	OAR 855-041-3205
<input type="checkbox"/>	<input type="checkbox"/>	58	Does the pharmacy ensure that? <ul style="list-style-type: none"> Only an OR licensed Pharmacist, Intern, and technician are providing pharmacy services to Oregon patients All licensees comply with applicable federal and state laws and rules; and NO DRUGS or DEVICES are permitted at a telework site 	OAR 855-041-3215 OAR 855-041-3235

Yes No

Rule Reference

		59	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
<input type="checkbox"/>	<input type="checkbox"/>	60	Does the pharmacy have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities?	OAR 855-041-3215 OAR 855-041-3245
<input type="checkbox"/>	<input type="checkbox"/>	61	Does the pharmacy maintain a continuously updated list of all licensees engaged in telework and the Telework Sites that includes all of the following: <ul style="list-style-type: none">• Address and phone number where telework is performed for each Telework Site?• Functions being performed by licensees engaged in telework?• The Pharmacist providing supervision, direction, and control for each non-pharmacist licensee?	OAR 855-041-3215 OAR 855-041-3250
<input type="checkbox"/>	<input type="checkbox"/>	62	Are all of the following supervision requirements met? <ul style="list-style-type: none">• Utilize technology that enables real-time audio and visual connections and interface to allow access to information required to complete assigned duties• Ensure telephone audio is recorded, reviewed, and stored, for all patient interactions completed by each Intern and technicians• Ensure a pharmacist is supervising, directing, and controlling each Intern and technician and that the continuous audio/visual connection is fully operational• Ensure that a pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the real-time 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	OAR 855-041-3220
<input type="checkbox"/>	<input type="checkbox"/>	63	Are all of the following supervision requirements met by the Pharmacist? <ul style="list-style-type: none">• Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed• Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request• Document the following within 48 hours of the review in<ul style="list-style-type: none">○ Number of each licensee's patient interactions;○ Number of each licensee's patient interactions pharmacist is reviewing;	OAR 855-041-3220

Yes No

Rule Reference

			<ul style="list-style-type: none"> ○ Date and time of licensee patient interaction pharmacist is reviewing; ○ Date and time of pharmacist review of licensee's patient interaction; and ○ Pharmacist notes of each interaction reviewed; and ● Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 48 hours of discovery and to the board within 10 days 	
		64	<p>How does the pharmacy ensure patient confidentiality?</p> <p>Note: All computer equipment used at the Telework Site must:</p> <ul style="list-style-type: none"> ● Establish and maintain a secure connection to the pharmacy and patient information; ● Utilize equipment that prevents unauthorized access to the pharmacy and patient information; ● Be configured so that the pharmacy and patient information is not accessible when <ul style="list-style-type: none"> ○ There is no Pharmacist actively supervising ○ There is no licensee at the telework site ○ When any component of the real-time audio-visual connection is not functioning ● Comply with security and confidentiality requirements 	OAR 855-041-3225 OAR 855-041-3240
<input type="checkbox"/>	<input type="checkbox"/>	65	<p>Is each technician or Intern able to access the pharmacy and patient information when a pharmacist is not actively supervising?</p>	OAR 855-041-3240
<input type="checkbox"/>	<input type="checkbox"/>	66	<p>Are the following technology requirements met?</p> <ul style="list-style-type: none"> ● Test the continuous audio and visual connection and document that it operates properly before engaging in telework. ● Develop, implement, and enforce a plan for responding to and recovering from an interruption of service which prevents a pharmacist from supervising, directing, and controlling the Intern and technicians at the Telework Site ● Ensure access to: <ul style="list-style-type: none"> ○ Appropriate and current pharmaceutical references based on the services offered; and ○ Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters. ● Train the Pharmacists, Interns, and technicians in the operation of continuous audio and visual connection 	OAR 855-041-3230
<input type="checkbox"/>	<input type="checkbox"/>	67	<p>If a pharmacist is performing verification via telework, are all of the following requirements met?</p> <ul style="list-style-type: none"> ● Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each 	OAR 855-041-3230(5)

Yes	No			Rule Reference
			<ul style="list-style-type: none"> ○ Source container including manufacturer, name, strength, lot, and expiration; ○ Dispensed product including the imprint and physical characteristics; ○ Completed prescription container including the label; and ○ Ancillary document provided to patient at the time of dispensing 	
<input type="checkbox"/>	<input type="checkbox"/>	68	Are all records maintained with in the requirements of OAR 855-041-3250?	OAR 855-041-3250

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
<input type="checkbox"/>	<input type="checkbox"/>	69	<p>Are drug outlet procedures compliant with Oregon laws and rules and do they reflect the practice at the outlet and include the following?</p> <ul style="list-style-type: none"> • Security • Operation, testing and maintenance of pharmacy systems and equipment; • Sanitation; • Storage of drugs; • Dispensing; • Pharmacist supervision, direction, and control of non-Pharmacists; • Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process; • Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians; • 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; 	OAR 855-041-1040

Yes	No		Rule Reference
		<ul style="list-style-type: none"> 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	
<input type="checkbox"/>	<input type="checkbox"/>	70	<p>Are all prescription dispensing records verified by a pharmacist within 24 hours of dispensing an ED pre-pack?</p> <p>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.</p> <p>Note: This includes verifying name, strength, quantity of medication dispensed, directions for use, performing a DUR and documenting the review.</p>	OAR 855-041-6410(1)(h)
<input type="checkbox"/>	<input type="checkbox"/>	71	<p>Does the pharmacy utilize an automated dispensing machine (i.e., Instymed® machine) for emergency room dispensing?</p> <p>Is the pharmacist performing a DUR for these dispensed drugs?</p>	OAR 855-041-6410
<input type="checkbox"/>	<input type="checkbox"/>	72	<p>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?</p>	OAR 855-041-1130
<input type="checkbox"/>	<input type="checkbox"/>	73	<p>Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent?</p> <p>Note: The prescription must bear a label in both English and the language requested.</p>	OAR 855-041-1132 ORS 689.564
<input type="checkbox"/>	<input type="checkbox"/>	74	<p>Does the pharmacy provide prescription readers for visually impaired patients? Are prescription readers available and appropriate to address a person's visual impairment?</p>	OAR 855-041-1131 ORS 689.561
<input type="checkbox"/>	<input type="checkbox"/>	75	<p>Does the pharmacy display information to patients that the pharmacy will offer language assistance to patients who need it including translated labels?</p>	OAR 855-041-1035 OAR 855-041-1131
<input type="checkbox"/>	<input type="checkbox"/>	76	<p>Does the practitioner or nurse label the container for emergency outpatient prescriptions with the following:</p> <ul style="list-style-type: none"> 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)
<input type="checkbox"/>	<input type="checkbox"/>	77	<p>Is the amount of medication contained in each ED prepack limited to an emergency supply to meet the acute care needs of a patient?</p> <p>Are prepack medications limited by policy and procedures?</p>	OAR 855-041-6410(3)

Yes No

Rule Reference

			Note: ED prepacks may not exceed 48-hour supply with limited exceptions permitted by Board rule.	
<input type="checkbox"/>	<input type="checkbox"/>	78	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:

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?

<u>LOCATION</u>	<u>TASKS/DUTIES</u>	<u>SUPERVISION, DIRECTION AND CONTROL</u>
<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>