Inspections

AUGUST 2023 BOARD MEETING

ORS 689.025

- 689.025 Policy; purpose. (1) The practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in the State of Oregon. This chapter shall be liberally construed to carry out these objects and purposes.

  (2) It is the purpose of this chapter to promote, preserve and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy and of the registration of drug outlets engaged in the manufacture, production, sale and distribution of drugs, medications, devices and such other materials as may be used in the diagnosis and treatment of injury, illness and disease.

Effective Control and Regulation of the Practice of Pharmacy

- Proactive and Reactive approach to ensure patient safety
- Value of inspections- Proactive approach:
  - 3 examples
    - New England Compounding Center (NECC)
    - Chicago Tribune Investigative Report
    - Global Pharma

New England Compounding Center (NECC)Fungal Meningitis Outbreak (2012)

- In 2012, 753 patients in 20 states were diagnosed with a fungal infection after receiving injections of preservative-free methylprednisolone acetate (MPA) manufactured by NECC.
  - Of those 753 patients, CDC reported that 64 patients in nine states died.
- In the end, a total of 793 patients were harmed by NECC's contaminated MPA. More than 100 patients died.
- Pharmacists compounded in unsafe manner and in insanitary conditions.
- In 2011, during a routine inspection, Colorado inspectors found that NECC had participated in the unregistered/unlicensed distribution of prescription drugs in Colorado. As a result, Colorado issued a cease-and-desist order against NECC in April 2011.
- Colorado provided a compliant to Massachusetts months before the outbreak stating NECC was distributing drugs without patient-specific prescriptions. No investigation was conducted by Massachusetts.

Chicago Tribune Investigative Report (2016)

- In 2016, a 9-month investigation involving 255 pharmacies
- Goal: To assess how many pharmacies would dispense dangerous medication pairings (contraindications) without consulting with the patient.
- Results: More than half (52%) of these pharmacies failed the test and dispensed the medications with no warnings about possible adverse effects.
- The Tribune study exposed fundamental flaws in the pharmacy industry.
  - Safety laws were not being followed
  - Computer alert systems designed to flag drug interactions either did not work or were ignored
  - Some pharmacies emphasize fast service over patient safety

Global Pharma Contaminated OTC Eye Drops (2023)

- OTC eyedrops from EzriCare LLC and Delsam Pharma LLC that were manufactured by Global Pharma in India were contaminated with Pseudomonas.
- The two affected OTC eye drop brands were widely available, were not counterfeit and were not imported illegally.
- CDC identified, 55 patients in 12 states reported of adverse events including eye infections, permanent loss of vision, and a death
  - 4 deaths
  - 18 cases of vision loss
- FDA recommended a voluntary recall on 2/2/2023 due current good manufacturing practice (CGMP) violations, including lack of appropriate microbial testing, formulation issues (the company manufactures and distributes ophthalmic drugs in multi-use bottles, without an adequate preservative), and lack of proper controls concerning tamper-evident packaging
- Global Pharma was allowed to ship hundreds of thousands of bottles of eyedrops without ever having the FDA inspect its factory.

Process Considerations

- Purpose of Inspections
- Time: length
- Confusion related to inspection processes overall, intent and use of the self inspection form and outlet self inspection process.
- Staff role
- Consistency in inspections- we will talk a lot about this.
- Recommendations for process changes

*Note: we are not going to address all issues raised today. We will save some topics for future discussions.

Regulations: Statutes

- **ORS 689.155 Authority of board over medications, drugs, devices and other materials; rules.** The State Board of Pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease
- (8) At all reasonable hours, in performance of the duties imposed by this section, enter, or cause its authorized representatives to enter upon, and examine the premises or records required by law of any drug outlet under the jurisdiction of the board.
  - (10) Cause to have made **a regular inspection of all pharmacies**.

- **ORS 689.776 Inspection; audit**. The State Board of Pharmacy shall ensure compliance with ORS 689.770 to 689.780 by:
  - (1) Inspecting the **Charitable Prescription Drug Program on a regular basis**;
    - (f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within the time allowed by the board.

Regulations: Rules

- **OAR 855-019-0300(4)** The PIC must perform the following the duties and responsibilities: (f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within the time allowed by the board.

- **OAR 855-001-0040 Inspections**
  - (1) A Compliance Officer is a board authorized representative and must be permitted entry to any drug outlet to conduct inspections at all reasonable hours.
  - (2) The Compliance Officer is authorized and must be permitted to perform the following to determine compliance with ORS 475, ORS 689, and OAR 855 and board orders including but not limited to:
    - (a) Inspecting conditions, structures, equipment, materials, and methods for compliance;
    - (b) Inspecting all drugs and devices;
    - (c) Taking photographs, recording video and audio; and
    - (d) Reviewing, verifying and making copies of records and documents.
  - (3) All records and documents required by ORS 475, ORS 689, and OAR 855:
    - (a) Must be stored on-site for 12 months and must be provided to the board immediately upon request at the time of inspection;
    - (b) May be stored in a secured off-site location after 12 months of on-site storage and must be provided to the board upon request within three business days; and
    - (c) May be in written or electronic format.
  - (4) All licensees and employees must fully comply and cooperate with all questions and requests made by the Compliance Officer at the time of inspection.
  - (5) Refusal to allow inspection is grounds for discipline.

Self-Inspection Form

- PIC and Outlets are required by rule to conduct a self inspection annually using the self inspection form
- Open Book Test
- Goal to update biannually (May annual version)
- Goal to not be all inclusive
  - Highlight areas related to new regulations, areas where we continue to see issues, cases, or questions and confusion, and areas with high patient safety risk or harm potential
- Inspection Form Length
- Review Self Inspection Form: Retail Pharmacy Drug Outlet

Self-Inspection Form Types

Pharmacy Drug Outlet Self-Inspection Forms

- Retail Drug Outlet self-inspection form v. 7/2023
- Non-Resident Retail Drug Outlet self-inspection form v. 7/2023
- Institutional Drug Outlet self-inspection form v. 7/2023
- Nuclear Pharmacy self-inspection form v. 7/2023
- Compounding Pharmacy self-inspection form v. 7/2023
- Remote Dispensing Site Pharmacy self-inspection form
- Home Dialysis self-inspection form
- Animal Euthanasia self-inspection form v. 7/2023
- Pharmacy Prescription Locker self-inspection form v. 7/2023
- Pharmacy Prescription Kiosk self-inspection form v. 7/2023

Non-Pharmacy Drug Outlet Self-Inspection Forms

- Community Health Clinic self-inspection form
- Dispensing Practitioner Drug Outlet self-inspection form
- Correctional Facility self-inspection form
- Wholesale Drug Outlet self-inspection form

Self-Inspection Feedback Form

https://www.oregon.gov/pharmacy/Pages/Self-Inspection-Forms.aspx

Self-Inspection Form Feedback

Complete and submit the form below to submit feedback on current self-inspection forms.

Self-Inspection Form Feedback Form

First & Last Name (required)*

Email Address (required)*

Choose a Pharmacy Drug Outlet Self-Inspection Form you wish to provide feedback on:

Select one...

Choose a Non-Pharmacy Drug Outlet Self-Inpection Form you wish to provide feedback on:

Select one...

Provide Feedback (required)*

I'm not a robot

reCAPTCHA
Privacy - Terms

Submit

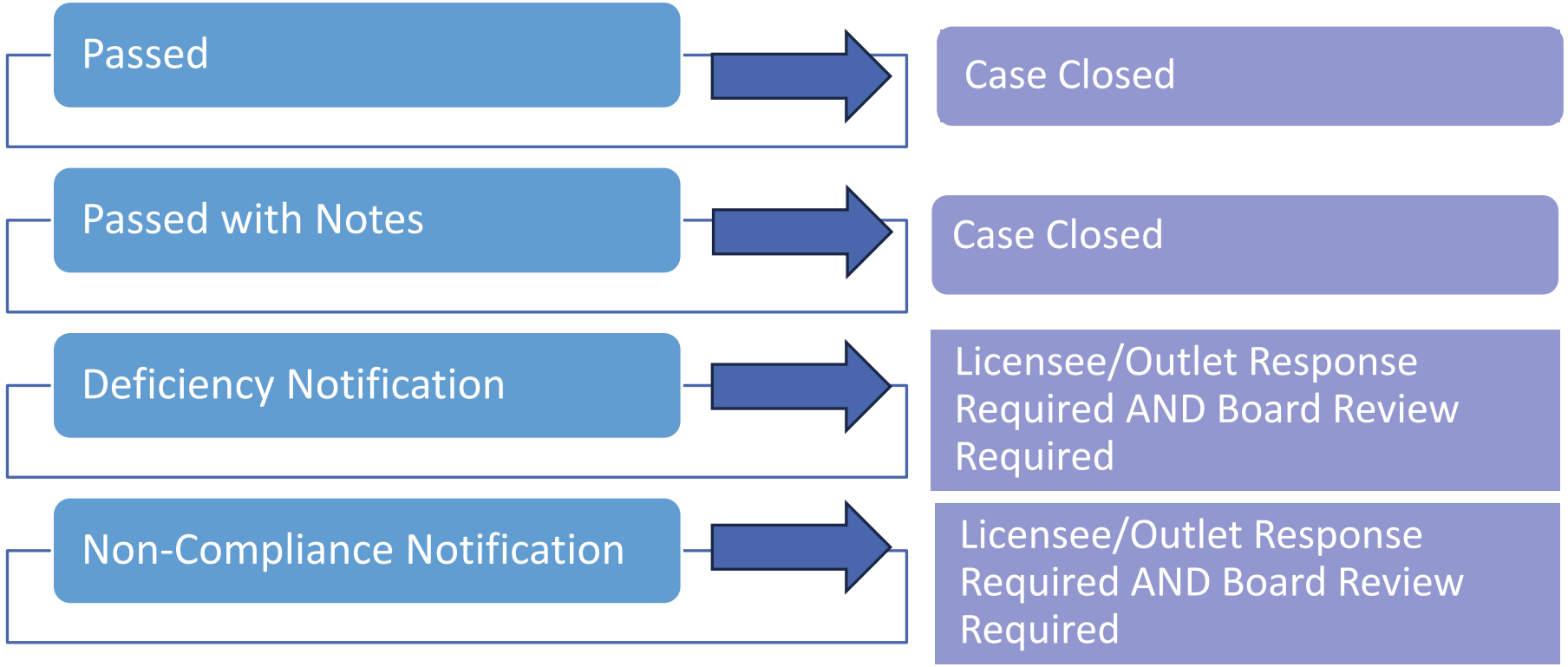
Inspection Process (Currently)

- CO assigned inspections and set tentative plan to complete within 2-year deadline
- CO use PIC completed Self Inspection Form to guide inspection, assess same information at each drug outlet, and document observations.
- CO completes inspection report and per previous board direction provides appropriate results and follow up.
- CO completes internal processing steps
- Board reviews and provides staff direction on how to proceed.

Board Inspection and Inspection Report

- Retail Drug Outlet Inspection Report- 2021-2023 Report
- Focus on Consistency
  - Audit content
  - Observations Documentation
  - Assessment and Determination of Results
- Inspection Report Results and Follow up

Inspection Results (Currently)



Board Inspection: Time to Complete

- *Biennial Inspection Cycle:*
  - *At April 2020 Board meeting:*
    - Regarding current KPM #3:
      - Change current KPM from annual inspections to biennial (Q2 year) pharmacy inspection cycle
      - This effort is to ensure that our processes are focused on achieving our mission to ensure patient safety. This will allow for more intentionality and focus towards high risk locations (RP and IPs) and likely will result in better patient safety outcomes.
      - Goal: To complete 100%
    - Board provided direction for staff to submit changes to KPM process due 4/30/2020 to be affected for 21-23 fiscal cycle, starting 7/1/2021.
  - Many key factors effect length of an inspection including registrant and licensee dependent factors

Board Inspection: Communication

- Staff is asking questions and having educational discussions with licensees and/or registrants regarding the practice and regulations.
- Staff will provide citations, resources via website or other agency information to assist licensee and registrants in making decisions

21-23 Biennium Inspection Results

Inspection List (RP/IP)	Inspections Completed	Non-Compliance Notification	Deficiency Notification	Passed with Notes	Pass
840	756 (90%)	175 (23%)	65 (8%)	344 (45%)	172 (22%)

Previous Inspection Cycles

2020-2021 Cycle

Inspection List (RP/IP)	Inspections Completed	Non-Compliance Notification	Deficiency Notification	Passed with Notes	Pass
X	74	4 (5%)	4 (5%)	57 (77%)	9 (12%)

2019-2020 Cycle

Inspection List (RP/IP)	Inspections Completed	Non-Compliance Notification	Deficiency Notification	Passed with Notes	Pass
X	855	41 (5%)	161 (19%)	586 (69%)	67 (8%)

Process Change Recommendation Rationale

- Board Members change
- Context or nuance of observations at time of inspection can vary slightly
- Consistent review and follow up
- Proportion and rationale response
- Time efficient inspections
- We believe we can address these and maintain compliance with rules
  - **OAR 855-019-0300(4)** The PIC must perform the following the duties and responsibilities:

    (f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within the time allowed by the board.

Goals:

- Consistent
- Targeted
- Transparent
- Accountable
- Agile
- Proportionate

Recommended Process

Passed	Consent Agenda	Case Review
No Observations or ALL observations made can be corrected in real time	Observations made that could not be corrected completely in real time require a corrective action response to include how to ensure this does not reoccur	Specific observations made and/or insufficient corrective action plan requires board review in Case Review section
*This would not include any observations that require board review in the Case Review section	Sufficient response received: • Case placed in Consent Agenda for board review • Board can pull any inspection for discussion and/ or further investigation. • If no further board discussion, case closed with no action and letter sent to outlet/PIC • *This would not include any observations that require board review in the Case Review section	Observation require board review: • Unlicensed personal or outlet • Practice outside of scope • Impairment or suspected impairment • Fraud or misrepresentation • Theft or large quantity of missing CS or high potential misuse drugs • * Full list part SDA discussion
Inspection Report	Inspection Report Inspection Response	Inspection Report Inspection Response

Recommended Process Continued

- Notify PIC of Inspection time frame:
  - Approximate 2-week time frame
  - Notification with in 4 weeks of inspection
  - Communication will include documents that will be reviewed

- Possible limitations:
  - Need accurate PIC email
  - PIC may choose to not utilize opportunity

Process Change Benefits

- Ensure clear board direction to staff of what is expected when an observation is made
- Provides transparent and consistent approach to inspections for licensees and registrants
  - Provide clear expectations of how the process works and how the results are processed
  - Provides more frequent up to date revisions
- Clearer Board opportunity to review inspection and corrective action responses

Proposed SDA Changes

24. Authorize Compliance Officer to open an investigation and request information/ corrective action for observations identified in inspections, that cannot be fully corrected in real time, and to determine what is a sufficient corrective action to the observation identified.

- Inspections with sufficient corrective action will be placed in the next applicable board meeting compliance agenda section with a recommendation to close case.
  - Board members may pull inspection cases for further discussion or investigations as they deem appropriate.
- Inspection with insufficient corrective action or that fall within #25 below will be placed in the next applicable board meeting Case Review section

Proposed SDA Changes

25. Authorize Compliance Officer to open an investigation if one or more of the following observations or similar observations are noted from an inspection:

- Unlicensed practice: personnel or outlet
- Practice outside of scope or unsupervised personnel
- Impairment or suspected impairment
- Fraud or misrepresentation
- Not completing the PIC Self-Inspection Form
- Theft or large quantity of missing controlled substances or high potential misuse drugs
- C2 reconciliation or annual inventory not done (missed at least one quarter)
- Temperature excursion, drug affected and dispensed when should not have been or no documentation of temperature excursion response
- No cold drug storage monitoring
- No documentation of counseling (Not just missing a few dates, no documentation of counseling)
- Accessing patient information inappropriately
- Nonsterile or sterile compounding in visibly dirty environment
- Missing (not late) initial and ongoing sterile compounding training
- Failure to complete initial competency (media fill, etc.) prior to sterile compounding in Primary Engineering Control(s)
- Compounding in Primary Engineering Control(s) and/or room that did not pass certification
- Using chemical grade ingredients when compounding

An investigation that identifies one of these possible violations will be placed in the next applicable board meeting Case Review section for board consideration

Board Direction Needed

- **Question: Would the board like to direct staff to use the new proposed inspection process?**

- *If yes, we will also need to review the proposed changes to SDA and approval, related to this section, will be necessary to implement these new processes.

Next Steps

THANK YOU!

2021-2023 RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY INSPECTION REPORT	
Oregon Board of Pharmacy 800 NE Oregon St, Suite 150 Portland, OR 97232 (971)-673-0001 Fax: (971)-673-0002 Pharmacy.compliance@bop.oregon.gov	
Compliance Officer	
Date Inspection performed	
PIC Name & License #	
PIC Work email	
Pharmacy Name	
Pharmacy Address	
Pharmacy Telephone	
Pharmacy Fax	
Retail Outlet Registration #	
Institutional Outlet Registration #	
DEA Registration # and Exp Date	
Nonprescription Drug Outlet Registration #	
Drug Take Back Kiosk: Y/N	
RPh participating in inspection	
Other staff (Name/Title) participating in inspection:	

General Requirements

		Inspection Review	Rule Reference	Observations
5	How many hours (weekly average) does the PIC work on site?	Document # of hours PIC provided on self-inspection form.	OAR 855-041-1010(1)	PIC documented on self-inspection form that they work ___ hours per week
6.	How many pharmacies is the PIC responsible for? Note: A pharmacist may not be designated PIC of more than three pharmacies without prior written approval by the board. If PIC for more than one location, where are the Quarterly PIC Compliance Audit Forms located?	Document # from self-inspection report. If > 1 pharmacy request quarterly report forms. Document any observations of possible violations.	OAR 855-019-0300	PIC documented on self-inspection form they are PIC of ____ locations ☐Quarterly report form required and reviewed ☐Quarterly report not required Details:
7	Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	Review licenses/registrations. Document any observations of possible violations	ORS 689.615	☐Licenses and registrations information accurate and up to date ☐Licenses and registration information missing Details:

Minimum Equipment, Procedures and Records

		Inspection Review	Rule Reference	Observations
12	Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet?	Document date from self-inspection report. .	OAR 855-041-1040	PIC documented on self-inspection form they reviewed with staff on __ date ☐Policies and Procedures reviewed annually ☐Policies and Procedures **NOT** reviewed with in past year Details:
13	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	Document if the pharmacy is not clean. Take images for evidence and provide detailed description.	OAR 855-041-1015(2)	☐Pharmacy is clean ☐Pharmacy is **NOT** clean

		Inspection Review	Rule Reference	Observations
				Details:
14	Does the pharmacy quarantine outdated, adulterated, misbranded, and suspect product?	Pull 5 drugs from pharmacy stock, in different areas of pharmacy stock. For expired, adulterated or misbranded drugs provide an image, name of drug, expiration date, and location found in pharmacy.	OAR 855-041-1025 OAR 855-041-1036(1)(d)	☐None observed ☐Observed outdated, adulterated, misbranded or suspect drug product Details:
16	Is the pharmacy registered with the DEA as an authorized collector for drug take back disposal? If yes, are the following requirements met? • Notify BOP within 30 days of initiating or terminating program • Receptacle stored in secured location, which is accessible to the public, inside the retail drug outlet, and within the view of the pharmacy counter but NOT behind the pharmacy counter • Adequate security measures for proper installation and maintenance of the collection receptable, tracking of liner, documentation and key accountability maintained • Appropriate training and accountability provided to all parties involved in	Prior to inspection: check MLO to see if registration is provided to BOP. If have box and there are observations document in details each observation of possible violation and record image. If have box and not identified in MLO but registered appropriately with DEA, please send to Compliance Coordinator for follow up.	OAR 855-041-1046	☐N/A do not have drug take back disposal ☐Have drug take back disposal and **no** observations made ☐Have drug take back disposal and observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
	maintaining the drug take back disposal box			
20	Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent? If not, what is the anticipated date of compliance? Note: The prescription must bear a label in **both** English and the language requested.	Ask RPH if they can provide in all 14 languages. • If unable to, ask if patient has requested label and if they were unable to provide. o Document if patient requested and they were unable to provide as an observation. o List details: language, date/ time patient requested, and follow up since	OAR 855-041-1132 ORS 689.564	☐ **No** observations made ☐ Observations are made (see details) Details:
21	Does the pharmacy have signage that provide patient notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels?	Review signage and document observations. If not in compliance provide link to website or handout of list created by OHA Here is the link: https://www.oregon.gov/pharmacy/Documents/Dual_Language_Labeling_Sign_Pharmacy.pdf	OAR 855- 041-1035 (1)(g)(B)	☐ **No** observations made ☐ Observations are made (see details) Details:
22	How is the public notified that prescription readers are available at the pharmacy?	Ask RPH if they can provide to patient "upon request"	ORS 689.561	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
	How does the pharmacy provide prescription readers for visually impaired patients?	• Ask if patient has requested and they were unable to provide "upon request" • If YES, document as observation and include detail of their current process.		

Controlled Substances

		Inspection Review	Rule Reference	Observations
24	Is the pharmacy identifying and CLEARLY DOCUMENTING AND EXPLAINING ALL VARIANCES on CII reconciliations? Note: The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least quarterly. If these records are maintained electronically, they must be accessible and producible at the time of inspection (audit, **variances, and explanations**). **Note**: Providing the count at the time of the reconciliation is not sufficient to meet this requirement. **Working copies or documentation** showing the audit **and all variance explanations** for all CIIs must be kept and will be requested for review at time of inspection.	• Collect the most recent 4 quarters of reconciliations and pick 2 quarters. Review for accurate and compete reconciliation and documentation: • 2 drugs (1 fast mover and 1 slow mover) for 2 quarters of the 4 provided Document Observations in detail and include images.	OAR 855-019-0300(5)(e)(h)	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
27	Was the controlled substance (CII-V) inventory performed on one day, within 12 months (367 days) of the last inventory?	Review and document observations in detail and include images.	OAR 855-080-0070	☐ **No** observations made ☐ Observations are made (see details) Details:
29	How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?	Review the following and document any observations of possible violations: • Where is their reverse distributor 222 documentation? • Review where quarantined drugs are stored when waiting to be sent back to wholesaler. If locked up, who has key? • If pharmacy destroys CS drugs on site, ask to see policy and documentation from the last 6 months of destroyed drugs? Is there a witness / double signature? • How do they ensure RXs have the correct quantity dispensed? Who counts? Are they double counted?*What is their process if a patient claims their RX was shorted?	OAR 855-041-1020	☐ **No** observations made ☐ Observations are made (see details) Details:

Security

		Inspection Review	Rule Reference	Observations
30	When no pharmacist is physically present in the pharmacy, are computers, records and medications properly secured to prevent entry and access to records by non-pharmacist employees?	Review and document if there are observations of possible violations in detail and include images.: • Do only licensed pharmacists have the key to the pharmacy? • Are their terminals outside of the pharmacy? Ask if non pharmacist staff can access	OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1)	☒ **No** observations made ☒ Observations are made (see details) Details:

		patient records when pharmacist is not present?		

Support Personnel

		Inspection Review	Rule Reference	Observations
32	Are pharmacists, interns, technicians, and clerks clearly identified as such to the public?	Review and document observations in detail and include images.	OAR 855-025-0025(3)	☐ **No** observations made ☐ Observations are made (see details) Details:
33	Is there documentation of initial and ongoing technician training? Where are the records located? Be prepared to retrieve documentation of training for ALL technicians when requested by a Board Compliance Officer.	Review 2 technicians training and document observations in detail and include images.	OAR 855-025-0025(6)	☐ **No** observations made ☐ Observations are made (see details) Details:
34	Do technicians know they cannot communicate with patients in terms of drug class or indication/use (such as when a patient asks for a refill of their "diabetes medication")? Note: Technicians can only communicate in terms of drug name and prescription number. **Pharmacists may not allow technicians to counsel, answer a patient's medication related questions, or allow a technician to relay information on their behalf**.	Ask Technician: • Review and document observations in detail and include images.	OAR 855-025-0040(3)(e) OAR 855-019-0200(2)(3) OAR 855-019-0230	☐ **No** observations made ☐ Observations are made (see details) Details:
35	Is each technician under the supervision, direction and	• Ask the pharmacist does pharmacy remain open when	ORS 689.486(6)	☐ **No** observations made ☐ Observations are made (see details)

	control of a pharmacist and does the pharmacist verify work performed by technicians and document this verification?	pharmacist takes their break? If so how does the pharmacist supervise direct and control tech(s) in those situations? • Ask the pharmacist how they ensure they verify all work performed by tech that requires discretion/judgement? • What tasks does this include? • Ask pharmacist how they ensure that tech does not communicate information to patients they are not permitted	OAR 855-025-0025(4)	Details:

Pharmacists

		Inspection Review	Rule Reference	Observations
36	Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration? How is a DUR performed? Please provide the following details: At which point in the process does a pharmacist perform a DUR? Does this process vary depending on the type of fill (new vs refill)? How is a DUR documented? **Note: A Pharmacist must perform a DUR on each fill (the computer may assist but does not replace RPH)**	Review the following and document observations in detail and include images: How does the RPH perform DUR? What does the RPH review? Where and when do DUR alerts occur? Who is able to override an alert? Review and document observations in detail and include images how a prescription is processed from beginning to completion.	OAR 855-019-0220(3)	☐ **No** observations made ☐ Observations are made (see details) Details: .

		Inspection Review	Rule Reference	Observations
38	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	1. Request a list of Rxs filled on a certain day within past 3 months. Select 5 Rxs numbers and check for allergies on Rx. Then check software system to ensure allergies and chronic medical conditions are in system. **OR** 2. Review total of 5 hard copies/VAR's for allergies and check software system to ensure allergies and chronic medical conditions are in the system Document observations in detail and include images:	OAR 855-019-0220(1) OAR 855-041-1165	☐ **No** observations made ☐ Observations are made (see details) Details:
39	Does the PIC ensure that policies and procedures are followed to ensure that prescriptions are correctly dispensed?	1. Request a list of Rxs filled on a certain day within past 3 months. Select 5 Rxs numbers and check for allergies on Rx. Then check software system to ensure Rx is filled correctly. **OR** 2. Review total of 5 hard copies/VAR's for allergies and check software system to ensure Rx is filled correctly. Request a list of Rxs filled on a certain day within past 3 months Document observations in detail and include images:	OAR 855-041-1105	☐ **No** observations made ☐ Observations are made (see details) Details:
41	Does the pharmacist document verification of '**return to stock**'	Review 3 RTS bottles from pharmacy stock and ensure RPH	OAR 855-025-0025(4)	☐ **No** observations made

		Inspection Review	Rule Reference	Observations
	medications **re-labeled** by a technician or intern?	verified, Rx is accurate and has appropriate information (exp) Document observations in detail and include images:	OAR 855-019-0200	☐ Observations are made (see details) Details:
42	Is a pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?	Have RPH run a report for will call if needed. Review 3 completed Rxs that would likely be in the manufactures packaging. Ensure that drugs that are in the fridge are also checked Document observations in detail and include images:	OAR 855-019-0200(2) OAR 855-041-1130(10)	☐ **No** observations made ☐ Observations are made (see details) Details:
45	How is a new prescription identified as requiring counseling?	Review 2 pharmacy staff interactions (counsels/tech sales/attempts to counsel/declines.) • Listen to tech talk to patients on phone ensure they are only assisting in practice as permitted • Listen to cashier interact with patients • When interacting with patients, are techs/ cashiers staying within their required role in the practice • OTC interactions, when patient asks for help • Document assessment on report of what you hear and what occurred. Document observations in detail and include images:	OAR 855-019-0230	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
47	Is the pharmacist/intern (not a patient/clerk/technician or point-of-sale keypad) personally documenting whether counseling is provided or declined on prescriptions that require counseling **at the time** of the counseling?	Review the following and document observations in detail and include images: Ask how they document their counsel or decline to counsel in real time **AND** Review 5 RPH counseling records.	OAR 855-019-0230(1)(c)	☐ **No** observations made ☐ Observations are made (see details) Details:

Drug Storage

		Inspection Review	Rule Reference	Observations
48	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. **Each excursion requires a detailed written explanation in accordance with the requirements of this rule.**	Request 1 year of data. Review 3 months (looking at 1 month per quarter starting with most recent full month), including any excursions during those months. Document observations in detail and include images:	OAR 855-041-1036 (2)(a)(A)	☐ **No** observations made ☐ Observations are made (see details) Details:
49	Are the thermometers/probes centrally placed, accurate and calibrated? When is the next calibration (to ensure temperature readings are correct) due?	• Review 2 temperature probes calibration/exp dates. Document observations in detail and include images:	OAR 855-041-1036(2)	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
51	**Explanation and documentation of ALL drug storage excursions must include at least all the following:** • The event date & time frame; • The name of person(s) involved in response; • How long drug(s)/vaccine(s) were out of range; • Temperature variances; • Pharmacist review of duration and variance; • The decision to quarantine for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; • Which pharmacist made the final decision; • The information resource used to determine whether drug/vaccine is safe for continued use.	Review excursion documents for excursions noted during the 3 months reviewed in #48 to include. • Ensure that appropriate action occurred when an excursion occurred. Excursion is when the drug is outside of the manufactures drug storage range. • Ensure that appropriate action occurred when an excursion occurred. Excursion is when the drug is outside of the manufactures drug storage range. Document observations in detail and include images:	OAR 855-041-1036(2)(b) (D-E)	☐ **No** observations made ☐ Observations are made (see details) Details:

Vaccine Drug Storage ☐ N/A

		Inspection Review	Rule Reference	Observations
53	Does the pharmacy store vaccines in the temperature stable sections of the refrigerator? Note: Including the central shelves, but not the door or crisper drawers.	Review fridge/freezer for location of thermometer. Document observations in detail and include images:	OAR 855-041-1036(3) (a)(A)	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
55	Does the pharmacy conduct quarterly **validations** of **EACH** *vaccine* storage unit and their monitoring equipment?	Review 2 quarterly validations of vaccine units (from documents collected in #48). Document observations in detail and include images:	OAR 855-041-1036(3) (a)(D)	☐ **No** observations made ☐ Observations are made (see details) Details:

Vaccine Administration ☐ N/A

Prescriptive Authority is per OHA vaccine protocol

		Inspection Review	Rule Reference	Observations
56	Do all immunizing pharmacists/interns have a current CPR card intended for healthcare providers? Is the CPR training applicable for the age of patient's staff are vaccinating?	For RPHs only, Review CPR cards. Document observations in detail and include images:	OAR 855-019-0270 OAR 855-019-0290(3)	☐ **No** observations made ☐ Observations are made (see details) Details:
57	Does the pharmacy have required equipment and supplies for managing adverse events and are reviews done to ensure all supplies are readily retrievable and that no medication will expire before the next review?	Review e-kit content with current protocol to ensure the appropriate drugs are in the kit and not expired. Document observations in detail and include images	OAR 855-019-0270	☐ **No** observations made ☐ Observations are made (see details) Details:
58	Does each pharmacist have access to ALERT and utilize it to perform a DUR and forecast potential immunizations?	Ask RPH: How and when do you check Alert. Document observations in detail and include images	OAR 855-019-0290	☐ **No** observations made ☐ Observations are made (see details) Details:
59	Is the pharmacist/intern who administers any vaccine/immunization recording and maintaining the following information:	Depending on Outlet processes: • Hardcopy: Assess at least 3 recent immunizations records to ensure accuracy.	OAR 855-019-0290	☐ **No** observations made ☐ Observations are made (see details) Details:

	• Name, address, gender, date of birth of the patient and phone number when available; • Date of administration; injection site; • Vaccine name, dose, manufacturer, lot number and expiration date; • Identity of administering pharmacist; the **date of the publication of the VIS**; and the date the VIS was provided?	• Electronic: Ask staff member to print list of vaccines dispensed in past 3 months. Review 3 immunizations records to ensure accuracy Document observations in detail and include images		

Collaborative Drug Therapy Management (CDTM) ☐ N/A

		Inspection Review	Rule Reference	Observations
60	Do pharmacists participate in Collaborative Drug Therapy Management (CDTM) agreements? Examples: Diabetes management, anti-coagulation, hypertension.	If yes, proceed to question #61. If no proceed to #64	OAR 855-019-0260	
61	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	Review 1 CDTM agreement and ensure the following criteria has been met: • RPHs and practitioner participating • Who is responsible for training and QA and how completed? • The "if this then that" protocol created to clearly articulate what a pharmacist may do and under what circumstances and when the practitioner is notified or followed up with?	OAR 855-019-0260 (2)(a-g) and (3)	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
		• When are they reviewed and updated (min of q 2 years) Document observations in detail and include images.		

Pharmacist Prescriptive Authority: (Public Health & Pharmacy Formulary Advisory Committee) ☐ N/A

		Inspection Review	Rule Reference	Observations
64	Do pharmacists at this location prescribe and dispense FDA approved drugs and devices included on either the Formulary or Protocol Compendia? Do pharmacists prescribe any drugs or devices to self or immediate family members? (Not allowed) Please list all Prescriptive Authority Protocols that the outlet's pharmacists are qualified to participate in. Attach a separate page if needed.	If N/A proceed to #67 If pharmacist participating in PHPFAC prescribing proceed. Review 2 records to ensure they are complying and following protocol or formulary and that accurate and complete documentation is recorded. Document observations in detail and include images.	OAR 855-020-0200 OAR 855-020-0300 OAR 855-020-0120	☐ **No** observations made ☐ Observations are made (see details) Details:

Pharmacist Prescriptive Authority: Contraceptive ☐N/A

		Inspection Review	Rule Reference	Observations
67	Do pharmacists at this location prescribe hormonal contraceptives? Where are records located? (Including Questionnaire, Visit Summary, prescription, etc.)	If no proceed to #69 If yes, assess 2 records to ensure that the protocol is followed. • Assess MEC and to ensure that all CI were referred, and no Rx prescribed	OAR 855-019-0425 OAR 855-019-0430 OAR 855-019-0435	☐ **No** observations made ☐ Observations are made (see details) Details:

		Inspection Review	Rule Reference	Observations
	Be prepared to show records at time of inspection. It is recommended to keep these records in a separate file/or log for easy retrieval. Note: A clinical visit is required every 3 years.	Document observations in detail and include images.		

Pharmacist Prescriptive Authority: Naloxone ☐ N/A

		Inspection Review	Rule Reference	Observations
69	Do pharmacists at this location prescribe naloxone? If yes, does the pharmacy provide written notice about naloxone accessibility in a conspicuous manner?	If no proceed to #70. If yes, review 2 records for compliance Document observations in detail and include images	OAR 855-019-0460 OAR 855-041-2340	☐ **No** observations made ☐ Observations are made (see details) Details:

Pharmacist Prescriptive Authority: Emergency Insulin and Supplies ☐ N/A

		Inspection Review	Rule Reference	Observations
70	Have any pharmacists completed a Board approved ACPE accredited training program to prescribe and dispense emergency refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices? If so, is the pharmacist ensuring that the person has evidence of a previous prescription from a licensed health care provider and are they prescribing the lesser of a 30-day supply or the smallest available package size, and not	If no proceed to #86 If yes review 2 documents to ensure compliance with rules: • Evidence of previous RX (how does RPH determine) • Prescribed supply for 30 days or less • No more than 3 emergency fills in one calendar year Document observations in detail and include images	OAR 855-019-0470	☐ **No** observations made ☐ Observations are made (see details) Details:

	more than three emergency refills and supplies in a calendar year?			

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

		Inspection Review	Rule Reference	Observations
86	Is the pharmacy ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-6310 AND that there is a practitioner's order to authorize the removal of medications? How is this being ensured?	If no move to next step. If yes, review and document observations in detail and include images. .	OAR 855-041-7060(2)(b) OAR 855-041-7060(5)	☐ **No** observations made ☐ Observations are made (see details) Details:
87	If the pharmacy accepts the return of previously dispensed prescriptions, is the facility in compliance with OAR 855-041-1045?	If doing this, review and document observations in detail and include images.	OAR 855-041-1045	☐ **No** observations made ☐ Observations are made (see details) Details:
90	Are all partially dispensed CII prescriptions (Note: Valid for up to a maximum of 60 days from the date written) documented with the following? • "LTCF patient" or "terminally ill" • Date of partial fill • Quantity dispensed • Remaining quantity authorized to be dispensed • Identification of the dispensing pharmacist for each partial fill	Review 3 Rxs for compliance. Document observations in detail and include images.	21 CFR 1306.13	☐ **No** observations made ☐ Observations are made (see details) Details:

- ***If the pharmacy is a Remote Dispensing Site (RDSP) Affiliated Pharmacy for a Remote Dispensing Site Pharmacy (RDSP), a RDSP Inspection report should also be completed.**

☐Pharmacy Performs Compounding: please see completed pharmacy Compounding Inspection Report

Compliance Officer Notes:

Inspection Completion
Pass ☐
Pass with Notes ☐
Deficiency Notification (DN) Issued ☐
Non-Compliance Notification (NCN) Issued ☐
The observations noted in this Inspection Report are not intended to be an all-inclusive list. All licensees and the registrant are responsible for complying with state and federal laws and regulations governing the practice of pharmacy

Compliance Officer Date

***Completed Inspection Report must be maintained for 3 years along with completed Self Inspection Report Forms**

IMAGES: (Question #, description)