

PHARMACIST-IN-CHARGE
TRAINING PROGRAM

MODULE II

VERSION 4/2024




1

DISCLAIMER

- This training is intended to provide interested persons with an overview of Oregon Board of Pharmacy statutes and rules found in the Oregon Revised Statutes (ORS), chapters 475 and 689 and Oregon Administrative Rules (OAR), chapter 855 as they relate to the responsibilities of a Pharmacist-in-Charge (PIC)
- While the intent is to periodically update the material to comply with applicable laws and rules it is incumbent upon you to use the current and effective laws and rules.
- Where in conflict, the applicable law or rule takes precedence over information contained in this training.

2

TRAINING PROGRAM OVERVIEW

 Module I Board PIC Qualifications, Limitations and Responsibilities Pharmacy Policies & Procedures Recordkeeping & Documentation	 Module II Inspections Investigations	 Module III Current Topics Resources
--	--	---

3

INSPECTIONS
MODULE II



4

PIC SELF-INSPECTION FORM

- Intended to help improve the pharmacy's compliance – "Open Book Test"
- Changes each year, based on trends and new laws/rules – Fill out the most current version on the [website](#)
- Compliance Officers generally follow the form for routine annual inspection
- Complete by July 1st each year and within 15 days of becoming PIC
- Read it carefully – take time with it
- Do not assume that the "way it's always been" is compliant
- Contact Board with questions

Compounding has a separate supplemental form that must be completed along with the primary license type PIC self-inspection form

5

TYPES OF PIC SELF-INSPECTION FORMS

- Pharmacy Drug Outlet Forms
 - Retail Drug Outlet self-inspection form
 - Non-Resident Retail Drug Outlet self-inspection form
 - Institutional Drug Outlet self-inspection form
 - Nuclear Pharmacy self-inspection form
 - Compounding Pharmacy self-inspection form*
 - Remote Dispensing Site Pharmacy self-inspection form
 - Home Dialysis self-inspection form
 - Animal Euthanasia self-inspection form
 - Pharmacy Prescription Locker self-inspection form
 - Pharmacy Prescription Kiosk self-inspection form
- Non-Pharmacy Drug Outlet 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

6

**PIC SELF-INSPECTION FORM OVERVIEW
RETAIL DRUG OUTLET**

- Location of required documents
- General requirements
- Equipment, procedures, records
- Pharmacy closures
- Controlled Substances
- Security
- Support Personnel
- Pharmacists
- Drug Storage
- Vaccine Drug Storage
- Vaccine Administration
- Collaborative Drug Therapy Management
- Prescriptive Authority
- Telework
- LTC/CBC Services

7

**PIC SELF-INSPECTION FORM OVERVIEW
INSTITUTIONAL DRUG OUTLET**

- Location of required documents
- PHE/COVID
- General requirements
- Controlled substances
- Labeling
- Drug Storage
- Emergency Kit/Code Cart
- Automated Distribution Cabinets (ADC), Floor Stock, Non-emergency Trays and Kits
- Final Verification
- Absence of Pharmacist
- Technician Checking Validation Program
- Collaborative Drug Therapy Management (CDTM)
- Medication History/Reconciliation
- Telework
- --If outpatient/retail pharmacy, also:
 - General requirements
 - Outpatient medications (including ED prepacks)

8

COUNSELING – PHARMACISTS
OAR 855-115-0145

(1) For each prescription, the pharmacist must determine the manner and amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.

(2) Counseling must be provided or offered to be provided to the patient or patient's agent on the use of a drug or device:

- (a) When the drug or device has not been previously dispensed to the patient by the Drug Outlet pharmacy;
- (b) When there has been a change in the dose, formulation, or directions;
- (c) When the prescription has been transferred to the Drug Outlet pharmacy by oral, written or electronic means; or
- (d) For any refill that the pharmacist deems counseling is necessary.

(3) An offer for the pharmacist to counsel under (1) and (2) must be made by a licensee.

9

COUNSELING – PHARMACISTS
[OAR 855-115-0145](#)

(4) The pharmacist must counsel the patient or patient's agent on the use of a drug or device upon request.

(5) When communicating (e.g., counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the pharmacist must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the pharmacist is proficient in the patient's preferred language.

(6) For a prescription where counseling has only been provided in writing, the pharmacist must provide drug information in a format accessible by the patient, including information on when the pharmacist is available and how the patient or patient's agent may contact the pharmacist.

(7) A pharmacist is not required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation. If refused:

(a) Only a licensee can accept a patient's or patient's agent's request not to be counseled, when counseling is required.

(b) The pharmacist may choose not to release the prescription until counseling has been completed.

10

COUNSELING – PHARMACISTS
[OAR 855-115-0145](#)

(8) Counseling must be provided under conditions that maintain patient privacy and confidentiality.

(9) Counseling, offers to counsel or declinations of counseling regarding prescriptions must be documented with the licensee's identity.

(10) Additional forms of drug information (e.g., Medication Guide, Patient Package Inserts, Instructions for Use) must be used to supplement counseling when required by federal law or rule.

11

COUNSELING- RETAIL

A	Does the pharmacist offer, or provide, counseling on all new prescriptions, and refills when determined necessary?	OAR 855-115-0145
B	How does the pharmacist denote that a new, or refilled, prescription requires the offer or provision of counseling?	OAR 855-115-0145
C	Does the pharmacist include all information necessary to promote safe use of the medication or device? Note: Using their professional judgment, only a pharmacist can determine the manner and amount of counseling that is reasonable and necessary.	OAR 855-115-0145
D	Are counseling activities (offer, and provision or declination) documented in real-time, including identity of the licensee involved?	OAR 855-115-0145(8)

12

CONTROLLED SUBSTANCES

- [OAR 855-115-0210](#) Pharmacist-in-Charge: Responsibilities

(1) In addition to the responsibilities of a Pharmacist outlined in OAR 855-115, a Pharmacist-in-Charge of a Drug Outlet pharmacy must:

 - (i) Ensure a controlled substance inventory with discrepancy reconciliation is accurately completed and documented:
 - (A) For all controlled drugs either prior to the opening or after the close of business on the inventory date:
 - (i) Within 15 days of a change in PIC; and
 - (ii) At least every 367 days; and
 - (B) For all Schedule II controlled drugs:
 - (i) At least every 93 days in a Retail Drug Outlet Pharmacy; and
 - (ii) At least every 31 days in an Institutional Drug Outlet Pharmacy.

13

CONTROLLED SUBSTANCES

- [OAR 855-115-0115](#) Responsibilities: Duty to Report

Each Pharmacist must report to the board as required by OAR 855-104-0010. In addition, unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a Pharmacist must report to the board without undue delay, but within 1 business day of:

 - (1) Confirmed significant drug loss; or
 - (2) Any loss related to suspected drug theft of a controlled substance.
- [OAR 855-041-1030](#) Reporting Drug Loss

 - (1) Disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices must immediately be reported to the board.
 - (2) The outlet must ensure that confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance is reported to the board within one business day.
 - (3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is sent to the board.

14

CONTROLLED SUBSTANCES- RETAIL

<p>A Are all licensees aware that they must report:</p> <ul style="list-style-type: none"> • Theft or significant loss of a controlled substance to the Board and DEA within 1 business day? • Felony arrests OR convictions, misdemeanor convictions, and suspected or known violations of state pharmacy laws and rules to the Board within 10 days? • Changes in legal name, name used when in pharmacy, preferred email address, personal phone number, physical address, mailing address, and employer within 15 days? <p>(Visit mylicense@goz to update.)</p>	<p>OAR 855-104-0010 OAR 855-041-1030 CFR 1301.76(b)</p>
<p>B Is the PIC ensuring that the ALL VARIANCES on C-II reconciliations are DOCUMENTED, and CLEARLY EXPLAINED (if recorded electronically, it MUST be made available at time of inspection)?</p> <p>Note: Simply providing an on-hand count is not sufficient to meet this requirement. The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least every 93 days in a Retail Drug Outlet Pharmacy.</p>	<p>OAR 855-115-0210(1)(i)</p>

15

CONTROLLED SUBSTANCES- RETAIL

<p>C Was the annual controlled substance inventory (C-II through C-V performed on one day, within 12 months (367 days) of the previous inventory?)</p> <p>Dates of the last two controlled substance inventories:</p> <p>____/____/____ and ____/____/____</p> <p>Note:</p> <ul style="list-style-type: none"> Inventory includes drugs in LTC e-kits, drugs used for compounding, items in the refrigerator, automated dispensing machines, outdated controlled substances, will call, etc. 24-hour pharmacies must indicate the time frame in which the inventory was completed. Non-24-hour pharmacies must indicate if the inventory was completed before opening or after closing. 	<p>OAR 855-080-2070 OAR 855-115-0210(1)(i)</p>
<p>D How does the Pharmacist/pharmacy maintain the security of controlled substances that have been quarantined?</p> <p>_____</p> <p>_____</p> <p>_____</p>	<p>OAR 855-041-1020 OAR 855-115-0125(c)</p>

16

CONTROLLED SUBSTANCES- HOSPITAL
[OAR 855-041-6600](#)

(1) The hospital must establish procedures and maintain records to account for all controlled substances and any other drugs designated by the appropriate hospital committee. Records must include:

- Name of drug;
- Dose ordered, dose dispensed, and dose administered;
- Identity of patient;
- Date and time of administration;
- Person administering the drug;
- Verification and documentation of any wasted drug including partial doses.

(2) The pharmacy must provide separately locked, securely affixed compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single-unit packaged drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

17

CONTROLLED SUBSTANCES- HOSPITAL
[OAR 855-041-6600](#)

(3) The pharmacy must obtain a delivery receipt for all controlled drugs supplied as floor-stock. This record must include the date, drug name and strength, quantity, hospital unit receiving drug and the signatures of the distributing pharmacist and the receiving nurse.

(4) A record must be kept of each administration of a controlled drug from floor-stock. The record must be returned to the pharmacy monthly and the PIC or designee must:

- Match returned records with delivery receipts to verify that all records are returned;
- Periodically audit administration records for completeness;
- Reconcile administration records with inventory and verify that sums carried from one record to the next are correctly recorded;
- Periodically verify that doses documented on administration records are reflected in the medical record; and
- Initial the returned record and file by date of issue.

18

CONTROLLED SUBSTANCES- INSTITUTIONAL		
A	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)
B	Is the hospital following established procedures to account for all controlled substances?	OAR 855-041-6600
C	Does the pharmacy utilize electronic surveillance or analytics to assist with this (e.g., monitoring drugs removed from stock, administered, and wasted)?	OAR 855-041-6600
D	What is the pharmacy's process for reconciling the quantity of controlled substances received on invoice with the quantity added to inventory? _____ _____	OAR 855-041-6600 OAR 855-041-6200(3)(c) OAR 855-019-0200(1)(2)

19

TELEWORK OAR 855-041-3200 THRU 855-041-3250	
<ul style="list-style-type: none"> 855-041-3200 Telework: Purpose and Scope 855-041-3205 Telework: Definitions 855-041-3210 Telework: Registration 855-041-3215 Telework: General Requirements 855-041-3220 Telework: Supervision Requirements 855-041-3225 Telework: Confidentiality 855-041-3230 Telework: Technology 855-041-3235 Telework: Personnel 855-041-3240 Telework: Security 855-041-3245 Telework: Policies and Procedures 855-041-3250 Telework: Records 	<p>(1) "Telework" means the practice or assistance in the practice of pharmacy physically located outside of a registered drug outlet when working as a contractor or an employee of an Oregon registered drug outlet in a telework site.</p> <p>(2) "Telework Site" means a location that is not a registered drug outlet where an Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician may assist in the practice of pharmacy as contractors or employees of an Oregon registered drug outlet.</p>

20

INSPECTIONS
<ul style="list-style-type: none"> ■ Board mandate in statute <ul style="list-style-type: none"> ■ ORS 689.025(2) Policy; purpose ■ ORS 689.155(10) Authority of board over medications, drugs, devices and other materials; rules. ■ Inspection notification (**Effective 10/1/2023**) <ul style="list-style-type: none"> ■ Notify PIC at work email address in e-Gov ■ Notify outlet at inspection notification contact email address in e-Gov ■ Prepare staff in advance of what to expect <ul style="list-style-type: none"> ■ Who will assist in PIC's absence ■ Consolidate required information into one location or clearly indicate where records can be found ■ Inspection time can vary greatly

21

INSPECTION CONCLUSION

- Review observations at end of inspection with Pharmacist on duty
- PIC will receive email regarding observations:
 - No Response Needed
 - Email notification may take a few weeks
 - Response Needed
 - Email notification may take longer

22

RESPONSE NEEDED

- [OAR 855-115-0210](#)
- (f) In addition to the responsibilities of a Pharmacist outlined in OAR 855-115, a Pharmacist-in-Charge of a Drug Outlet pharmacy must:
- (g) Develop, implement and submit a plan of correction for observations noted on an inspection within the time allowed by the board:
 - Corrective Active Response
 - 30-day deadline
 - Steps taken to correct observation
 - Describe changes to prevent issue(s) from reoccurring
 - Board review
 - All cases are reviewed by the Board members
 - Email notification including final inspection report
 - Lines of accountability (i.e. outlet and PIC)
 - May be subject to discipline (public record)

23

WHAT HAPPENS NEXT?

If the board motions to...

- Close the case
 - Public Record = No
 - Published on website = No
- Issue a Letter of Education
 - Public Record = No
 - Published on website = No
- Issue Discipline (e.g., civil penalty, suspension, revocation)
 - Public Record = Yes
 - Published on website = Yes

24

COMMON COMMUNITY/RETAIL PHARMACY FINDINGS

- Documentation
 - Counseling
 - Training
 - CII quarterly reconciliation
 - Vaccines- VIS dates, lot/expiration, old protocol versions
 - Temperature logs
 - RTS/re-labeled drugs missing RPH initials
- Expiration Dates
 - Expired drugs on shelf
 - "Use by" dates on patient prescription bottles greater than manufacturer expiration dates
 - Emergency kit supplies
- Drug storage violations
 - Temperature excursions not responded to adequately or at all
- Pharmacist Prescriptive Authority


25

COMMON HOSPITAL/INSTITUTIONAL PHARMACY FINDINGS

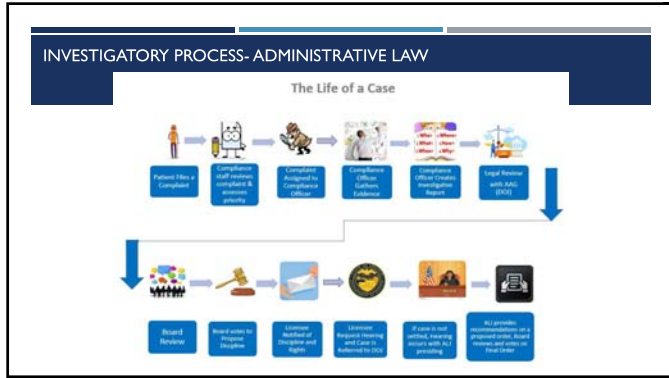
- Documentation
 - Required reports
 - Controlled Substances
 - Compounding
 - Code cart and kit labeling
- Sterile Compounding
 - Policy and procedures
 - Training and media fill testing
 - Hood certification
- Expiration dates
 - Expired drugs in floor stock
 - Open vials not dated
- Drug storage violations
 - Temperature excursions not responded to adequately or at all
- Inadequate supervision / security

26

INVESTIGATIONS
MODULE II



27



28

RESPONDING TO COMPLIANCE OFFICER REQUEST FOR INFORMATION

- Agency staff may contact you via phone, email or mail
 - As PIC, you are the primary point of contact for your outlet
- Read the request
 - Summary of complaint/allegation
 - Tells you what to do, when/how to respond
 - List of items requested
 - Contact information for Compliance Officer
- Respond to the request
 - Within the timeframe indicated
 - Fully and completely
 - Ensure staff responds as noted if requested

29

SCAM: IMPERSONATORS

- Impersonating BOP, DEA, FDA staff
- Claim disciplinary action, revoked license or arrest if you do not pay fine immediately over the phone
- Do NOT confirm or give payment information over phone
- Agency staff will never ask for or accept payment for any fees by phone

Pharmacist and her license were targeted by scammers. How to avoid becoming a victim.

Betty Linn-Foster
TSA TODAY

Published 5:31 a.m. ET March 24, 2021 | Updated 10:52 a.m. ET March 26, 2021

<https://www.usdtoday.com/story/news/2021/03/24/professionals-with-licenses-targeted-scams-online-phones/7294726007/>

Photo by Tara Winstead <https://www.usdtoday.com/photos/dose-up-shot-of-3116-2311601/>

30

DUTY TO REPORT

- ORs 689.455(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, a pharmacist or pharmacy technician shall report:

 - (a) Any suspected violations of this chapter or of ORs 475.005 to 475.285 and 475.752 to 475.980 to the State Board of Pharmacy; and
 - (b) Any prohibited conduct as defined in ORs 676.150 in the manner provided in ORs 676.150.

31

DUTY TO REPORT

- QAR 855-104-0010(1) Unless state or federal laws relating to confidentiality or the protection of health information prohibit disclosure, each licensee must report to the board without undue delay, but within:

 - (b) **10 working days** if they have reasonable cause to believe that another licensee (of the board or any other Health Professional Regulatory Board) has engaged in **prohibited** or **unprofessional conduct** to that licensee's board; or
- QAR 855-041-1010(2) 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**

32

PROHIBITED CONDUCT

- QAR 855-006-0005 Definitions

(24) "Prohibited conduct" means conduct by a licensee that:

 - (a) Constitutes a criminal act against a patient or client; or
 - (b) Constitutes a criminal act that creates a risk of harm to a patient or client.

33

UNPROFESSIONAL CONDUCT

- QAR 855-006-0020 Unprofessional Conduct Defined

"Unprofessional conduct" means conduct unbecoming of a licensee or detrimental to the best interests of the public, including conduct contrary to recognized standards of ethics of pharmacy or conduct that endangers the health, safety or welfare of a patient or client. Unprofessional conduct includes but is not limited to:

- (a) Fraud or misrepresentation in dealings relating to pharmacy practice with:
 - (A) Customers, patients or the public;
 - (B) Practitioners authorized to prescribe drugs, medications or devices;
 - (C) Insurance companies;
 - (D) Wholesalers, manufacturers or distributors of drugs, medications or devices;
 - (E) Health care facilities;
 - (F) Government agencies; or
 - (G) Drug outlets.

34

UNPROFESSIONAL CONDUCT

- QAR 855-006-0020 Unprofessional Conduct Defined

- (b) Illegal use of drugs, medications or devices without a practitioner's prescription, or otherwise contrary to federal or state law or regulation;
- (c) Any use of intoxicants, drugs or controlled substances that endangers or could endanger the licensee or others;
- (d) Theft of drugs, medications or devices, or theft of any other property or services under circumstances which bear a demonstrable relationship to the practice of pharmacy;
- (e) Dispensing a drug, medication or device where the pharmacist knows or should know due to the apparent circumstances that the purported prescription is bogus or that the prescription is issued for other than a legitimate medical purpose, including circumstances such as:
 - (A) Type of drug prescribed;
 - (B) Amount prescribed; or
 - (C) When prescribed out of context of dose.

35

UNPROFESSIONAL CONDUCT

- QAR 855-006-0020 Unprofessional Conduct Defined

- (f) Any act or practice relating to the practice of pharmacy that is prohibited by state or federal law or regulation;
- (g) The disclosure of confidential information in violation of Board rule;
- (h) Engaging in collaborative drug therapy management in violation of ORS Chapter 689 and the rules of the Board;
- (i) Authorizing or permitting any person to practice pharmacy in violation of the Oregon Pharmacy Act or the rules of the Board;
- (j) Any conduct or practice by a licensee or registrant which the Board determines is contrary to accepted standards of practice; or
- (k) Failure to cooperate with the Board pursuant to QAR 855-001-0035.

36


REPORTING

- 15 business days:
 - Change of address, worksite, email, etc.
- 10 working days:
 - Suspected prohibited or unprofessional conduct
 - Another healthcare provider's violation of law or rule to their board
 - Pharmacists, Interns, Technicians to Board of Pharmacy
 - Employment termination or resignation in lieu of termination
- 10 days:
 - Felony arrest
 - Conviction of misdemeanor or felony
- 1 day:
 - Significant drug loss / theft
- Immediately:
 - Child abuse - mandatory reporter

37

END OF MODULE II

- To earn a PIC training course completion certificate and continuing pharmacy education, you must complete all 3 modules.
- Questions? Contact us directly
 - Phone: 971-673-0001 / Fax: 971-673-0002
 - General Inquiries - pharmacy.board@bop.oregon.gov
 - Compliance Inquiries - pharmacy.compliance@bop.oregon.gov
 - Licensing Inquiries - pharmacy.licensing@bop.oregon.gov
 - [Controlled Substance Resources](#)
 - [PIC Info & Resources](#)



38