

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

OREGON BOARD OF PHARMACY MISSION, VISION, VALUES

- Mission: The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by
 ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and
 distribution of drugs.
- Vision: All Oregonians have equitable access to medication and pharmacy services, provided safely and
 conveniently, through a network of highly skilled and dedicated Pharmacists, Interns and Pharmacy Technicians
 along with a well-regulated manufacturing and distribution network.
- Values: Equity, Service, Safety, Adaptability, Professionalism, Integrity & Accountability

LEARNING OBJECTIVES

- Interpret Oregon statutes and rules related to the pharmacist-in-charge.
- Describe the foundational responsibilities of a state board of pharmacy.
- Explain how the board conducts inspections, investigations and issues disciplinary actions.
- Develop, implement and enforce policies and procedures to assure regulatory compliance of the pharmacy.
- Comply with reporting requirements
- Supervise Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians consistent with applicable requirements of state law.

4



5



WHAT IS "THE BOARD"? **BOARD MEMBERS**

- Composition:
- Five licensed pharmacists
- Two licensed technicians
- Two public representatives
- Each member:
- Applies via the Oregon.gov Boards & Commissions
- Appointed by the Governor subject to State Senate confirmation
- Serves a four-year term with reappointment possible
- Qualifications- ORS 689.115
- Oregon resident
- Pharmacist / Technician:
 - License in good standing
- Engaged in practice / assistance in practice Experience (5 years RPH, 3 years Technician)
- Public Member:
- At least 18 years old
- No financial interest in pharmacy
- No direct activity related to pharmacy practice

7

WHAT IS "THE BOARD"? AGENCY STAFF

LICENSING

- Application review and processing
- License renewal and management
- Continuing pharmacy
- education audits Background checks
- Financial management

COMPLIANCE

- Inspections and investigations
- Complaint investigation and reporting
- Disciplinary and legal proceedings
- Outreach and education
- Continuous learning and improvement

OPERATIONS

- Manage budget and finances
- Oversee agency administration
- Manage agency staff and operations
- Regulatory policy management
- External communications
- Board and public meeting management

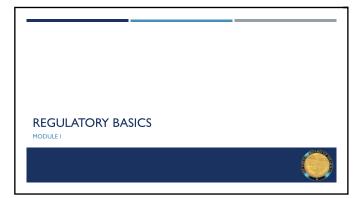
Information provision

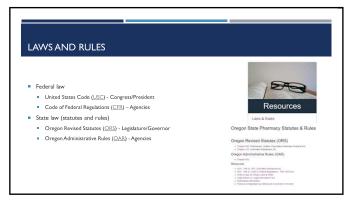
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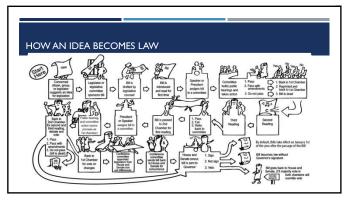
WHAT IS "THE BOARD"? **BOARD MEETINGS**

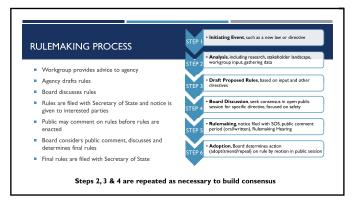
- Board Meetings
- Day One: Executive Session- Compliance Case Review, Legal Advice
- Day Two: Approximately ½ Executive Session and ½ Open Session
- Day Three: Open Session- Policy Discussion, Rule Review, Staff Updates, Motions for Compliance Cases
- Board Meeting Typical Schedule
- February, April, June, August, October, December
- Board Meeting Agendas and Meeting Summaries with video are posted on our <u>website</u>

WHO DOES "THE BOA PEOPLE & PLACES	RD" REGULATE!	
Pharmacist Preseptor Internation Preseptor Internation Preseptor Internation Pharmacy Technician Pharmacy Technician	REGISTRATION TYPES (PL Retail Drug Outlet Pharmacy Charitable Pharmacy Remote Dispensing Site Pharmacy Pharmacy Prescription Locker Pharmacy Prescription Knock Institutional Drug Outlet Pharmacy Prescription Knock Institutional Drug Outlet Pharmacy Romacy Romacy LTC/Residential Home Dispuss Home Dispuss Home Dispuss Correctional Facility	ACES) Community Health Clinic Dispensing Practitioner Drug Outlet Correctional Facilities Non-Prescription Drug Outlet Non-Prescription Drug Outlets Medical Device / Equipment / Gases Manufacturer Wholesalers Drug Distribution Agents / Third-Party Logistics



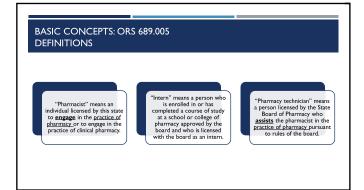


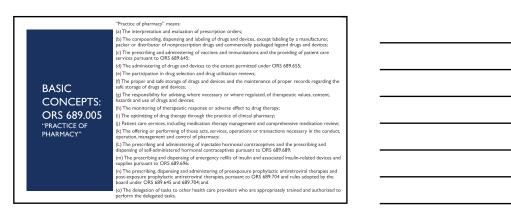






	DIVISION VISION DRAFT			
100	Definitions	136 DO Pharmacy (RP)	18	6 DO Nonprescription
102	Board Admin.	139 DO Remote Dispensing Site Pharmacy	18	
110	Universal Rules Fees	(RP) 141 DO Kiosk (RP)	19	
112	Public Health Emergency	143 DO Locker (RP)	19	
115	Pharmacist	I44 DO Charitable Pharmacy (RP)	19	DO Fractitorier Dispensing (KF)
120	Intern/Preceptor	156 DO Pharmacy (IP)		DO CITES
125	COPT/PT	159 DO Drug Room (IP)	19	DO Animai Eddianasia
135	HPSP CPE	161 DO RDF/RDM (IP)	20	Facility- Manufacturer
	G/L	164 DO Nuclear (IP)	20	3 Facility-Wholesaler
		167 DO LTC/Residential (IP)	20	6 Facility- DDA
		170 DO Home Infusion (IP)		
		173 DO Home Dialysis (IP)		
		176 DO Home Health Care (IP)		
	lics= Revision Complete	177 DO Correctional Facility (IP)		
	old= In Progress	180 Controlled Substances		
		183 Compounding		





BASIC CONCEPTS: ORS 689.005 "PRACTICE OF CLINICAL PHARMACY" "Practice of clinical pharmacy" means:

- (a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;
- (b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and $\frac{1}{2} \frac{1}{2} \frac{1$
- (c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.

19

BASIC CONCEPTS: ORS 689.225 & ORS 689.486 SUPERVISION, DIRECTION & CONTROL

ORS <u>689.225</u>(4)

(4) The State Board of Pharmacy shall adopt rules relating to the use of pharmacy technicians working under the supervision, direction and control of a pharmacist. For retail and institutional drug outlets, the board shall adopt rules which include requirements for training, including provisions for appropriate on-the-job training, guidelines for adequate supervision, standards and appropriate ratios for the use of pharmacy technicians. Improper use of pharmacy technicians is subject to the reporting requirements of OR3 689-455.

ORS 689.486(6)

(6) A person licensed to perform the duties of a pharmacy technician may perform the duties of a pharmacy technician only <u>under the supervision</u>, <u>direction and control</u> of a <u>licensed pharmacist</u>.

20

OAR 855-115-0122 RESPONSIBILITIES: SUPERVISION - PHARMACISTS

- (1) When supervising a Certified Oregon Pharmacy Technician or Pharmacy Technician, each Pharmacist may supervise as many Certified Oregon Pharmacy Technicians or Pharmacy Technicians as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare.
- (2) When supervising an Intern, each Pharmacist may supervise:
- (a) No more than four Interns participating in direct patient care activities.
- (b) As many Interns as they believe in their reasonable professional judgment is appropriate to promote and protect patient health, safety and welfare for Interns participating in non-direct patient care activities such as informational health fairs that provide general information, but not patient-specific information.

SUPERVISION, DIRECTION AND CONTROL	
OAR 855-125-0001 (2) Only persons licensed with the board as a Certified Oregon Pharmacy Technic Pharmacis in the practice of pharmacy and must act in compliance with statutes a control of a Pharmacist.	
OAR 855-125-0105 (3) A Certified Oregon Pharmacy Technician and Pharmacy Technician must: (b) Only assist in the practice of pharmacy under the <u>supervision, direction, and ce</u> (c) Know the identity of the Pharmacist who is providing <u>supervision, direction and</u> (d) Only work within the scope of duties permitted by their license; (e) Only work within the scope of duties permitted by the Pharmacist providing <u>standards</u>	d control at all times;
OAR 855-125-0135 Certified Oregon Pharmacy Technicians or Pharmacy Technicians: (i) Must only assist in the practice of pharmacy as authorized by the rules of the b providing supervision, direction, and control.	poard and as permitted by the Pharmacist

JUDGMENT AND VERIFICATION OAR 855-125-0135 Responsibilities: Permitted Practices Certified Oregon Pharmacy Technicians or Pharmacy Technicians:

(2) Must ensure that work is verified by a Pharmacist if $\underline{\underline{\underline{\underline{udgment}}}}$ is utilized when assisting in the practice of pharmacy.

OAR 855-125-0150 Prohibited Practices

Each Certified Oregon Pharmacy Technician and Pharmacy Technician must not:

(3) Perform any task while assisting in the practice of pharmacy that requires <u>judgment unless it is verified</u> by a Pharmacist.



WHAT IS A PHARMACIST IN CHARGE (PIC)?

- Statutory directive ORS 689.315
- Outlet requirement OAR 855-041-1010
- Oualifications & limitations- OAR 855-115-0205
- Responsibilities- OAR 855-115-0210 & OAR 855-041
- Customized PIC requirements for each outlet type (e.g., telepharmacies)
- Primary liaison to the Board
- There is no such thing as an "interim" PIC
- When the PIC of record is not present, the pharmacist on duty is recognized as the PIC at that time.

25

PIC QUALIFICATIONS & LIMITATIONS OAR 855-115-0205

- Must be a pharmacist (licensed in Oregon)
 - Complete at least one year of pharmacy practice or
- Complete board approved PIC training course either before PIC appointment or within 90 days after the appointment and
- Be employed by the outlet
- Maximum 3 pharmacies (does not include kiosks and lockers)
- Effective 7/1/2025, complete a board provided PIC training course at least every 5 years

26

NON-RESIDENT (OUT-OF-STATE PHARMACY) PIC OAR 855-041-1060

- Every non-resident pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC)
- When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the Board within I0 business days and identify a contact person.
 The pharmacy must have an Oregon licensed PIC employed within 90 days.
- PIC is responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy.
- Hold a license to practice pharmacy in the resident state -> *state where pharmacy is physically located;
- Be normally present in the pharmacy for a minimum of 20 hours per week;
 Complete the annual non-resident PIC self-inspection report prior to July 1st each year; and
- Provide the PIC self-inspection report as requested by the Board.
 PIC requirements by outlet type include:
- OAR 855-139-0030 Non-Resident RDSP Affiliated Pharmacies
- OAR 855-141-0030 Non-Resident PPK Affiliated Pharmacies
 OAR 855-143-0030 Non-Resident PPL Affiliated Pharmacies





PIC RESPONSIBILITIES OAR 855-115-0210 Actively engaged in pharmacy activities Physically present on a regular basis For a sufficient amount of time as needed to ensure Drug Oudet pharmacy compliance Ongoing conduct, operation, management and control of pharmacy Written policies and procedures Complete and accurate records Continuous quality improvement program

PIC RESPONSIBILITIES OAR 855-115-0210

- Plan of correction for observations noted on an inspection within the time allowed by the board;
- Self-inspection of the pharmacy using the Self-Inspection Form
- July I each year and
- Within 15 days of becoming PIC
- Controlled substance inventory with discrepancy reconciliation
- All controlled drugs either prior to the opening or after the close of business on the inventory date
 - Within 15 days of a change in PIC and
 - At least every 367 days and
- For all Schedule II controlled drugs:
- At least every 93 days in a Retail Drug Outlet Pharmacy
- At least every 31 days in an Institutional Drug Outlet Pharmacy

31

CREATING, MAINTAINING, AND ENFORCING WRITTEN POLICIES AND PROCEDURES

- A Pharmacist-in-Charge of a Drug Outlet pharmacy must establish, maintain, and enforce written policies and
 procedures governing the practice of pharmacy that are compliant with federal and state laws and rules.
- · Keep up with new and proposed rules
- Rulemaking Information on OBOP website
- Subscribe to Rulemaking Notices & Adoption of Rules list-serv
- Subscribe to the quarterly Newsletter
- Establish/enforce policies and procedures to run a compliant pharmacy and PROVIDE SAFE, QUALITY PATIENT CARE

32

OUTLET POLICIES & PROCEDURES OAR 855-041-1040

- Operation, testing and maintenance of pharmacy systems and equipment
- Sanitation
- Storage of drugs Dispensing
- Pharmacist supervision, direction and control of non-Pharmacists
- Documenting the date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process
- Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians
- Certified Oregon Pharmacy Technician or Pharmacy Technician final verification and/or vaccination, if utilized
- Drug and/or device procurement
- Receiving of drugs and/or devices
- Disposal of drugs and/or devices including hazardous and pharmaceutical waste
- Delivery of drugs and/or devices
- Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling)
- Recordkeeping
- Patient confidentiality
- Continuous quality improvement
- Plan for discontinuing and recovering services in the event of a pharmacy closure
- Training: initial and ongoing
- Interpretation, translation and prescription reader services

PROPER STORAGE OF DRUGS: GENERAL OAR 855-041-1036

- $\mbox{(1) A pharmacy must maintain proper storage of all drugs. This includes, but is not limited to the following:} \\$
- (a) All drugs must be stored according to manufacturer's published or USP guidelines.
- (b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.
- (c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.
- (d) A pharmacy must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.

34

PROPER STORAGE: MANUFACTURER GUIDELINES OAR 855-041-1036

- (2) A pharmacy must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).
- (a) All drug refrigeration systems must:
- (A) Maintain refrigerated products between 2 to 8 °C (35 to 46 °F); frozen products between -25 to -10 °C (-13 to 14 °F); or as specified by the manufacturer.
- (B) Utilize a centrally placed, accurate, and calibrated thermometer;
- (C) Be dedicated to pharmaceuticals only; and
- (D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings.

35

PROPER STORAGE: MANUFACTURER GUIDELINES OAR 855-041-1036

- (b) A pharmacy must adhere to a monitoring plan, which includes, but is not limited to:
- (A) Documentation of training of all personnel;
- (B) Maintenance of manufacturer recommended calibration of thermometers;
- (C) Maintenance of records of temperature logs for a minimum of three years;
- (D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;
- (E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination that it is safe for continued use. This documentation must include details of the information source;
- (F) A written emergency action plan; and
- (G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment.

PROPER STORAGE: VACCINES OAR 855-041-1036

(3) Vaccine Drug Storage:

(a) A pharmacy that stores vaccines must comply with section two of this rule and the following:

(A) Vaccines must be stored in the temperature stable sections of the refrigerator;

(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 $^{\circ}$ C variance must be utilized;

 $(C) \ Each \ freezer \ and \ refrigerator \ compartment \ must \ have \ its \ own \ exterior \ door \ and \ independent \ thermostat \ control;$

(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and (E) Must adhere to a written quality assurance process to avoid temperature excursions.

(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.

37

DRUG STORAGE / TEMPERATURE MONITORING

- Be organized! Know where all supporting documentation is kept
- Be knowledgeable! Learn about your drug storage equipment and what to do when things go wrong
- Empower all staff members to participate in drug storage oversight expectations:
- Understand how to monitor the system and read the data reports
- Recognize how to handle system alerts and proactive QA procedures
- Do you know the steps to take when your refrigerated drug products have gone out of range?
- Do you know what documentation is necessary for each excursion?
- What is the procedure for notifying PIC or other management?
- Would you dispense this med to a family member?

38

RECORDKEEPING & DOCUMENTATION



RECORD AND DOCUMENT RETENTION OAR 855-104-0055

(1) Each licensee and registrant must create documents and retain records required by ORS 475, ORS 689, and OAR 855. Documents and records:

(a) May be in written or electronic format;

- (b) Must be stored securely;
- (c) Must be made available to the board upon request; and
- (d) Must be retained for 3 years except that:
- (A) Clinical pharmacy records must be retained for 7 years; and
- (B) Training records for immunization administration and protocol and formulary compendia prescribing, must be retained for 6 years or uploaded into the licensee's electronic licensing record with the board;
- (2) Records generated by a registrant:
 (a) Must be stored on-site by the registrant for at least 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 storage at the registrant and must be provided to the board upon request within 3 business days;

40

RECORD AND DOCUMENT RETENTION OAR 855-104-0055

- (3) Records generated in the practice of pharmacy that do not belong to a registrant must be stored by a Pharmacist in a secure manner and provided to the board upon request within 3 business days; and
- (4) Records must be retained for longer periods of time than required under this rule if:
- (a) Federal law provides for a longer retention schedule; or
- (b) Licensee or registrant has received notice of a Board investigation to which the records would be relevant;
- (c) Licensee or registrant has received a Board request to retain the records for a longer period of time.

41

END OF MODULE I

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

