



Oregon

John A. Kitzhaber, MD, Governor

Oregon Board of Pharmacy

800 NE Oregon Street, Suite 150

Portland, OR 97232

Phone: 971 / 673-0001

Fax: 971 / 673-0002

E-mail: pharmacy.board@state.or.us

Web: www.pharmacy.state.or.us

READ THIS PAGE CAREFULLY

2012

**RETAIL AND LONG TERM CARE PHARMACY
PHARMACIST- IN-CHARGE
PHARMACY SELF-INSPECTION REPORT**

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

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

Following your self-inspection and completion of the report, please review it with your staff pharmacists, technicians and interns, correct any deficiencies noted, sign and date the report, and file it so it will be readily available to Board inspectors. **DO NOT MAIL** to the Board office. You are responsible to ensure your completed report is available at the time of inspection.

The primary objective of this report, 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 your complete compliance with all laws and rules of the practice of pharmacy.) The inspection report also serves as a necessary document used by Board inspectors during an inspection to evaluate a pharmacy's level of compliance.

When a Board inspector discovers an area of non-compliance, they may issue either a **Deficiency Notice** or a **Notice of Non-Compliance**. Both require a written response from the PIC. Identifying and correcting an area of non-compliance prior to a Board inspection may eliminate the receipt of a Deficiency Notice/Notice of Non-compliance for that item. Do not *assume* that you are in compliance with any statement; take the time to personally verify that compliance exists. A situation of non-compliance that "is the way it has been for years" is the current PIC's responsibility to immediately correct to avoid the possibility of a Notice and/or disciplinary action. If you have any questions, please fax your questions, "attention inspectors", prior to an inspection to 971-673-0002.

The most common reason for issuing a Deficiency Notice is either not having or not being able to readily retrieve required documents and records. Because Board inspections are unscheduled, it is common for the PIC to be absent or unavailable. 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) dramatically reduces the chance that you will receive a Deficiency Notice.

By answering the questions and referencing the appropriate laws/rules/CFR provided, you can determine whether you are 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.

A PIC training course is now being offered at the Board office. Check the Board website for dates.

THE OREGON BOARD OF PHARMACY INTERNET LAW EXAM TO OBTAIN ONE C.E. OF CREDIT WILL BE AVAILABLE AT WWW.PHARMACY.STATE.OR.US IN JANUARY.

PHARMACY PERSONNEL—KEEP CURRENT THROUGHOUT THE YEAR AS NEEDED

Have each licensee review this inspection form, corresponding documents and procedures, and be prepared to assist in locating information during an inspection and sign below certifying their review.

Please check the box next to the technicians name to indicate you have verified that you have documentation of each individual's technician training available for Board inspection.

NAME	CPT LICENSE NUMBER	CPT LICENSE EXPIRATION DATE	LICENSEE'S SIGNATURE
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
<input type="checkbox"/>	CPT-		
NAME	LICENSE TYPE & # TECHNICIAN, INTERN, PHARMACIST	EXPIRATION DATE	LICENSEE'S SIGNATURE
<input type="checkbox"/>	T-		
<input type="checkbox"/>	T-		
<input type="checkbox"/>	RPH-		
<input type="checkbox"/>	RPH-		
<input type="checkbox"/>	RPH-		
<input type="checkbox"/>	RPH-		
<input type="checkbox"/>	RPH-		
<input type="checkbox"/>	I-		
<input type="checkbox"/>	I-		

**2012 PHARMACIST-IN-CHARGE
PHARMACY SELF-INSPECTION REPORT
OREGON BOARD OF PHARMACY
TEL: 971-673-0001 FAX: 971-673-0002
www.pharmacy.state.or.us**

All PICs of Retail, Compounding, Home Infusion, and Long-Term Care pharmacies MUST complete and sign this inspection report and have it available for inspection within 15 days of becoming PIC and by 2/1/2012 (as required by OAR 855-019-0300). DO NOT MAIL TO THE BOARD OFFICE.

Date PIC Inspection was performed: ____ / ____ / ____

Signature of PIC: _____

Print Name & Lic. #: _____

Pharmacy: _____ Telephone: _____ Fax: _____

Address: _____ DEA #: _____; Exp: ____ / ____ / ____

Retail Outlet Cert #: _____ Institutional Outlet Cert #: _____ Nonprescription Drug Outlet Cert #: _____

Inspector Signature: _____

Date: _____ Deficiency Notice: _____

Comments: _____

CAREFULLY CONFIRM WHETHER OR NOT YOU ARE COMPLIANT AND MARK THE APPROPRIATE BOX TO THE LEFT OF EACH ITEM. IF YOU FIND ITEMS THAT NEED CORRECTING, RECTIFY THE DEFICIENCY AND WRITE THE DATE OF CORRECTION AND THEN MARK THE "YES" BOX. DO NOT MARK 'YES' UNLESS THE ANSWER IS 'YES'. NOTE: THE CORRECT ANSWER TO SOME QUESTIONS IS 'NO'.

Yes **No** **NA**

1. Are you a retail pharmacy, compounding, home infusion, or a long term care pharmacy? This is **not** the self inspection report for a hospital or nuclear pharmacy. Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with all laws and rules of the practice of pharmacy. **Bolded items will be emphasized.**
2. Do you compound Category 2 through 5 products?
If Yes, download and complete the additional inspection form for compounding in addition to this form.
3. Are you PIC of more than one location? If so, are you completing the required quarterly compliance audit?
If yes, where is the quarterly compliance audit kept? _____
4. Is page 2 completed? Please note that certified pharmacy technicians are required to be licensed by the Board and to maintain their certification with PTCB/ICPT.
5. ORS 689.615 Are your current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted? ALSO – remind certified pharmacy technicians that they are required to maintain certification with ICPT or PTCB in addition to a license with the Board.
6. OAR 855-019-0100 Does this pharmacy utilize any off-site personnel to enter, verify prescription information, or fill prescriptions? If yes, explain: _____
7. Have you verified the wholesaler you purchase medication from is registered in Oregon? You may verify licenses and registrations on the Board website www.pharmacy.state.or.us.
Name of primary and secondary wholesaler(s) and registration number:

8. Are pharmacists, technicians, & interns **aware that they must report** arrests, convictions, **and** suspected **and** known violations **to the Board** within 10 days as required by OAR 855-019-0205, OAR 855-025-0020, and OAR 855-031-0020? Employment & residence address changes must be reported within 15 days.

Where are the following items located inside the pharmacy (be as specific as possible, there can be many filing cabinets and binders)?

Current CPR Cards & Immunization Certification documents _____

PIC Inspection Reports for the last 3 years: _____

Quality Assurance plan/documents: _____

Current written annual controlled substance inventory: _____

Current technician procedures: _____

Technician training documents: _____

Current written Drug Outlet Procedures: _____

Schedule II Invoices for the last 3 years: _____

Schedule III-V Invoices for the last 3 years: _____

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

Quarterly Schedule II reconciliation: _____

Vaccine administration records: _____

Yes No NA Minimum Equipment, Procedures, and Records

- 9. OAR 855-041-0060(7) Are your drug outlet procedures current, compliant with Oregon laws and rules, and do they reflect the practice at your outlet? (Note: includes corporate procedures).
 - Date you reviewed procedures with staff:

List page number from procedure book on where to locate each of the following:

- _____ • Securing legend drugs and the area in which they are prepared, compounded, stored or repackaged;
- _____ • **Performing mandatory prospective drug utilization reviews (Note: includes refills, cash patients, etc.);**
- _____ • Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;
- _____ • Documenting the identification of the pharmacist(s) responsible for the verification of each dispensed medication;
- _____ • **Ensuring the delivery of each completed prescription to the correct party;**
- Note: The Board has received many complaints of distribution errors.
- _____ • Providing appropriate confidential professional advice concerning medications to patients or their agents;
- _____ • **Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties. Note: Are you ensuring that a pharmacy technician obtaining a certified pharmacy technician license with the Board?**

- | <u>Yes</u> | <u>No</u> | <u>NA</u> | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 10. OAR 855-019-0300(5)(g) Does the outlet's quality assurance plan meet the requirements. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 11. OAR 855-041-0040(1-2) Do you have the most current electronic (E) or hard copy issue (HC) with supplements of the following (<u>CIRCLE WHICH APPLIES</u>) and are they readily accessible by all staff: <ul style="list-style-type: none"> • Pharmaceutical reference; E AND/OR HC Name of reference: _____ • Current Oregon Revised Statutes (Chapters 689 and 475) and Current Oregon Administrative Rules (Chapter 855); E AND/OR HC • Board of Pharmacy quarterly newsletters (for the past 3 years). E AND/OR HC |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 12. Are you mailing prescriptions to residents of a state other than Oregon? Have you obtained a license in that state, if required? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. OAR 855-041-0036 Have you quarantined all out-dated medications (both prescription and OTC)? Are controlled substances secured? Where are they stored? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. Do you sell medications to doctors? Where are invoices: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 15. ORS 689.508 & OAR 855-041-0060 Are your prescription records on site and readily retrievable for 3 years? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 16. OAR 855-041-0065 Is the identity of the responsible pharmacist documented for all prescriptions (new, refill, emergency supply, and fill on arrival balances)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 17. OAR 855-041-0065(3) When verbal refill authority is given (i.e. refill OKs), have you documented the name of the authorizing prescriber/prescriber's agent. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 18. OAR 855-019-0210 and OAR 855-041-0075 Have you verified that all pharmacists at your outlet are noting – the date prescription is received and their name or initials and the name of the person transmitting the telephone prescription? Note: this includes, documenting 'per prescriber' (or something similar) if the prescriber calls in a prescription. <i>Note: Technicians may NOT transcribe from voicemail.</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 19. OAR 855-041-0056 Have you labeled drugs (including medications placed into automated dispensing machines like ScriptPro®, Baker Cell®, etc.,) that are prepackaged for use at a later time with the following information: <ul style="list-style-type: none"> • Brand name, or generic name & manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used. • <u>Note:</u> a pharmacist is required to verify a technician's work when a technician loads a machine/pre-packs. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20. OAR 855-041-0025(2) Is the pharmacy clean (refrigerator, sink, counting trays, counting machines)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 21. OAR 855-041-0065(7)(k) Do your labels have the physical description of the medication? Note: This includes labeling liquid and compounded medications with their physical description (i.e. color)? |
| | | | <u>Controlled Substances</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 22. <u>OAR 855-019-0300(5) Are you identifying and explaining variances on CII reconciliations? Any theft or significant loss must be reported to the Board and DEA.</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 23. <u>OAR 855-080-0070 Did you take your Controlled Substance (CII-V) Inventory on one day, within 12 months (365 days) of your last inventory? Date of your last CII-CV Inventory: _____/_____/_____.</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 24. Is outlet compliant with federal regulations? This includes filing CII invoices separately from CIII-CV, filling out all lines on DEA 222 forms with date and quantity received (enter 0 and date line if no medication received), and storing CII's in a locked cabinet or dispersed throughout the stock of non-controlled substances. |
| | | | <u>Security</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 25. <u>OAR 855-041-0025(1) and OAR 855-041-0026(3) When no pharmacist is physically present in the pharmacy or institutional facility (i.e. when the pharmacist leaves the building), is the pharmacy/prescription area (including pharmacy records and computers) secured to prevent entry and access to records?</u> |

Yes **No** **NA**

26. Are ALL keys, codes to lockboxes, and codes to the pharmacy in the possession of an Oregon licensed pharmacist only?
Note: Technicians, Supervisors, Managers, Owners who are not Oregon licensed pharmacists may not have keys/codes/electronic swipe cards permitting access to the pharmacy department when the pharmacist is not present. **If entry may be gained by electronic means (key pad, swipe card) how does the pharmacist prevent entry by non-Oregon licensed pharmacist (i.e. deadbolt)?**
-

27. Do technicians process/receive prescriptions before a pharmacist arrives or after the pharmacist leaves?

28. Are technicians able to access pharmacy records/computer when a pharmacist is not on site?

Technicians

29. OAR 855-025-0025(3) Are your Pharmacists, Interns and Technicians clearly identified as such to the public?

30. OAR 855-025-0025(5) and (6) Do technicians know what duties/tasks they may perform and do you have documentation of their training?

31. OAR 855-025-0025(4) Does a pharmacist verify all work performed by technicians and document this verification?

Drug Utilization Reviews and Counseling

32. **OAR 855-019-0220 Is a pharmacist (not just computer) performing a drug utilization review on prescription refills? Note: A pharmacist must perform a DUR on every prescription even if the computer does not prompt an alert. How does the pharmacist evaluate prescription refills for over/under utilization?**
-

33. Does the pharmacist review all DUR messages (including those from insurance companies)?
Note: Technicians are not allowed to override or pass through DURs.

34. **OAR 855-019-0220 Is the pharmacist making an effort in obtaining, recording, and maintaining the patient's allergies and chronic medical conditions? Note: Many prescriptions indicate allergies! How is this done?**

35. **OAR 855-041-0065 Are prescriptions correctly dispensed? Note: This includes verifying the expiration date on the prescription label is not longer than the expiration date on the stock container which is a frequent violation noted during inspections. COMMON VIOLATION FOUND**

36. OAR 855-019-0230(1)(a) Is pharmacist/intern counseling the patient (not just asking the patient if they have questions)?

37. OAR 855-019-0230 Is a pharmacist or intern initiating counseling?
How is a new prescription identified as requiring counseling? _____
-

How does a pharmacist identify a prescription refill as requiring counseling? _____

Note: A pharmacist may indicate that a prescription 'refill' with a new prescription number does not require counseling, if, after performing a DUR the pharmacist determines nothing has changed (continuation of therapy).

38. OAR 855-019-0230 Does the pharmacist/intern counseling include information necessary to promote the safe use of the medication and facilitate an appropriate therapeutic outcome?

39. **OAR 855-019-0230(1)(c) Is the pharmacist/intern documenting whether counseling is provided or declined on new prescriptions and refills that require counseling? (The pharmacist, not the patient, must specify if counseling is provided or declined at the time of the interaction.)**

N/A

Vaccine administration

Yes **No** **NA**

40. OAR 855-019-0290 Do all immunizing Pharmacists/Interns have documentation/certificate of training and a current CPR card on site and available for inspection?
41. OAR 855-019-0270 Do you monitor and log storage temperature of vaccines?

Where is this kept? _____

Do you have a process in place to ensure products are unadulterated if (or when) temperature falls out of storage range?

42. **OAR 855-019-0270 Does pharmacy have required equipment and supplies for managing adverse events and are quarterly reviews completed and recorded to assure supplies are complete and that no medication will expire sooner than one month after the date of the next review?** Includes-breathing bag with mask, sphygmomanometer, stethoscope, epinephrine, diphenhydramine 50mg/ml, smelling salts - see protocol for complete list.
43. OAR 855-041-0056 If syringes are pre-drawn, are they labeled with the required information?
- o Brand name, or generic name & manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used.
44. OAR 855-019-0280(3) Is the appropriate Vaccine Information Statement given to the patient or legal representative? Does the pharmacist ensure that the information was read and all questions are answered before administration?
45. OAR 855-019-0270 and OAR 855-019-0280 Are you following the new protocols and providing an Adolescent Well Visit Referral document for patient's aged 11-18 available at: <http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Pages/pharmpro.aspx>
46. **OAR 855-019-0290 Is all information reported to the OHA ALERT Immunization System within 15 days of administration?**
47. OAR 855-019-0290 Is pharmacist/intern who administers any vaccine/immunization maintaining the following information: name, address, gender, date of birth of the patient and phone number when available; date of the administration; injection site; name, dose, manufacturer, lot number, and expiration date of the vaccine; identity of administering pharmacist; the date of publication of the VIS; and the date the VIS was provided.

N/A

Long Term Care/Community Based Care Services

48. OAR 855-041-0105, 855-041-0115 & 855-041-0145 Do you provide prescriptions to patients in a Long Term Care Facility?
If yes, do you have the required institutional drug outlet license? Registration #IP _____
49. OAR 855-041-0160(2) Are you providing emergency drug kits to any facilities? Have you ensured that these facilities are allowed by their license to have an emergency drug kit?
50. OAR 855-041-0160(2) (b) & (5) Are you ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-0120(3)? **AND** that there is a practitioner's order to authorize the removal of medications?
How? _____
51. OAR 855-080-0070 and 21 CFR 1304.11 Did you include emergency kit controlled substances (CII-V) in your Controlled Substance inventory?
52. OAR 855-041-0080(3) Do you accept the return of previously dispensed prescriptions?
53. OAR 855-041-0080(3) Do you dispense medications that have been previously dispensed and returned?
54. OAR 855-041-0160(1)(a) Are you assisting in the establishment and supervision of the policies & procedures for the safe storage, distribution, administration & disposition of drugs, and for professional advice/medication counseling of patients and/or caregivers?

Yes **No** **NA**

55. OAR 855-041-0160(1)(c) Is a pharmacist performing the quality assurance activities defined in OAR 855-041-0132? **Where** are the findings/conclusions of the monitoring, evaluation, and problem solving activities documented? _____

Compounding and Sterile Parenteral Products

Compounding is separated into five categories (1-5).
Examples of each category are:

Category 1- Miracle/magic mouth wash, mixing two creams together

Category 2- Making capsules, tablets, suppositories,

Category 3- Antibiotic in an IV solution, Two additives in an IV solution

Category 4- Multiple medications in an IV, TPNs - Total parenteral nutrition solutions with multiple additives

Category 5- Non sterile Morphine powder used to prepare solutions for IV pump infusions.

56. Do you compound Category 2 through 5 products?
If Yes, download and complete the additional inspection form for compounding.

I hereby certify that I have verified this outlet is in compliance with all laws and rules, have read and verified that written polices and procedures reflect current practices, have documented training of technicians, and the answers marked on this report are true and correct.

Pharmacist-in-charge Signature

License #

Date



Cut on this line, fill in location of each item, and post next to outlet license on the wall.

DO NOT SEND ANY PART OF THIS REPORT TO THE BOARD OFFICE.

KEEP IN THE BOARD OF PHARMACY LAW BOOK, COPIES SENT TO THE BOARD WILL BE DISCARDED.

LOCATION OF PIC SELF-INSPECTION FORM: _____

LOCATION OF BOARD OF PHARMACY LAWS AND RULES: _____