



# Oregon

John A. Kitzhaber, MD, Governor

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## **READ THIS PAGE CAREFULLY**

2014

### **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 SEND** 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" 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 IS AVAILABLE AT [WWW.PHARMACY.STATE.OR.US](http://WWW.PHARMACY.STATE.OR.US).

**2014 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 2/1/2014 (as required by OAR 855-019-0300). DO NOT SEND 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 #: \_\_\_\_\_

Non-prescription 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'.**

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: \_\_\_\_\_

Vaccine administration records: \_\_\_\_\_

PIC Inspection Reports for the last 3 years: \_\_\_\_\_

Continuous 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: \_\_\_\_\_

\*\*Please see the Board's website for proposed rule changes including a "duty to report" change to OAR 855-019-0205(6)\*\*



<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Are you a retail pharmacy, compounding, home infusion, or a long term care pharmacy? This is <b>not</b> the self inspection report for a hospital or nuclear pharmacy. Note: Neither the self-inspection nor a Board inspection evaluates your complete compliance with <u>all</u> laws and rules of the practice of pharmacy.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Are you PIC of more than one location? If so, are you completing the required quarterly compliance audit (revised 11/2012)? If yes, where is the quarterly compliance audit kept? _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Are your <u>current</u> pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and technician license(s) posted?	ORS 689.615
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Are pharmacists, technicians, & interns <b>aware that they must report</b> arrests, convictions, <b>and</b> suspected <b>and</b> known violations <b>to the Board</b> within 10 days? Employment & residence address changes must be reported within 15 days.	OAR 855-019-0205 OAR 855-025-0020 OAR 855-031-0020
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Are pharmacists taking appropriate uninterrupted rest periods and meal breaks?	OAR 855-041-1170(3)

**Minimum Equipment, Procedures, and Records**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Are your drug outlet procedures current, compliant with Oregon laws and rules, and <u>do they reflect the practice at your outlet?</u> <b>(Note: This rule has changed and procedures need to reflect the change).</b> • Date you reviewed procedures with staff: _____	OAR 855-041-1040
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Do you have appropriate references to perform an adequate DUR for humans and animals readily accessible to all staff? Note: The Board's website is the best resource for current rules.	OAR 855-041-1035(1-2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Have you quarantined all out-dated medications (both prescription and OTC)? Note: This includes compounding supplies and items in the refrigerator.	OAR 855-041-1025
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Do you sell medications to doctors? Where are invoices: _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. When your pharmacists receive a telephone prescription, are they documenting their name, the date, and the name of the person transmitting the prescription? Note: this includes, documenting 'per prescriber' (or something similar) if the prescriber calls in a prescription. <u>Note: Technicians may NOT transcribe from voicemail.</u>	OAR 855-019-0210 OAR 855-041-1150
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Are you able to identify brand name, or generic name & manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used for <b><u>medications placed into all cells in automated dispensing machines like ScriptPro®, Baker Cell®, etc.,</u></b> that are prepackaged for use at a later time?  How does the pharmacist verify and document that the technician is properly loading the machine? _____ _____	OAR 855-041-1135  OAR 855-025-0040(2)(f)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Do your labels have the physical description of the medication? Note: This includes labeling liquid, OTCs, and compounded medications with their physical description as required (i.e. color, shape and impression)?	OAR 855-041-1130(1)(k)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. If you combine refill quantities into a single filling for prescriptions that are not for a controlled substance or psychotherapeutic drug, do you notify the prescriber of the change after the fact?	OAR 855-041-1120(4)

### Controlled Substances

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. <b><u>Are you identifying and explaining variances on CII reconciliations at the time of the audit? Any theft or significant loss must be reported to the Board and DEA.</u></b>	OAR 855-019-0300(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. <b><u>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: ___ / ___ / ___. Was it taken before opening or after closing (not throughout the day)? Note: This includes e-kits, compounding supplies and items in the refrigerator.</u></b>	OAR 855-080-0070
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Is your annual CII inventory filed separately from your CIII-CV inventory and are your CII invoices and prescriptions filled separately from other prescriptions and invoices?	21 CFR 1304.04
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. Are all lines of DEA 222 order forms filled out completely with receiving dates and quantity received? (Enter '0' if none received and date line)	21 CFR 1305.13(e)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18. Are CIIs ordered electronically? If so, do you create a record of the quantity and date received that is electronically linked to the original order and archived?	21 CFR 1305.22(g)

### Security

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19. When no pharmacist is physically present in the pharmacy or institutional facility (i.e. when the pharmacist leaves the building); are computers, records and medications properly secured to prevent entry and access to records?	OAR 855-041-1020(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20. Can technicians process/receive prescriptions before a pharmacist arrives or after the pharmacist leaves?	OAR 855-041-1020(3)

### Support Personnel

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21. Are your Pharmacists, Interns, Technicians and clerks <u>clearly identified</u> as such to the public?	OAR 855-025-0025(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22. Do technicians and clerks know what duties/tasks they may perform and do you have documentation of their training? <b><u>(Board's basic law training forms available online)</u></b>	OAR 855-041-1040(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23. Does a pharmacist verify all work performed by technicians and document this verification?	OAR 855-025-0025(4)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24. Is page 3 completed? Please note that certified pharmacy technicians are required to be licensed by the Board <u>and</u> to maintain their certification with PTCB/NHA (ICPT). Note: Certified Pharmacy Technicians must have an active national certification when they attest to it on their renewal each year.	

**Drug Utilization Reviews and Counseling**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25. Is a pharmacist personally (not just computer) performing a drug utilization review on all new and refill prescriptions? <b>How does the pharmacist evaluate prescription refills for over/under utilization?</b> _____ _____	OAR 855-019-0220
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26. Do you utilize the Prescription Drug Monitoring Program (PDMP) when performing a DUR on a controlled substance (CII-CIV)?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27. Is the pharmacist making an effort in obtaining, recording, and maintaining the patient's allergies and chronic medical conditions? <b><u>Note: Many prescriptions from EMR systems at the clinic indicate allergies.</u></b>	OAR 855-019-0220
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28. Are prescriptions correctly dispensed? Note: This includes verifying the expiration date on the prescription label <b><u>is not longer</u></b> than the expiration date on the stock container which is a frequent violation noted during inspections.	OAR 855-041-1105 OAR 855-041-1130
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29. Is a pharmacist or intern initiating counseling on new prescriptions and refills requiring counseling? (Note: This is NOT a pharmacist head nod/making eye contact with patient from across the pharmacy or a cashier/technician asking patient if they have questions).  Is the denial of counseling made directly to the pharmacist or intern? How is a new prescription identified as requiring counseling? _____  How does a pharmacist identify a prescription <b>refill</b> as requiring counseling? _____  Note: A pharmacist (not technician) may indicate that a prescription 'refill' with a new prescription number does not require counseling, if, after performing a DUR <b>the pharmacist determines <u>nothing</u></b> has changed (continuation of therapy (CT) and it is appropriate to release the prescription without speaking to the patient.)	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30. Does the pharmacist/intern counseling include information necessary to promote the safe use of the medication and facilitate an appropriate therapeutic outcome? Note: Asking the patient if they have any questions does not fulfill this requirement.	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31. Is the pharmacist/intern personally documenting whether counseling is provided or declined on new prescriptions and refills that require counseling at the time of counseling? <b><u>(The pharmacist or intern, not the patient/clerk/technician, must specify if counseling is provided or declined at the time of the interaction.)</u></b>	OAR 855-019-0230(1)(c)

**Vaccine administration**

N/A

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32. Do all immunizing Pharmacists/Interns have documentation/certificate of training and a current CPR card on site and available for inspection? Note: A pharmacist may NOT continue to provide immunizations or oversee interns immunizing if their CPR certification has lapsed.	OAR 855-019-0290
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33. Does CPR training/re-training include a hands-on training component? Please attach a copy of all CPR cards to the back of this report.	OAR 855-019-0270(3)(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34. Do you monitor and log storage temperature of vaccines? What do you do with medications when the temperature falls out of the required temperature storage range? _____	OAR 855-019-0270
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35. Does the pharmacy have required equipment and supplies for managing adverse events and are reviews done to ensure supplies are complete and that no medication will expire before the next review? See protocol for complete list.	OAR 855-019-0270
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36. Are you following the new protocols and providing an Adolescent Well Visit Referral document for patient's aged 11-18? <b><u>ENSURE PROTOCOLS ARE THE MOST CURRENT VERSION PRIOR TO ADMINISTERING.</u></b>	OAR 855-019-0270 OAR 855-019-0280
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37. Do pharmacists have access to the OHA ALERT Immunization Information System?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38. Are pharmacists evaluating ALERT information for needed vaccines? See protocol for details/exclusions.	OAR 855-019-0280
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39. Is all information reported to the OHA ALERT Immunization Information System within 15 days of administration?	OAR 855-019-0290
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40. Is the 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.	OAR 855-019-0290

**Long Term Care (LTC)/Community Based Care (CBC) Services**

N/A

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41. Do you provide prescriptions to patients in a Skilled Nursing Facility (SNF) and/or Intermediate Care Facility (ICF)? If yes, do you have the required institutional drug outlet license? Registration #IP _____	OAR 855-041-5005 OAR 855-041-5015 OAR 855-041-7050
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42. Are you providing emergency drug kits to any facilities? <b><u>Have you ensured that these facilities are allowed by their license to have an emergency drug kit?</u></b> If yes, how does a pharmacist verify and document verification of the kit? _____	OAR 855-041-7060(2)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	43. Are you ensuring that only a licensed nurse is accessing the emergency drug kit or on-site pharmacy pursuant to OAR 855-041-6310? <b>AND</b> that there is a practitioner's order to authorize the removal of medications? How? _____ _____	OAR 855-041-7060(2)(b) OAR 855-041-7060(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44. Do you accept the return of previously dispensed prescriptions?	OAR 855-041-1045(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45. Do you dispense medications that have been previously dispensed and returned?	OAR 855-041-1045(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46. 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?	OAR 855-041-7060(1)(a)

**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.

<u>Yes</u>	<u>No</u>	<u>N/A</u>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47. Do you compound <b><u>Category 2 through 5</u></b> products? <b>If Yes, download and complete the additional inspection form for compounding.</b>

I hereby certify that I have verified this outlet is in compliance with all laws and rules, have read and verified that written policies and procedures reflect current practices, have documented training of technicians, and the answers marked on this 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.  
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**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: \_\_\_\_\_