



# Oregon

John A. Kitzhaber, MD, Governor

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**READ THIS PAGE CAREFULLY**

**2014**

**HOSPITAL PHARMACY/HOSPITAL WITH RETAIL  
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 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) may result in disciplinary action. DO NOT MAIL TO THE BOARD OFFICE.

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

**2014 PHARMACIST-IN-CHARGE  
HOSPITAL SELF-INSPECTION REPORT  
OREGON BOARD OF PHARMACY**

TEL: 971-673-0001                      FAX: 971-673-0002  
www.pharmacy.state.or.us

All PICs of hospital 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 MAIL TO THE BOARD OFFICE

Date PIC Inspection was performed: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Signature of PIC: \_\_\_\_\_

Print Name & Lic. #: \_\_\_\_\_

Chief Pharmacy Officer Name & Lic # \_\_\_\_\_

Pharmacy: \_\_\_\_\_ Telephone: \_\_\_\_\_ Fax: \_\_\_\_\_

Address: \_\_\_\_\_ DEA #: \_\_\_\_\_; Exp: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Retail Outlet Cert #: \_\_\_\_\_ Institutional Outlet Cert #: \_\_\_\_\_

Non-prescription Drug Outlet Cert #: \_\_\_\_\_

Hours of operation: \_\_\_\_\_

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)?

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: \_\_\_\_\_

Perpetual Schedule II inventory and reconciliation: \_\_\_\_\_

Accrediting body pharmacy related inspection results: \_\_\_\_\_

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



**General Requirements**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. Is this hospital accredited? If yes, by whom: _____ Date of their last inspection: __/__/__ *Please attach any pharmacy recommendations.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. Are your current 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"/>	3. Is the hospital part of a healthcare organization? If yes, who is the Chief Pharmacy Officer? _____	OAR 855-041-6150(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Does this pharmacy utilize any off-site personnel to verify order information, perform DURs, or is the pharmacy providing these services to another entity? If yes, explain: _____	OAR 855-019-0100
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Has this pharmacy been granted any exceptions by the Board or DEA to any laws or rules? If yes, please attach a copy. This includes written approval for the Technician Checking Validation Program. *Please note that rule changes may invalidate an old waiver.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Are any prescriptions dispensed from this pharmacy to outpatients such as take-home prescriptions for discharged inpatients, relabeled medications for take home, (i.e. topicals, inhalers), ER patients (ER pre-packs), employees, hospice patients, etc.? (Note: If you answer yes, this pharmacy also needs to be registered as a retail drug outlet and you will need to complete the retail pharmacy inspection section <b>at the end of this form</b> ). Retail Drug Outlet Cert# _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Are pharmacists, technicians, & interns <b>aware that they must report</b> arrests, convictions, <b>and</b> suspected <b>and</b> known violations to the Board within 10 days as required? 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"/>	8. Is page 3 completed? Please note that certified pharmacy technicians are required to be licensed by the Board and 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.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. 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"/>	10. Are your drug outlet procedures current, compliant with Oregon laws and rules, and <u>do they reflect the practice at your outlet?</u> Date you reviewed procedures with staff: _____	OAR 855-041-1040
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Is pharmacy clean (refrigerator, sink ...)?	OAR 855-041-1015(2) OAR 855-041-6150(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Do technicians know what duties/tasks they may perform and do you have documentation of their training?	OAR 855-025-0025(5) OAR 855-025-0025(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Does a pharmacist verify all work performed by technicians and document this verification?	OAR 855-025-0025(4)

**Scheduled II-V 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. Did you take your Annual Controlled Substance (CII-V) Inventory on one day, within 12 months (365 days) of your last inventory? Date of your last CII-CV Inventory: ____/____/____. (Remember to include floor stock, ER pre-packs and crash carts) Note: Inventory may NOT be taken throughout the day (24 hour pharmacies need to indicate the time frame in which the inventory was completed).	OAR 855-080-0070
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15. Is your annual CII inventory filed separately from your CIII-CV inventory and are your CII invoices and prescriptions filed separately from other prescriptions and invoices?	21 CFR 1304.04
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16. Is there a procedure and record that accounts for all controlled substances that includes: identity of patient, dose administered, person administering the drug, verification and documentation of any wasted drug including partial doses?	OAR 855-041-6600(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17. Can the pharmacy track every dose of controlled drugs (paper or electronic)? How? _____	OAR 855-041-6600(3) OAR 855-041-6600(4)

**Scheduled II Drugs**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18. 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"/>	19. Are CII's 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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20. Is there a perpetual CII inventory system for drugs received, stored, and distributed by the pharmacy that is reconciled with an actual inventory at least <u>monthly</u> ? Where is this kept? _____	OAR 855-041-6610(1)(a)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21. Is schedule II floor stock controlled with a perpetual inventory system?	OAR 855-041-6610(1)(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22. Is there a random reconciliation of a sample of perpetual CII inventory sheets conducted at least <u>quarterly</u> that includes documentation of dose-by-dose administration? (example: compare Pyxis report to administration records.) Where is this kept? _____	OAR 855-041-6610(1)(c)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23. Are schedule II drugs kept in a locked area/secured storage system?	OAR 855-041-6610(1)(d)

**Security, Drug Distribution and Control, Records**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24. 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"/>	25. When no pharmacist is present is the pharmacy department secured to prevent entry by unauthorized personnel?	OAR 855-041-1020(3) OAR 855-019-0200(7)(c) OAR 855-041-6150(7)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26. Are keys and/or key cards which are used for access to the pharmacy made or distributed by anyone other than a pharmacist? (Note: This is not permitted; for example, a security department may not make/issue a key card for access to the pharmacy unless there is a deadbolt in which pharmacists have the only keys.)	

**Labeling**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27. Does the pharmacy identify and document the pharmacist who verifies a drug?	OAR 855-041-6270(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28. Is pre-packed drug/hospital unit-dosed drug labeled to contain: <ul style="list-style-type: none"> <li>• Name, strength, and expiration date of drug, and</li> <li>• Drug manufacturer and lot number or an internal pharmacy code that references these items</li> </ul>	OAR 855-041-6270(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29. Do you add a bar code or an electronic label to any drug? If yes, the pharmacist must verify and document the accuracy prior to distribution.	OAR 855-041-6270(6)

**Emergency Kit and Code Cart**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30. Does a pharmacist verify and document the contents of each kit?	OAR 855-041-6420(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31. Does the kit use a tamper-evident system and is it stored to prevent unauthorized access?	OAR 855-041-6420(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32. Is kit/cart labeled to indicate it is a drug supply for emergency use and does the label/list contain the name, strength, and quantity of drugs in the kit/cart? Note: The label/list must be on the exterior of the cart (not the drawer inside the cart).	OAR 855-041-6420(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33. Is the kit/cart labeled with appropriate expiration date?	OAR 855-041-6420(7)

**In-Patient Drug Profile**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34. Does the patient profile contain: <ul style="list-style-type: none"> <li>• Patient age, height, weight, chronic disease states, allergies, identification of RPH responsible for entry/order verification, drug name, strength, dosage form, route and directions for administration; and if applicable, drug therapy start and end date.</li> </ul>	OAR 855-041-6150(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35. Does the pharmacist enter an order and perform a DUR before the medication is released for administration?	OAR 855-041-6500(2) OAR 855-041-6510(2)

**Automated Distribution Cabinets (ADC), Floor Stock, Non-emergency Trays and Kits**

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"/>	36. Does the outlet have required P&Ps for inspection of drug storage areas (at least every 2 months) that includes verification and documentation of proper storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and integrity of emergency drug supply?	OAR 855-041-6200(3)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	37. Do labels applied to a drug in a secondary or remote storage area by a nurse/physician contain the required information (patient name/identifier, quantity and concentration of drug added to primary IV solution, date/time of addition, nurse/physician initials)?	OAR 855-041-6270(8)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38. Does a pharmacist verify name, strength, and accuracy of ADC replenishment stock?	OAR 855-041-6540(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39. Is a nurse permitted to place a drug in an ADC? Note: A nurse is not permitted to return a drug to an ADC after removing it, except to place in a return bin.	OAR 855-041-6540(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	40. Is a count confirmation performed at all times a controlled substance is accessed (loading, unloading, removing, and inventorying) in an ADC? Is discrepancy documented and reconciled?	OAR 855-041-6540(8)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41. Is floor-stock stored in a secured area only accessible to pharmacy-authorized personnel?	OAR 855-041-6560(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42. Does a pharmacist verify the accuracy and secure the contents of each tray or kit prepared in the pharmacy?	OAR 855-041-6570(2)

**Absence of a Pharmacist**

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"/>	43. Does the hospital use a night cabinet?	OAR 855-041-6305
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44. Is access to night cabinet limited to one authorized registered nurse on a shift? Where is the authorized nurse's identity designated in writing with documentation of the nurse(s) training in the proper procedure for access, removal of drugs, and recordkeeping: _____	OAR 855-04-6305(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45. Does the nurse initial and leave a copy of practitioner's order? Does the pharmacist verify the order for accuracy and initial order?	OAR 855-041-6305(1)(c)(B)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46. Are only prepackaged/unit of use drugs in the cabinet?	OAR 855-041-6305(2)(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47. Are controlled substances in the night cabinet accounted for using a reconciled perpetual inventory and is an audit conducted at least once per month?	OAR 855-041-6305(2)(e-f)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	48. Is after hours access to the pharmacy limited to one authorized registered nurse on a shift? Where is authorized nurse's identity designated in writing with documentation of the nurse(s) training in the proper procedure for access, removal of drugs, and recordkeeping: _____	OAR 855-041-6310
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	49. When a drug is removed, is a copy of the practitioner's order left with either the container from which the drug was removed or with an identical unit-dose for the pharmacist to verify the accuracy?	OAR 855-041-6310(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	50. Is there a record of the name and hospital location of the patient, name and strength of drug distributed, units used, date and time of distribution, and the initials of nurse supervisor distributing the drug and the pharmacist who confirmed the accuracy of the transaction?	OAR 855-041-6310(2)

**Technician Checking Validation Program**

N/A

<b>Yes</b>	<b>No</b>	<b>N/A</b>		<b>Rule Reference</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51. Is the PIC documenting any error or irregularity?	OAR 855-041-5120
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	52. Does technician training include a minimum of 1 year drug distribution experience, training, and Initial Validation Process?	OAR 855-041-5130(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53. Does training session include trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning? Does the trainee perform initial check with a pharmacist verifying all doses, trainee completing validation process with a pharmacist verifying all doses, and introduction of artificial errors?	OAR 855-041-5130(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	54. Are errors found during training documented?	OAR 855-041-5130(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	55. Did trainee make more than 3 errors in 1500 doses for unit of use cart fill? (1500 total doses, divided among 5 separate training checks with the pharmacist introducing at least 3 errors in each training check.)	OAR 855-041-5140(1)(a)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56. Did trainee make more than 1 error in 500 doses for ADC or non-emergent tray and kits? (500 total doses, divided among 5 separate training checks with the pharmacist introducing at least 3 errors in each training check.)	OAR 855-041-5140(1)(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57. Are quality checks being performed on technician checker(s) at least monthly? Where is the documentation being kept? _____	OAR 855-041-5140(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	58. Did checker make more than 1 error in any quality check? (If yes, did they stop working as a checker until criteria met?)	OAR 855-041-5140(2)

**Compounding and Sterile Parenteral Products**

OAR 855-045-0210

Compounding is separated into five categories.

- Category 1: Nonsterile- simple: the mixing of two or more commercial products. This is not considered to be compounding. (i.e. miracle/magic mouth wash, mixing two commercial creams together, antabuse suspension pursuant to a prescription)
- Category 2: Nonsterile- complex: compounding with bulk drug substances or when calculations are required. (i.e. making non-patient specific capsules, tablets, suppositories, antabuse suspension in anticipation of multiple prescriptions)
- Category 3: Sterile- low-risk. No more than 3 sterile products, no more than two additives in an IV solution (i.e. antibiotic in an IV solution)
- Category 4: Sterile- medium-risk. Multiple medications (2 or more) in an IV (i.e. TPNs - Total parenteral nutrition solutions with multiple additives)
- Category 5: Sterile- high-risk, using non-sterile ingredients or non-sterile devices (i.e. non-sterile Morphine powder used to prepare solutions for IV pump infusions)

Immediate-use: generally considered low-risk if all criteria are met as outlined in OAR 855-045-0250(4): administration must begin within 1 hour of preparation

Same-day –use: generally considered low or medium-risk if all criteria are met as outlined in OAR 855-045-0250(5): the administration of the preparation shall commence within 24 hours from the time of preparation.

**General Information**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59. Do you compound Category 2, 3, 4, 5 products? If yes, list which categories: _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60. Do you compound immediate-use or same-day products? If yes, which category? _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	61. Do you participate in any Shared Service Agreements with another pharmacy or practitioner? <u>If yes, please attach a copy of the required Board approved Shared Service Agreement.</u>	OAR 855-045-0200(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	62. Do you provide sample(s) of compounded products to prescriber(s) or compound products to be sold OTC? <b>If yes, attach a copy of your FDA and Board of Pharmacy manufacturing registrations.</b>	OAR 855-060-0001
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	63. Are only products that are not commercially available compounded? Note: You may compound commercial products that are temporarily in short supply or otherwise unavailable with Board approval.	OAR 855-045-0230(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	64. Do you have policies and procedures that contain protocols for initial <b>and ongoing</b> training and testing of all personnel pursuant to their level of compounding? Where is the documentation? _____	OAR 855-045-0220(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	65. Are policies and procedures relevant to your practice setting reviewed annually and complied with by all staff?	OAR 855-045-0230(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	66. Do you have a QA plan and supporting documentation? What procedures are you performing to ensure the integrity of your products? _____	OAR 855-045-0230(2)(g)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	67. Does your QA plan include record keeping requirements for cleaning, testing and calibration of all equipment and devices? Where are your records kept? _____	OAR 855-045-0230(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	68. Do you have procedures for establishing a BUD for your products?	OAR 855-045-0230(2)(k)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	69. Are bulk chemical containers labeled with <b>the date pharmacy obtained the chemical and an expiration date of not more than 5 years from the date container was opened?</b>	OAR 855-045-0230(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	70. Are compounding logs, formula worksheets and documentation of the preparation, verification, dispensing or transfer of compounded products stored in an organized manner? Note location of the records _____	OAR 855-045-0270(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	71. Do formula worksheets include all of the following: (Note- this is not required for patient specific IVs) <ul style="list-style-type: none"> <li>● Drug name and strength</li> <li>● Quantity prepared</li> <li>● Date prepared</li> <li>● Pharmacy unique lot number</li> <li>● Manufacturers' lot numbers and expiration dates of all ingredients in compounded product</li> <li>● BUD</li> <li>● Name of verifying pharmacist</li> </ul>	OAR 855-045-0270(2)

			71 <i>continued</i> <ul style="list-style-type: none"> <li>● Names of all technicians involved in the process</li> <li>● Copy of the label used for the compounded product</li> <li>● Mixing instructions</li> <li>● Physical evidence of the proper weight of each dry chemical or drug used</li> <li>● Pharmacist verification that the correct formula and the correct weights or volumes of chemical or drugs were used</li> <li>● Certification of completion of any additional testing that might be required in your policies and procedures</li> </ul>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	72. Is the pharmacist confirming the drug, dose, and dosage form are appropriate and the calculations, drug, and quantity of each drug are correct?	OAR 855-045-0220(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	73. Is there documentation of verification that includes the initials of the pharmacist responsible for the review and accuracy of compounded products?	OAR 855-045-0220(5)(b) OAR 855-045-0240(1)(E)

**Nonsterile (NS)**       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"/>	74. Is each product labeled with its physical description for compounds sold on a prescription?	OAR 855-045-0220(5) OAR 855-041-1130(1)(k)

**Compounded Sterile Products (CSP)**       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"/>	75. Are CSP prepared in an ISO 5 certified or better Biological Safety Cabinet, or a Compounding Aseptic Isolator, or a Laminar Airflow Hood?	OAR 855-045-0260(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	76. Do you test personnel in aseptic manipulative skills? How often (every 6 months - category 5; every 12 months - Category 3-4)? _____	OAR 855-045-0220(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Where are training records kept? _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	77. Do you access single dose vials in <u>less</u> than an ISO 5 environment? BUD may not exceed 1 hour from time of initial entry.	OAR 855-045-0250(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	78. Do you access single dose vials in an ISO 5 environment? BUD may not exceed 24 hours from time of initial entry.	OAR 855-045-0250(6)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	79. Do you label multi-dose vials with a BUD of 1 month or less from time of initial entry?	OAR 855-045-0250(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	80. Are all ISO classified areas checked and certified at least every 6 months and whenever LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered? Where are the records kept? _____	OAR 855-045-0260(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	81. Do your compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks?	OAR 855-045-0230(2)(e)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	82. Do you have documentation of environmental monitoring to show that the compounding environment is properly maintained? Where is is located? _____	OAR 855-045-0230(3)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	83. Does the admixture label contain? <ul style="list-style-type: none"> <li>● Rate of infusion (if applicable)</li> <li>● BUD</li> <li>● Storage requirements or special conditions</li> <li>● Name, quantity and concentration of all ingredients contained in the products, <b>including primary solution</b></li> <li>● Hand written initial of the verifying pharmacist</li> <li>● <b>Identification of the pharmacy</b>, patient name and location, auxiliary labels as needed and date mixed</li> <li>● The expiration date</li> <li>● The scheduled time for administration</li> <li>● The name or initials of person performing admixture</li> </ul>	OAR 855-045-0240(1) OAR 855-041-6270(7)

**Category 3 - 5**       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"/>	84. Are surfaces and furniture in buffer room/anteroom nonporous, smooth, non-shedding, impermeable, cleanable and resistant to disinfectants?	OAR 855-045-0260(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	85. In ISO 7 and 8 areas, are floors and work surface areas cleaned at least daily and are walls, ceilings, and empty shelving cleaned at least monthly either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant?	OAR 855-045-0260(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	86. If <b>Category 3</b> CSP are prepared in an ISO 5 environment without a separate buffer room, is there a partitioned area to create a buffer zone (i.e. line of demarcation)?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	87. Are <b>Category 3</b> manipulations limited to the following? <ul style="list-style-type: none"> <li>● No more than 3 sterile products and no more than 2 entries into each sterile container</li> <li>● Aseptically opening ampoules</li> <li>● Penetrating sterile stoppers on vials with sterile needles and syringes</li> <li>● Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products and sterile containers for storage &amp; dispensing</li> </ul>	OAR 855-045-0250
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	88. Are <b>Category 3-5</b> CSP's properly stored and BUDs properly labeled?	OAR 855-045-0250
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	89. Does the buffer room contain a sink or drain (not permitted for Category 5)?	OAR 855-045-0260(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	90. Do you have a positive pressure clean air room for preparing <b>Category 4 and Category 5</b> compounds which has an ISO 8 certified or better anteroom, ISO 7 or better buffer room which contains a certified ISO 5 or better compounding cabinet or equivalent environment?	OAR 855-045-0260(3) OAR 855-045-0260(4)

**Immediate Use**       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"/>	91. Does the administration of <b>immediate-use</b> compounded preparations begin within 1 hour of the time of preparation?	OAR 855-045-0250(4)

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	92. Are <b>immediate-use</b> compounds prepared by someone other than the person who will administer the drug? If yes, labeling must include patient name, name and quantity of ingredients, name of person who prepared compound, and exact one hour BUD.	OAR 855-045-0250(4)

**Same Day Use**       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"/>	93. Does the administration of <b>same-day use</b> compounded preparations begin within 24 hours of the time of preparation?	OAR 855-045-0250(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	94. Does the environment in which the <b>same-day use</b> compound is prepared meet or exceed the following requirements: <ul style="list-style-type: none"> <li>● The mixing cabinet (ISO 5 or better) is located in an area that restricts airflow to prevent drafts and reduce particle counts;</li> <li>● There is a partitioned area around the mixing cabinet, which is at least the width of the hood in front of the mixing cabinet;</li> <li>● The buffer zone is clearly identified to prevent cardboard or outer packing material from intruding;</li> <li>● The environment is cleaned daily.</li> </ul>	OAR 855-045-0250(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	95. Do batch preparations of <b>same-day use</b> compounded preparations exceed 8 CSPs (not permitted)?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	96. Does the preparer of the <b>same-day use</b> compounded preparations complete the preparation without interruption and with no direct contact contamination?	

**If you also have a Retail Registration for your Hospital Pharmacy complete the following:**

2014 PHARMACIST-IN-CHARGE  
**INSPECTION REPORT FOR RETAIL DRUG OUTLETS LOCATED WITHIN HOSPITAL PHARMACIES**  
 OREGON BOARD OF PHARMACY  
 TEL: 971-673-0001 FAX: 971-673-0002

PLEASE NOTE: COMPLETE THE FOLLOWING *IF YOU HAVE A RETAIL DRUG OUTLET REGISTRATION* FOR AN OUTPATIENT PHARMACY LOCATED WITHIN THE HOSPITAL PHARMACY DEPARTMENT. DO NOT USE THIS FORM IF YOU HAVE A RETAIL DRUG OUTLET LOCATED IN ANY AREA THAT IS OUTSIDE THE PHYSICAL CONFINES OF THE HOSPITAL PHARMACY DEPARTMENT. IF THE PHARMACY PREPARES ER DISCHARGE MEDICATIONS, RELABELS PATIENT MEDICATIONS TO TAKE HOME, FILLS EMPLOYEE PRESCRIPTIONS OR DISPENSES DISCHARGE MEDICATIONS TO PATIENTS, THE PHARMACY MUST HAVE A RETAIL REGISTRATION.

Pharmacy: \_\_\_\_\_ Tel: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 DEA #: \_\_\_\_\_ Exp: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ Retail Drug Outlet Cert #: \_\_\_\_\_  
 Hours of operation: \_\_\_\_\_

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	97. Has this pharmacy been granted any exceptions by the Board or DEA to any laws or rules? If yes, please attach a copy to this report.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	98. Please indicate the types of prescriptions dispensed from this retail drug outlet: <input type="checkbox"/> Take-home prescriptions for discharged inpatients. <input type="checkbox"/> Take-home prescriptions for emergency room patients. <input type="checkbox"/> Employee prescriptions. <input type="checkbox"/> Staff physicians (non-employees). <input type="checkbox"/> Prescriptions for hospice patients. <input type="checkbox"/> Walk-in customer prescriptions (emergency only). <input type="checkbox"/> Other (please specify): _____	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	99. Are your written drug outlet procedures, technician procedures, and sterile parenteral procedures developed for your institutional drug outlet applicable to your retail drug outlet? (If yes, it is not necessary to develop additional procedures for your retail outlet).	OAR 855-041-1040

**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"/>	100. Do your CII-V hardcopy prescriptions contain the following information? (Note: DEA requires this information to be on all hardcopy prescriptions (not just in computer), discharge prescriptions, employee prescriptions and emergency night packs).  <ul style="list-style-type: none"> <li>● Date when filled;</li> <li>● Patient's name and address;</li> <li>● Prescriber's name, DEA number and address; and</li> <li>● Name of drug, strength, directions for use and quantity; when a generic drug is used, the manufacturer or distributor must be identified.</li> </ul>	21 CFR 1306.05

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	101. Are all faxed CII prescriptions for patients in Long-term care facilities, Community-based care facilities, Hospice or Home Infusion patients manually signed by the prescriber PRIOR to dispensing? Are CII prescriptions faxed to the pharmacy for hospice patients identified as such by documenting "hospice patient" on the prescription?	21 CFR 1306.11
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	102. Are all partially dispensed CII prescriptions (Note: valid for up to a maximum of 60 days from the date written) documented with the following? <ul style="list-style-type: none"> <li>● "LTCF patient" or "terminally ill";</li> <li>● Date of partial filling;</li> <li>● Quantity dispensed;</li> <li>● Remaining quantity authorized to be dispensed; and</li> <li>● Identification of the dispensing pharmacist for each partial fill.</li> </ul>	21 CFR 1306.13

**Outpatient Medications (including ER pre-packs)**

<u>Yes</u>	<u>No</u>	<u>N/A</u>		<u>Rule Reference</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	103. Are all emergency outpatient prepackaged prescriptions <u>verified by a pharmacist within 24 hours</u> ? If the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing. This includes verifying: <ul style="list-style-type: none"> <li>● Name, strength, quantity of medication dispensed, directions for use and performing a DUR</li> </ul>	OAR 855-041-6410
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	104. Are all outpatient prescriptions labeled with the name, address, and telephone number of the hospital, name of drug, strength, number of units, identifier of the manufacturer or distributor for generics without brand names, accessory cautionary information, <u>product identification label</u> and an expiration date? Are you educating the patient on how to use product identification label?	OAR 855-041-1130
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	105. Is the quantity of emergency outpatient medications limited by policy and procedures? May not exceed 48 hour supply with limited exceptions permitted by Board rule.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	106. Is <u>written</u> drug information provided to the patient?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	107. Does the nurse supervisor label the container for emergency outpatient prescriptions with the following: name of patient, directions for use, date, identifying number, name of prescribing practitioner, and the initials of the nurse supervisor?	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	108. Is the pharmacist/intern documenting counseling on new prescriptions and refills that require counseling at the time of interaction? (pharmacist/intern must specify if counseling is provided or declined.)	OAR 855-019-0230
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	109. Please explain the method used in your pharmacy to identify prescriptions that require counseling: _____ _____	

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.

**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: \_\_\_\_\_