



Oregon

John A. Kitzhaber, MD, Governor

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READ THIS PAGE CAREFULLY

2012

**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 2/1/2012 (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 WILL BE AVAILABLE AT WWW.PHARMACY.STATE.OR.US FROM 1/5/2012 THROUGH 5/31/2012.

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. Attach additional sheets if necessary.

NAME	CPT LICENSE NUMBER	CPT LICENSE EXPIRATION DATE	PTCB/ICPT CERTIFICATION NUMBER	PTCB/ICPT CERTIFICATION 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-				

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 hospital pharmacies MUST complete and sign this inspection report and have it available for inspection within 15 days of becoming PIC and by 2/1/2012 (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. #: _____

Chief Pharmacy Officer Name & Lic. #: _____

Pharmacy: _____ Telephone: _____ Fax: _____

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

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

Hours of operation: _____

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 Oregon Laws & Rules and Newsletters: _____

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: _____

Inspector Signature: _____
Date: _____ Deficiency Notice: _____
Comments: _____

Yes No NA General Requirements

1. Is this hospital accredited? If yes, by whom: _____ Date of their last inspection: __/__/__
2. 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? _____
3. 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.
4. 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?
5. OAR 855-041-6150(2) Does the hospital have more than one pharmacy (i.e. Legacy, Providence)? If yes, who is the Chief Pharmacy Officer? _____
6. OAR 855-019-0100 Does this pharmacy utilize any off-site personnel to verify order information, perform DURs, or ...? 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 you purchasing medication from another pharmacy? (If yes, have you verified the pharmacy is licensed in Oregon?)
9. Has this pharmacy been granted any exceptions by the Board or DEA to any laws or rules? If yes, please attach a copy. Please note that rule changes may invalidate an old waiver.
10. Do you compound Category 2 through 5 products?
If yes, download and complete the additional compounding inspection form in addition to this form.
11. 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 form). Retail Drug Outlet Cert# _____
12. 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 policy number and 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 registered and adequately trained to perform their duties.

- | <u>Yes</u> | <u>No</u> | <u>NA</u> | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 13. OAR 855-041-0040(1-2) & OAR 855-041-6150(6) 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; <u>E AND/OR HC</u> Name of reference: _____ • Current Oregon Revised Statutes (Chapters 689 and 475) and Current Oregon Administrative Rules (Chapter 855); <u>E AND/OR HC</u> • Board of Pharmacy quarterly newsletters (for the past 3 years). <u>E AND/OR HC</u> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 14. OAR 855-041-0025(2) & OAR 855-041-6150(5) Does the pharmacy have adequate space and is it clean (refrigerator, sink, machines ...)? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 15. OAR 855-025-0025(3) Are your Pharmacists, interns and technicians <u>clearly identified</u> as such to the public? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 16. OAR 855-025-0025(4) Does a pharmacist verify all work performed by technicians and document this verification? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 17. OAR 855-025-0025(5) and (6) Do technicians know what duties/tasks they may perform and do you have documentation of their training? |

Security, Drug Distribution and Control, Records

- | | | | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 18. OAR 855-041-0026(3), 855-019-0200(7)(c) & 855-041-6150(7) When no pharmacist is present is the pharmacy department secured to prevent entry by unauthorized personnel?
Note: Keys and/or key cards which are used for access to the pharmacy may not be made or distributed by anyone other than a pharmacist? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 19. Are technicians ever working at the hospital when there is not a pharmacist? If yes, what duties do they perform: _____
Note: Technicians may not have access to the pharmacy (including records) without a pharmacist present. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 20. OAR 855-041-6200(3) Has the CPO (PIC if outlet not required to have CPO) established P&Ps for: <ul style="list-style-type: none"> • Inspection of drug storage areas (at least every 2 months) that includes verification of proper storage, documentation of distribution and administration of controlled substances, absence of outdated drugs, and integrity of emergency drug supply. • Quality Assurance program that includes monitoring, evaluation, and assessment of data. Does the CPO participate in this QA program? • Recall procedure |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 21. OAR 855-041-6200(4) Does the CPO maintain an emergency and disaster plan for pharmacy services, and participate in the plan? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 22. OAR 855-041-6220(1) Are all records stored onsite for at least one year? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 23. OAR 855-041-6220(1) Are off-site records retrievable within 3 business days? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 24. OAR 855-041-6240(1) Is a drug only administered on an order initiated by a licensed practitioner or an authorized member of medical or house staff. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 25. OAR 855-041-6240(3) Are patient's permitted to self-administer a drug?
If yes, <ul style="list-style-type: none"> • Has this been approved by the treating or ordering practitioner? • Who teaches the patient in the proper self-administration of the drug? _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 26. OAR 855-041-0036 Have you quarantined all out-dated medications (both prescription and OTC)?
Are controlled substances secured?
Where are they stored? _____ |

- | <u>Yes</u> | <u>No</u> | <u>NA</u> | <u>Labeling</u> |
|--|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 27. OAR 855-041-6270(1) Does the pharmacy identify and document the pharmacist who verifies a drug? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 28. OAR 855-041-6270(2) Is pre-packed drug/hospital unit-dosed drug labeled to contain: <ul style="list-style-type: none"> • Name, strength, and expiration date of drug, and • Drug manufacturer and lot number or an internal pharmacy code that references these items |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 29. OAR 855-041-6270(3) Are drugs dispensed to in-patients in other than unit-dose or manufacturer's unit-of-use packaging? If yes, does label include name and location of patient? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 30. OAR 855-041-6270(4-5) Do labels for outpatient prescriptions meet requirements? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 31. OAR 855-041-6270(6) 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 32. OAR 855-041-6270(7) When a drug is added to a parenteral solution does the admixture label contain: <ol style="list-style-type: none"> a. Name, quantity and concentration of drug added to the primary solution; b. The date and time of addition; c. The expiration date; d. The scheduled time for administration; e. The infusion rate, when applicable; f. The name or initials of person performing admixture; g. The identification of the pharmacy where the admixture was performed; and h. The name or initials of the verifying pharmacist. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 33. OAR 855-041-6270(8) 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)? |
| <u>Schedule II-V Controlled Substances</u> | | | |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 34. 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: ___/___/___. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 35. 21 CFR 1304.11 Did you note on the inventory if it was taken before opening or after closing? Inventory may NOT be taken throughout the day (24 hour pharmacies need to indicate the time frame in which the inventory was completed). |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 36. 21 CFR 1304.04 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 37. OAR 855-041-6600(1) 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 38. OAR 855-041-6600(2) Are bulk controlled substances stored in separately locked and securely affixed compartments? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 39. OAR 855-041-6600(3) Does the pharmacy obtain a delivery receipt for all controlled drugs supplied as floor stock that includes the date, drug name and strength, quantity, and signatures of distributing RPH and receiving nurse? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 40. OAR 855-041-6600(4) Are you keeping a record of each administration of a controlled drug from floor stock that is returned to the pharmacy monthly? <ul style="list-style-type: none"> • Is this record initialed and filed by date of issue; are records of additions/removals reconciled, administration records audited, is there periodic verification that the doses documented on administration records are reflected in the medical record. |

- | Yes | No | NA | <u>Schedule II Drugs</u> |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 41. 21 CFR 1305.13(e) Are <u>all lines</u> of DEA 222 order forms filled out completely with receiving dates and quantity received? (Enter '0' if none received and date line) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 42. OAR 855-041-6610(1)(a) 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> ? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 43. OAR 855-041-6610(1)(b) Is schedule II floor stock controlled with a perpetual inventory system? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 44. OAR 855-041-6610(1)(c) 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 45. OAR 855-041-6610(1)(d) Are schedule II drugs kept in a locked area/secured storage system that tracks the identity of the person accessing the medication? |

Controlled Substance Electronic Safe System

- | | | | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 46. Does the pharmacy utilize an electronic safe system? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 47. OAR 855-041-6620(1) Do you have policies that include: training, access, downtime procedures? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 48. OAR 855-041-6620(2) Does the system electronically record all transactions: who accessed, why accessed, name of patient for whom drug ordered (when applicable)...? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 48. OAR 855-041-6620(5) Does anyone besides an intern, technician, or pharmacist access the safe? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 49. 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 50. 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? (<u>The pharmacist</u> , not the patient, must specify if counseling is provided or declined at the time of the interaction.) |

Emergency Kit and Code Cart

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 51. OAR 855-041-6420(2) Does a pharmacist verify and document the contents of each kit? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 52. OAR 855-041-6420(3) Is the list and quantity of drugs included in the kit reviewed annually? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 53. OAR 855-041-6420(4) Does the kit use a tamper-evident system and is it stored to prevent unauthorized access? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 54. OAR 855-041-6420(6) Is kit/cart labeled to indicate it is a drug supply for emergency use and does the label contain the name, strength, and quantity of drugs in the kit/cart.
Note: The label must be on the <u>exterior</u> of the cart. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 55. OAR 855-041-6420(7) Is the kit/cart labeled with appropriate expiration date? |

Practitioner's Drug Order

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 56. OAR 855-041-6500(2) & OAR 855-019-0220 Is a pharmacist (not just computer) performing and documenting drug order review and drug utilization review before an initial dose is dispensed? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 57. OAR 855-041-6500(3) Do drug orders contain required information? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 58. OAR 855-041-6500(4) Does the hospital receive verbal drug orders and are these orders initialed or signed by the prescribing practitioner as soon as possible? |

In-Patient Drug Profile

- | | | | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 59. OAR 855-041-6150(1) Does the patient profile contain: <ul style="list-style-type: none"> • 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 60. OAR 855-041-6150(2) Does the pharmacist enter an order and perform a DUR before being released for access by a nurse? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 61. OAR 855-041-6150(3) Does the pharmacist monitor the appropriateness of each patient's drug utilization throughout the patient's stay in the hospital? |

<u>Yes</u>	<u>No</u>	<u>NA</u>	
		<input type="checkbox"/>	<u>Automated Distribution Cabinets, Floor Stock, Non-emergency Trays and Kits</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	62. OAR 855-041-6540(2) Do you have P&P for ADC that includes: security, accuracy, downtime procedures, and training of personnel granted access to the ADC.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	63. OAR 855-041-6540(3) Are all events involving contents of ADC recorded (i.e. which ADC accessed, who accessed, type of transaction, date/time, drug accessed)?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	64. OAR 855-041-6540(5) Does a pharmacist verify name, strength, and accuracy of ADC replenishment stock?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	65. OAR 855-041-6540(7) Is a nurse permitted to place a drug in an ADC? Note: A nurse is not permitted to stock an ADC and, with limited exceptions, may not return a drug to an ADC.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	66. OAR 855-041-6540(8) Is a count confirmation performed at all times a controlled substance is accessed (loading, unloading, removing, and inventorying) in an ADC? Discrepancy documented?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	67. OAR 855-041-6560(3) Does the pharmacy have a list of floor stock drugs that identifies drugs (including quantity) for each area where floor stock is kept?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	68. OAR 855-041-6560(4) Is floor-stock stored in a secured area only accessible to pharmacy-authorized personnel?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	69. OAR 855-041-6570(2) Does a pharmacist verify the accuracy and secure the contents of each tray or kit prepared in the pharmacy?
		<input type="checkbox"/>	<u>Investigational Drugs</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	70. OAR 855-041-6260 Does the hospital use investigational drugs?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	71. OAR 855-041-6260(2) Do you have information concerning dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions and symptoms of toxicity available in the pharmacy?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	72. OAR 855-041-6260(4) Does each order for investigational drugs include the appropriate protocol number?
		<input type="checkbox"/>	<u>Absence of a Pharmacist</u>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	73. OAR 855-041-6305 Does the hospital use a night cabinet?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	74. OAR 855-041-6305(1) Is access to night cabinet 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:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	75. <u>OAR 855-041-6305(1)(c)(B)</u> Does the nurse initial and leave a copy of practitioner's order in the night cabinet? Does the pharmacist verify order for accuracy and initial order?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	76. OAR 855-041-6305(2)(b) Are only prepackaged drugs in the cabinet?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	77. OAR 855-041-6305(2)(e-f) Are controlled substances in the night cabinet accounted for using a reconciled perpetual inventory and is an audit conducted at least once per month?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	78. OAR 855-041-6310 Is afterhours access to the pharmacy permitted?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	79. OAR 855-041-6310 Is after hour's 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:
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	80. OAR 855-041-6310(2) 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?
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	81. OAR 855-041-6310(2) 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?

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

2012 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: _____

- | <u>Yes</u> | <u>No</u> | <u>NA</u> | |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 82. 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"/> | 83. Please indicate the types of prescriptions dispensed from this retail drug outlet:
Take-home prescriptions for discharged inpatients.
Take-home prescriptions for emergency room patients.
Employee prescriptions.
Staff physicians (non-employees).
Prescriptions for hospice patients.
Walk-in customer prescriptions (emergency only).
Other (please specify): _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 84. Does your retail pharmacy sell legend drugs or controlled substances to practitioners intended for office use? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 85. OAR 855-041-0060(7) 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). |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Emergency Outpatient Medications</u>
86. OAR 855-041-06410. Are all emergency outpatient prepackaged prescriptions <u>verified by a pharmacist</u> ? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 87. Are the emergency outpatient prescriptions labeled with the name, address, and telephone number of the hospital, name of drug, strength, number of units, manufacturer or distributor for generics without brand names, accessory cautionary information, product identification label OAR 855-041-0065(6)(k) and an expiration date? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 88. Is the quantity of emergency outpatient medications limited by policy and procedures? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 89. Is <u>written</u> drug information provided by pharmacy? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 90. Are the original written orders for emergency outpatient medications complete with name, strength, quantity of medication dispensed and directions for use? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 91. Does the original written order for controlled substance have the prescriber's signature and DEA number, facility address and the patient's address in accordance with federal regulations?
<u>Note:</u> This must be on the paper prescription not just in the computer. |

- | <u>Yes</u> | <u>No</u> | <u>No</u> | |
|--------------------------|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 92. Are the original written orders for emergency outpatient medications verified by a pharmacist, initialed, dated and filed separately from other prescriptions, and in accordance to CFR regulations for three years? Where are they filed?
<hr/> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 93. 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"/> | 94. OAR 855-041-0065(6) Do your labels have the <u>physical description</u> of the medication and the <u>imprint code</u> ? (Note: Drugs dispensed in <u>manufacturer's unit dose or manufacturer's unit of use packaging</u> is exempt from this rule). |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Minimum Equipment</u>
95. ORS 689.515(4) Do you have a sign easily seen by patrons at the counter stating, "THIS PHARMACY MAY BE ABLE TO SUBSTITUTE A LESS EXPENSIVE DRUG WHICH IS THERAPEUTICALLY EQUIVALENT TO THE ONE PRESCRIBED BY YOUR DOCTOR UNLESS YOU DO NOT APPROVE"? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Controlled Substances</u>
96. 21 CFR 1306.05 Do your CII-V hardcopy prescriptions contain the following information? (Note: DEA requires this information to be on all hardcopy prescriptions, discharge prescriptions, employee prescriptions and emergency night packs).
<ul style="list-style-type: none"> • Date when filled; • Patient's name and address; • Prescriber's name, DEA number and address; and • Name of drug, strength and quantity; when a generic drug is used, the manufacturer or distributor must be identified. CII prescriptions |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 97. 21 CFR 1306.11 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? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 98. 21 CFR 1306.13 Are all partially dispensed CII prescriptions (Note: valid for up to a maximum of 60 days) documented with the following?
<ul style="list-style-type: none"> • "LTCF patient" or "terminally ill"; • Date of partial filling; • Quantity dispensed; • Remaining quantity authorized to be dispensed; and • Identification of the dispensing pharmacist. |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Telephone prescriptions</u>
99. OAR 855-041-0065 When a prescription for a retail patient is transmitted orally by phone is the receiving pharmacist's name or initials and the name of the person transmitting noted on the prescription? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Records</u>
100. OAR 855-041-0060 & OAR 855-041-0065(4) Are your prescription records on site and are they readily retrievable for 3 years from last activity? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | 101. OAR 855-019-0220 Do you maintain retail patient records/profiles and are they readily retrievable for 3 years? |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <u>Labeling</u>
102. ORS 689.765(6) & OAR 855-041-0065(6)(e) When you dispense a drug that does not have a brand name, does the manufacturer/distributor or NDC number appear on the prescription and the label? |

Yes No NA

 103. OAR 855-041-0065(6)(k) Do your out-patient labels meet the retail requirement to contain the physical description of the medication and the imprint code? (Note: Drugs dispensed in manufacturer's unit dose or manufacturer's units of use packaging (inhalers, creams, ophthalmic etc.) are exempt from this rule. This does not include unit dose medications repackaged by the pharmacy department.)
Are you educating the patient on how to use this feature? Please circle: YES NO

 104. Counseling
OAR 855-019-0230 and OAR 855-001-0040 Is the pharmacist/intern documenting whether counseling is provided or declined on new prescriptions and refills that require counseling? (Specify if counseling is provided or declined.)

 105. Please explain the method used in your pharmacy to identify prescriptions that require counseling:

 106. _____
OAR 855-019-0230 Do pharmacists provide verbal counseling on all new or discharge prescriptions dispensed from your retail drug outlet?
If not, please explain:

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: _____