2021
COMPOUNDING PHARMACY
SELF- INSPECTION FORM

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Oregon law holds the pharmacist-in-charge (PIC) 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 form by February 1, 2021 and within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.

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

Following your self-inspection and completion of the form, please review it with staff pharmacists, technicians and interns, correct any deficiencies noted, sign and date the form and file it in a readily retrievable manner. DO NOT SEND the form to the Board office. You are responsible for ensuring the completed form is available at the time of inspection.

Board inspections are not scheduled; therefore, it is common for the PIC to be absent or unavailable at the time of the inspection. 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) increases compliance and may improve the efficiency of the inspection.

Do not assume that you are in compliance. Take the time to personally verify that compliance exists. If you have any questions, please call (971) 673-0001 or email your questions to pharmacy.compliance@oregon.gov, "attention Compliance Officers", prior to completing the form. The Board does not provide individualized legal advice on how the law applies to practice in the field. Please review Board regulations. You may also want to contact a qualified attorney.

By answering the questions and referencing the appropriate laws and rules provided, you can determine whether the pharmacy is 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 may be offered at the Board office, check the board website www.oregon.gov/pharmacy for upcoming dates.

Please note: This is not a standalone self-inspection form. It is meant to be filled out in conjunction with another self-inspection form (i.e. retail, hospital, etc.).

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All PIC's must complete this form **in addition to the Retail, Home Infusion, or Long-Term Care inspection form** and have it available for inspection within 15 days of becoming PIC and by 2/1/2021 (as required by OAR 855-019-0300).

Date PIC Inspection was performed:_____

PIC Name: _____

PIC License #: _____

PIC email:_____

Pharmacy:_____

Telephone: _____

Fax: _____

Address:_____

City/State/Zip Code: _____

DEA #: _____ Exp Date:_____

Institutional Outlet Registration #: _____

Retail Outlet Registration #: _____

Nonprescription Drug Outlet Registration #: _____

Wholesale Outlet Registration #: _____ Manufacturer Registration #: _____

NPI #: _____

Date:_____

Compliance Officer:_____

RPh present for inspection: _____

Result:_____

Comments:_____

_____

Please list where the following items are located inside the pharmacy. Be as specific as possible; there can be many filing cabinets and binders.

Self-Inspection Forms/Reports for the last 3 years:_____

Compounding policies and procedures: Please attach the following P&Ps:

- Gowning and Garbing
- Cleaning
- Material Handling

Initial and ongoing personnel training documents:

- Aseptic Training:_____
- Media Fill / Gloved Fingertip competency documents:_____

Equipment:

- Hood Certification documentation:_____
- Cleaning documenation:_____
- Environmental monitoring documentation: _____
- Surface sampling documentation: _____

Records:

- Bulk Chemical Certificates of Analysis:_____
- Master Formulation Records:_____

Compounding Worksheets:_____

Compounding References (i.e. minimum required USP): _____

General Requirements

Yes	No	N/A			Rule Reference
☐	☐	☐	1	Does the pharmacy have access to current USP Chapters? Please list sterile and nonsterile compounding references available for staff use:	OAR 855-041-1035
☐	☐	☐	2	Does the pharmacy have a compounding accreditation? (Examples: VPP, PCAB, Joint Commission-Medication Compounding Certification) If yes, please specify: Date of the last accreditation: ***Please attach copy of accreditation report to this form.***	
			3	What type of compounding is performed? Please check all that apply: Nonsterile: ☐ HRT ☐ veterinary ☐ pain creams ☐ other: Sterile: ☐ IV's ☐ TPN ☐ eye drops ☐ pellets ☐ intrathecal ☐ lyophilization ☐ other:	
☐	☐	☐	4	Does the pharmacy use marketers or third-party companies to direct prescriptions to your pharmacy? Do prescriptions come directly to the pharmacy from the prescriber or are they routed through a third party?	ORS 475.188
☐	☐	☐	5	Does the pharmacy provide sample(s) of compounded products to prescriber(s) or compound products to be sold OTC? **If yes, include a copy of the pharmacy's FDA and Board of Pharmacy manufacturing registrations.**	OAR 855-060-0001 OAR 855-045-0210
☐ ☐	☐ ☐	☐ ☐	6	Does the pharmacy have policies and procedures for **initial and ongoing** training and testing of all personnel according to the type of compounding performed? Are the current policies and procedures compliant with all applicable USP Chapters and Oregon laws and rules? Note: All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties. Date of last review? _____	OAR 855-045-0220 OAR 855-045-0270

				Where are the records located?	
☐	☐	☐	7	Describe supervision of the compounding process in the pharmacy: Note: A technician may only compound under the direction, supervision and control of a pharmacist.	ORS 689.486(6)
☐	☐	☐	8	Does the pharmacy have standard operating policies and procedures for cleaning, testing and calibration of all equipment and devices? Where are the records located?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	9	Does the pharmacy have standard operating policies and procedures for establishing beyond-use dates (BUDs) for compounded products? Where are the records located?	OAR 855-045-0220
☐ ☐	☐ ☐	☐ ☐	10	Does the pharmacy handle hazardous drugs (HD's)? Is the pharmacy currently in compliance with USP 800? If so, where are the policies and procedures located? If not, what is the anticipated date of compliance? _____ Note: Handling HDs includes, but is not limited to, the receipt, storage receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.	OAR 855-045-0200 USP 800
☐	☐	☐	11	Does the pharmacy extend any BUD's beyond USP standards? If so, please describe your QA process to ensure sterility and/or stability are maintained: How often are samples sent for testing to an independent laboratory? Note: The products must be tested to account for the facility's unique processes.	OAR 855-045-0220

☐	☐	☐	12	Does the pharmacy batch compounded products? Where are the standard operating policies and procedures, including date of last documented review?	
☐ ☐	☐ ☐	☐ ☐	13	Do bulk drug substances have the required certificate of analysis? Are bulk drug substances acquired only from Board registered manufacturers or wholesalers?	e-CFR 503A Guidance Document 503B Guidance Document
☐	☐	☐	14	Is the pharmacy only using active pharmaceutical ingredients (API's) that are approved for use in humans? Note: The use of laboratory/research grade API's in compounded drugs for human use is prohibited.	e-CFRs
☐	☐	☐	15	Do the master formulation records include all required elements? To include, when appropriate: • The name, strength and dosage form of the preparation; • Physical description of the final preparation; • Ingredient identities and amounts; • Complete instructions for preparing the product, including equipment, supplies, and a description of the compounding steps; • Calculations needed to determine and verify quantities of components and doses of ingredients; • Compatibility and stability information, including references; • BUD assignment and storage requirements, including reference source; • Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration; • Quality control procedures and expected results; and • Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate. Be prepared to provide documentation at the time of inspection.	OAR 855-045-0270
☐	☐	☐	16	Do completed compounding records include all required elements? • Drug name, strength, and dosage form of the preparation; • Physical description of the final preparation, when dispensed to a patient for self-administration; • Master formulation record reference for the preparation, when applicable; • Quantity prepared; • Date and time prepared; • Pharmacy unique lot number; • Name, quantity, and manufacturers' lot numbers and expiration dates for all ingredients used to prepare compounded product, to include the name of the base, diluent, or primary excipient; • BUD; • Pharmacist documented verification of order accuracy; • Identity of all personnel involved in each step of the process;	OAR 855-045-0270

				• Documentation of the proper weight and measurement of each ingredient; • Pharmacist documented verification of compounded product accuracy including the correct formula, calculations, and the correct measurements and drugs used; • Total quantity compounded; • BUD assignment and storage requirements, including reference source, if differs from master formulation record; • Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver, or other person, to include corrective actions for any failure; • Records of dispensing or transfer of all compounded preparations; and • Any other information required by the pharmacy's policies and procedures.	
☐	☐	☐	17	How does the pharmacy retain the identity of all personnel involved in each step of the compounding process?	OAR 855-045-0270
			18	How does the pharmacy retain documentation of the proper weight/measurement of each ingredient of a compounded product?	OAR 855-045-0270
☐	☐	☐	19	Does the pharmacist document verification of compounded product accuracy, including correct formula, calculations, and use of correct drugs and measurements? Where are the records located?	OAR 855-045-0270
☐	☐	☐		Do you have documentation showing which pharmacist is responsible for the supervision of the compounding process?	ORS 689.486(6)
☐	☐	☐	20	Does the pharmacy have a standard operating policy for adverse event reporting and recall procedures, to include notification to the Board within 10 working days in the event of a patient-level recall of a compounded drug? Where are the policies and procedures and records located?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	21	Does the pharmacy have standard operating policies and procedures for continuous quality assurance/quality controls? Where are documentation records located?	OAR 855-045-0200 OAR 855-045-0270

Compounded Sterile Products (CSP's) ☐ N/A

Yes	No	N/A			Rule Reference
☐	☐	☐	22	Are CSP's prepared in an ISO 5 certified Primary Engineering Control (PEC)?	OAR 855-045-0200
☐	☐	☐	23	Are all ISO classified areas checked and certified per USP guidelines every 6 months and whenever a PEC is relocated or the physical structure of the buffer room or anteroom has been altered?	OAR 855-045-0220
☐	☐	☐	24	Is ISO determination taken under dynamic conditions while simulated compounding is occurring?	OAR 855-045-0200
☐	☐	☐	25	Are surfaces and equipment in buffer room and anteroom nonporous, smooth, non-shedding, impermeable, cleanable and resistant to disinfectants?	OAR 855-045-0200
☐	☐	☐	26	Does the pharmacy have standard operating policies and procedures that routinely monitor the compounding environment for microbial or fungal growth? Please attach policy and procedure addressing recommended action levels for microbial/fungal contamination.	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	27	Does the pharmacy perform surface sampling? How often? Incubation time? Incubation temperature?	OAR 855-045-0220 OAR 855-045-0270
			28	How often does the pharmacy test **all** compounding personnel, including verifying pharmacists, in aseptic manipulative skills, gowning and garbing and gloved fingertip sampling? Where are the records located? _____	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	29	Do compounding procedures include requirements for use of gowns, shoe covers, hair covers, sterile gloves and masks? Note: Makeup, jewelry, artificial nails/fingernail polish and exposed skin are not permitted.	OAR 855-045-0220 OAR 855-045-0200
☐	☐	☐	30	Does the pharmacy document environmental monitoring to ensure that the compounding environment is properly maintained, including temperature, humidity and pressure differential? Where are the records kept?	OAR 855-045-0270
☐	☐	☐	31	In addition to regular labeling requirements, does a CSP label include? • The generic or official name of each active ingredient; • The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation; • The dosage form and route of administration;	OAR 855-045-0240

				• Rate of infusion, for a sterile parenteral preparation; • The total quantity of the drug product; • A BUD, compliant with current USP standards; and • Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.	
			32	How does the pharmacy retain documentation of the pharmacist's verification of finished CSP's? Note: There is a 3-year requirement for record retention.	OAR 855-045-0270
☐	☐	☐	33	In ISO 7 and 8 areas, are floors and work surface areas cleaned daily and are walls, ceilings and shelving cleaned at least monthly? Where are the records kept?	OAR 855-045-0200
☐	☐	☐	34	Are staff, including nonpharmacy personnel, that perform cleaning and disinfecting in ISO classified areas trained in accordance with USP? Where are these training records kept? Who performs cleaning and disinfecting of ISO classified areas in your pharmacy?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	☐	35	What products are used to clean and disinfect? How often? What is the dwell time? Is the disinfectant a germicidal detergent? What sporicidal is used? How often? What is the dwell time?	OAR 855-045-0220 OAR 855-045-0270

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 staff and the answers marked on this form are true and correct.

PIC Signature:_____License #:_____Date:_____