2023
RETAIL DRUG OUTLET and INSTITUTIONAL DRUG OUTLET
COMPOUNDING PHARMACY
SELF-INSPECTION FORM–UPDATE 7/2023

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

Please note: **This is not a standalone self-inspection form. This form is meant to be filled out in conjunction with the Drug Outlet Self-Inspection Form (i.e. Retail Drug Outlet, Institutional Drug Outlet, etc.).**

This Self-Inspection Form has been updated to reflect rule changes that were adopted at the December 2022, February 2023, April 2023, and June 2023 Board Meetings. Completion of this version (v. 7.2023) is only required with a PIC change.

Per OAR 855-019-0300: Duties of a Pharmacist-in-Charge
(4) The PIC must perform the following duties and responsibilities:
(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC

(5) The PIC is responsible for ensuring that the following activities are correctly completed:
(c) Conducting an annual self-inspection of the pharmacy using the annual Self-Inspection Form provided by the board, by July 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion.*

> ***Please note this rule becomes effective 8/1/2023.** Required completion of the Compounding Pharmacy Self-Inspection Form by July 1 starts in 2024. The Self-Inspection Form due by July 1, 2024 will be released in May of 2024 (v. 5.2024), allowing PICs to complete this form by the annual deadline.

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 drug outlet's level of compliance.

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All PIC's must complete this form **in addition to the Drug Outlet Inspection Form (i.e. Retail Drug Outlet, Institutional Drug Outlet, etc.)** and have it available for inspection within 15 days of becoming PIC and by 7/1/2024 (as required by OAR 855-019-0300).

Date PIC Inspection was performed:

PIC Name:

PIC License #:

PIC Work email:

Pharmacy Name:

Telephone #: Fax #:

Address:

City: State: Zip:

DEA #: Exp Date:

Institutional Drug Outlet Registration #:

Retail Drug Outlet Registration #:

Nonprescription Drug Outlet Registration #:

Wholesale Outlet Registration #:

Manufacturer Registration #:

NPI #:

Please specifically list where the following items are located inside the pharmacy. OAR 855-001-0040 states all records are required to be stored on-site and **MUST be provided to the board immediately upon request at the time of inspection.**

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

Compounding References (i.e. current USP):

Compounding policies and procedures
Gowning and Garbing:

Cleaning:

Material Handling:

Initial and ongoing personnel training documents
Aseptic Training:

Media Fill / Gloved Fingertip competency documents:

Nonsterile compounding training:

Equipment
Hood Certification documentation:

Cleaning documentation:

Environmental monitoring documentation:

Surface sampling documentation:

Records
Bulk Chemical Certificates of Analysis:

Master Formulation Records:

Compounding Worksheets:

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: Note: USP has pending updates with and anticipated effective date of 11/1/2023.	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 most recent accreditation report to this form.***	

Yes	No	N/A			Rule Reference
			3	What type of compounding is performed? Please check all that apply: **Nonsterile**: ☐ HRT ☐ pain creams ☐ compounding kits ☐ veterinary ☐ hazardous ☐ other: **Sterile**: ☐ IV's ☐ TPN ☐ eye drops ☐ pellets ☐ intrathecal ☐ lyophilization ☐ chemotherapy ☐ cardioplegia ☐ other:	
☐	☐	☐	4	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
☐ ☐	☐ ☐	☐ ☐	5	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.	OAR 855-045-0220 OAR 855-045-0270

Yes	No	N/A			Rule Reference
				Date of last review?	
			6	Describe supervision of the compounding process in the pharmacy: Note: A technician may only compound under the supervision, direction and control of a pharmacist.	ORS 689.486(6)
☐	☐	☐	7	Does the pharmacy have standard operating policies and procedures for cleaning, testing and calibration of all equipment and devices?	OAR 855-045-0220 OAR 855-045-0270
☐ ☐	☐ ☐	☐ ☐	8	Does the pharmacy have standard operating policies and procedures for establishing beyond-use dates (BUDs) for compounded products? Does the pharmacy extend BUD?	OAR 855-045-0220
☐	☐	☐	9	Does the pharmacy extend any BUD's beyond USP standards? If so, please describe the 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
☐ ☐	☐ ☐	☐ ☐	10	Does the pharmacy handle hazardous drugs (HD's)? Is the pharmacy currently in compliance with USP 800? Note: Handling HDs includes, but is not limited to the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.	OAR 855-045-0200 USP 800
☐	☐	☐	11	Does the pharmacy batch compounded products?	
☐	☐	☐	12	Do bulk drug substances have the required certificate of analysis?	e-CFR 503A Guidance Document 503B Guidance Document

Yes	No	N/A			Rule Reference
☐	☐	☐		Are bulk drug substances acquired only from Board registered manufacturers or wholesalers?	
☐	☐	☐	13	Is the pharmacy only using active pharmaceutical ingredients (API's) and excipients 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
☐	☐	☐	14	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
☐	☐	☐	15	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; • Pharmacist documented verification of order accuracy; • Identity of all personnel involved in each step of the process; • 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;	OAR 855-045-0270

Yes	No	N/A			Rule Reference
				• Records of dispensing or transfer of all compounded preparations; and • Any other information required by the pharmacy's policies and procedures.	
			16	How does the pharmacy retain the identity of all personnel involved in each step of the compounding process?	OAR 855-045-0270
			17	How does the pharmacy retain documentation of the proper weight/measurement of each ingredient of a compounded product?	OAR 855-045-0270
☐ ☐	☐ ☐	☐ ☐	18	Does the pharmacist document verification of compounded product accuracy, including correct formula, calculations, and use of correct drugs and measurements? Is there documentation showing which pharmacist is responsible for the supervision of the compounding process including compounding techniques used when preparing each compound?	OAR 855-045-0270 ORS 689.486(6)
☐ ☐	☐ ☐		19	Does the pharmacy have policies and procedures for adverse event reporting and recalls, 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? Have you had any patient level recalls for compounded products in the past year?	OAR 855-045-0220 OAR 855-045-0270
☐	☐		20	Does the pharmacy have 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			Rule Reference
☐	☐	21	Are CSP's prepared in an ISO 5 certified Primary Engineering Control (PEC)?	OAR 855-045-0200
☐	☐	22	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
☐	☐	23	Is ISO determination taken under dynamic conditions while simulated compounding is occurring?	OAR 855-045-0200
☐	☐	24	Are surfaces and equipment in buffer room and anteroom nonporous, smooth, non-shedding, impermeable, cleanable, and resistant to disinfectants?	OAR 855-045-0200
☐	☐	25	Does the pharmacy have policies and procedures that routinely monitor the compounding environment for microbial or fungal growth?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	26	Does the pharmacy perform surface sampling? How often? Incubation time? Incubation temperature?	OAR 855-045-0220 OAR 855-045-0270
		27	How often does the pharmacy test **all** compounding personnel, including verifying pharmacists, in aseptic manipulative skills, gowning and garbing and gloved fingertip sampling?	OAR 855-045-0220 OAR 855-045-0270
☐	☐	28	Do compounding procedures include requirements for use of gowns, shoe covers, hair covers, sterile gloves and masks? **Note**: Makeup, jewelry, and artificial nails/fingernail polish are not permitted in the buffer room.	OAR 855-045-0220 OAR 855-045-0200
☐	☐	29	Does the pharmacy document environmental monitoring to ensure that the compounding environment is properly maintained, including temperature, humidity, and pressure differentials?	OAR 855-045-0270
☐	☐	30	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; • Rate of infusion or titration parameters, for a sterile parenteral preparation;	OAR 855-045-0240

Yes	No			Rule Reference
			• 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.	
		31	How does the pharmacy retain documentation of the pharmacist's verification of finished CSP's for a minimum of three years?	OAR 855-045-0270
☐	☐	32	In ISO 7 and 8 areas, are floors and work surface areas cleaned daily and are walls, ceilings and shelving cleaned at least monthly?	OAR 855-045-0200
☐	☐	33	Are individuals that perform cleaning and disinfecting in ISO classified areas trained in accordance with USP? Who performs cleaning and disinfecting of ISO classified areas in the pharmacy?	OAR 855-045-0220 OAR 855-045-0270
		34	What products are used to clean and disinfect? How often? What is the dwell time for each? 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.

Signature of PIC:

Printed Name of PIC:

PIC License #:

Date: