

2024 DISPENSING PRACTITIONER DRUG OUTLET (DPDO) SELF-INSPECTION FORM

ATTENTION: MEDICAL DIRECTOR OR DESIGNATED REPRESENTATIVE

<u>Failure by the DPDO to complete this form by July 1, 2024, may result in disciplinary action (OAR 855-043-0560).</u>

OAR 855-043-0510

- (1) Unless subject to an exemption in OAR 855-043-0510(2), a practitioner's facility that engages in dispensing FDA-approved human prescription drug therapies <u>must register the dispensing site with the board as a DPDO.</u>
- (2) A practitioner's facility is exempt from this registration requirement if the practitioner and facility only engage in:
 - (A) Dispensing FDA approved drug samples; or
 - (B) Dispensing Medication Assistance Program (MAP) drugs; or
 - (C) Dispensing homeopathic products; or
 - (D) Dispensing natural thyroid supplemental products; or
 - (E) Dispensing a small amount of drugs to start therapy or incidental to a procedure or office visit, up to a 72 hour supply; or
 - (F) An amount greater than a 72 hour supply if the drug is:
 - (i) A drug in the manufacturer's original unit-of-use packaging, such as a metered-dose-inhaler or bottle of fluoride rinse; or
 - (ii) A full course of therapy, if in the professional judgment of the practitioner would be in the patient's best interest, such as a course of antibiotic therapy.

Requirements: Oregon law states that the Dispensing Practitioner is responsible for ensuring the drug outlet is compliant with all applicable state and federal laws and rules. This form must be provided to the Board immediately upon request at the time of inspection and retained for 3 years in compliance with laws and rules.

Scope: The primary objective of completing the self-inspection is to identify and correct areas of non-compliance with any state and federal laws and rules. This process is not exhaustive, however, and laws and rules often change between annual updates to this form. Subsequently, it is your responsibility to ensure compliance with any changes, or applicable laws and rules, not referenced herein.

Internal Use: Following completion of the self-inspection form, ensure it is signed and dated, reviewed by all staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to store the documents in a binder, using tabs to partition and organize where possible. Otherwise, please CLEARLY indicate on the form where auxiliary documents are located.

Agency Use: During an inspection, Compliance Officers use the self-inspection form as a general guide to assess drug outlet compliance. These inspections are scheduled in advance with the DPDO. However, all staff should be able to retrieve the form and locate any referenced auxiliary documents..

Email all compliance-related questions to: pharmacy.compliance@bop.oregon.gov

2024 DISPENSING PRACTITIONER DRUG OUTLET (DPDO) SELF-INSPECTION FORM

Date Self-Inspection Completed:				
Outlet Name:		Outlet Registration #:		
Address:				
City:	State:	Zip Code:		
Telephone:	Fax:			
Medical Director/Dispensing F	Practitioner Name:			
Medical Director/ Dispensing Practitioner Work Email:				
Medical Director/Designated Representative Direct Phone Number:				
Dispensing Practitioners' Names and DEA Registration Numbers:				
Name:		DEA Registration #:		
Name:		DEA Registration #:		
Name:		DEA Registration #:		
Name:		DEA Registration #:		

INSTRUCTIONS

You are required to confirm whether the outlet is compliant. Mark the appropriate box to the left of each item, resolve all deficiencies and write the date of correction, if applicable.

Yes	No		Rule Reference		
		1	Does the outlet have policies and procedures for drug security, acquisition, storage, dispensing and drug delivery, disposal, and record keeping?	OAR 855-043-0520	
			Where are they located?		
		2	Does the outlet keep all drugs in a locked drug cabinet or drug storage area that denies access to unauthorized persons?	OAR 855-043-0525	
		3	Does the outlet only acquire drugs from an Oregon-registered Drug Outlet (e.g. Wholesaler, Manufacturer, Pharmacy, etc.)? Name of suppliers and OBOP registration numbers:	OAR 855-043-0530 OAR 855-065-0006(1) OAR 855-060-0004(1)	
		4	https://orbop.mylicense.com/verification/ Are all drugs stored in appropriate conditions with regards to temperature, light, humidity, sanitation, ventilation, and space? How are proper temperatures ensured and maintained?	OAR 855-043-0535	

Yes	No			Rule Reference
		5	Are all recalled, outdated/expired, damaged, deteriorated, suspect, illegitimate, misbranded, or adulterated drugs properly quarantined and physically separated from other drugs until destroyed or returned to the supplier? Where does the outlet keep drugs quarantined, awaiting destruction or disposal?	OAR 855-043-0550
		6	 Are all drugs prepackaged for later own use dispensed in a container that meets USP standards and is labeled to identify the following information, at minimum? Drug name (brand, or generic name plus manufacturer or distributor) Strength Lot number Manufacturer's expiration date, or an earlier date if preferable 	OAR 855-041-1135(1)(a-d)
		7	 Are all prescriptions properly labeled? Name of patient Name of prescriber Name, address, and phone number of the clinic Date of dispensing Drug name and strength – when a generic name is used, the label must also contain the identifier of the manufacturer or distributor Quantity dispensed Directions for use Cautionary statements, if any, as required by law; and Manufacturer's expiration date, or an earlier date if preferable, after which the drug should not be used. Physical description, including any identification code that may appear on tablets and capsules (unless in unit dose or unit of use packaging). 	OAR 855-043-0540
		8	Are dual language prescription labels available in each of the 14 required languages, and provided upon request by the patient or patient's agent? Note: The prescription must bear a label in both English and the language requested.	OAR 855-043-0541
		9	Are drugs dispensed in compliance with the current provisions of the Poison Prevention Packaging Act in CFR Title 16, Chapter II, Subchapter E, Parts 1700 – 1702 (01/01/2023)?	OAR 855-043-0545(4)
		10	Are all patients that require a Medication Guide provided one unless an exemption applies?	OAR 855-043-0545(9)

Yes	No			Rule Reference
		11	Are all of the following requirements met for each prescription that is delivered or mailed to a patient? • Drug is maintained in proper storage conditions • Offer for direct counseling is provided in writing, along with instructions on how to contact the practitioner, and information about the drug, including but not limited to: • Drug name, class, and indications • Proper storage and use • Common side effects • Precautions and contraindications • Significant drug interactions	OAR 855-043-0545(7)
		12	Is staff aware that a DPDO may not accept the return of drugs from a previously dispensed prescription, may not re-dispense a prescription that was already released to a patient and must maintain a list of sites in Oregon where drugs may be disposed?	OAR 855-043-0545(6)
		13	Is a unique dispensing record maintained separately from the patient chart and kept for a minimum of 3 years? Where are the records kept?	OAR 855-043-0555(1)
		14	Does the dispensing record contain all of the following required elements? Name of patient Unique identifier ("prescription number") Drug name (brand, or generic name plus manufacturer or distributor), dose, dosage form, and QTY dispensed Directions for use Date of dispensing Initials of person dispensing the prescription	OAR 855-043-0555
I here	by cer	15	Are all records for the receipt and disposal of drugs kept for a minimum of three years? Where are the records kept? that to the best of my knowledge, this outlet is complian	OAR 855-043-0555 t with all applicable laws and
rules, and that the answers marked on this form are true and correct. Date:				
Dispensing Practitioner or Medical Director Printed Name and Title:				
Signat	ure:			