

# 2022 RETAIL/LONG TERM CARE/HOME INFUSION 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. <u>Failure to complete this form by February 1, 2022, and within 15 days of becoming PIC (as required by OAR 855-019-0300) may result in disciplinary action.</u>

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 your 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 your 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 your 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 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 the pharmacy is in compliance. Please review Board regulations and take the time to personally verify that compliance exists. Email all Compliance related questions to <a href="mailto:pharmacy.compliance@bop.oregon.gov">pharmacy.compliance@bop.oregon.gov</a>. (Note: The Board does not provide individualized legal advice on how the law applies to practice in the field. 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 discrepancies, please write 'corrected' and the date of correction by the appropriate question.

The Board offers a PIC training course. Check the Board website for more information.

## 2022 RETAIL/LONG TERM CARE/HOME INFUSION PHARMACY SELF-INSPECTION FORM

All PIC's must complete and sign this inspection form and have it available for inspection within 15 days of becoming PIC and by 2/1/2022 (as required by OAR 855-019-0300).

Date PIC Inspection was pe	erformed:	
Print PIC Name & License #	#: <u> </u>	Date:
		In person or Virtual Inspection: (circle)
		Compliance Officers
	Fax:	
Address:		
City/State/Zip Code:		Result:
DEA #:	Exp:	Comments:
Retail Outlet Registration #:		
Institutional Outlet Registrat	tion #:	
Nonprescription Drug Outlet	t Registration #:	
many filing cabinets and l	binders.	oharmacy. Be as specific as possible; there can be
PIC Inspection Reports for the	he last 3 years:	
Policies and Procedures:		
Continuous Quality Ass	urance Plan/documents:	
Current written Drug Ou	utlet Procedures:	
Current technician proce	edures:	
CDTM:		
Training Documents:		
Initial and annual techni	ician training documents:	
Telework:		
Controlled Substances:		
Current written annual o	controlled substance inventory:	
Schedule II invoices for	the last 3 years:	
Completed CII order for	ms (DEA form 222) for last 3 years: _	
Quarterly CII reconciliat	ions with detailed explanations of all	variances:

<u>Immun</u>	ization	Record	<u>s</u> :					
Va	ccine a	dminist	ration	records:				
Va	Vaccine Adverse Event Protocol and dedicated supplies:							
Cu	rrent C	PR Car	ds & I	mmunization Certification documents:				
Cold D	rug Sto	rage R	ecords	<u>3</u> :				
Poli	cies an	d Proce	edures	:				
Ten	nperatu	re logs:						
Qua	arterly v	alidatio	n reco	ords:				
Dru	g stora	ge mon	itoring	plan:				
Eme	ergency	action	plan:					
Telewo	rk Rec	ords:						
Tele	ework w	ritten a	green	nent:				
Tele	ephone	Audio I	Record	dings:				
Doc	umenta	ation of	patien	t interactions reviewed:				
Still	image	capture	s or s	tore and forward prescription information:				
CDTM:	_							
Agr	eement	s:						
Prescri	ptive A	uthority	:					
Poli	cies an	d proce	dures	:				
Pha	rmacist	t prescr	ibing r	records:				
Trai	ning do	cumen	tation:					
		_						
Public	Healt		ergen	cy (PHE) and COVID				
Yes	No	N/A			Rule Reference			
			1	Are staff aware that Division 7 rules are ONLY in effect during a Public Health Emergency declared by the Governor?	OAR 855- <u>007</u>			
			2	Are staff familiar the COVID-19 resources on the Board of Pharmacy website (COVID Communication Update)?				
				https://www.oregon.gov/pharmacy/Pages/COVID-19.aspx				
			3	Are staff wearing masks or appropriate face coverings per current OHA requirements?	OAR 855-007-0088 OAR 333-019-1011 OAR 333-019-1025			

	4	Are staff familiar with the Oregon Occupational Safety and Health Administration (OSHA), and how they are involved with workplace safety during the COVID-19 PHE?	https://osha.oregon.go v/covid19/Pages/defau lt.aspx
		OSHA sets and enforces protective workplace safety and health standards as well as providing information, training and assistance to employers and workers.	
		To file a complaint with OSHA: https://osha.oregon.gov/workers/Pages/index.aspx	

### **General Requirements**

Yes

No

N/A

Yes	No	N/A			Rule Reference
			5	How many hours (weekly average) does the PIC work on site?	OAR 855-041-1010(1)
			6	How many pharmacies is the PIC responsible for?  Note: A pharmacist may not be designated PIC of more than three pharmacies without prior written approval by the board.  If PIC for more than one location, where are the Quarterly PIC Compliance Audit Forms located?	OAR 855-019-0300
			7	Are the current pharmacy license(s), DEA registration, pharmacist license(s), intern license(s), preceptor license(s) and	ORS 689.615
				technician license(s) posted?	
			8	Are pharmacists, technicians & interns aware that they must report felony arrests, felony, or misdemeanor convictions, and suspected and known violations to the Board within 10 days and suspected or known drug theft within 1 business day?  Note: Any theft or significant loss of drug must be reported by the outlet to the Board and DEA within 1 business day.  Note: Employment and residence address changes must be reported to the Board within 15 days.	OAR 855-019-0205 OAR 855-025-0020 OAR 855-031-0020 OAR 855-041-1030 CFR 1301.76(b)
			9	Is the PIC/pharmacy reporting all employment <b>terminations or resignations in lieu of termination</b> of licensees' employment to the Board within 10 days?	OAR 855-041-1010(2)
			10	Does the pharmacy provide or mail prescriptions and/or provide pharmacy services to patients located in other states?	
				Continued below	

**Rule Reference** 

		Is the pharmacy appropriately licensed in the other states where it does business?	
		If yes, please attach a list of all states in which the pharmacy does business with the corresponding license number(s) and expiration date(s).	
	11	Does the pharmacy use marketers or third-party companies to direct prescriptions to the pharmacy?  Do prescriptions come directly from the prescriber or are they routed from a third party?	ORS 475.188

**Rule Reference** 

### **Minimum Equipment, Procedures and Records**

Yes

N/A

No

Yes	No	N/A			Rule Reference
			12	Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet? Items to be addressed:  • Drug Security  • DUR (both new and refilled prescriptions)  • Prescription verification and identification of the responsible pharmacist  • Delivery of completed prescription(s)  • Counseling  • Verifying appropriate licensure and training of all staff  • Continuous Quality Assurance Program  • Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132.	OAR 855-041-1040
			13	Is the pharmacy clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-041-1015(2)
			14	Does the pharmacy quarantine outdated, adulterated, misbranded, and suspect product?	OAR 855-041-1025 OAR 855-041-1036(1)(d)
			15	Is the pharmacy aware that a Drug Take Back Box may be requested free of charge?	https://www.oregon.gov/de g/Hazards-and- Cleanup/hw/Pages/drugta keback.aspx
			16	Is the pharmacy registered with the DEA as an authorized collector for drug take back disposal?	OAR 855-041-1046
				If yes, are the following requirements met?	

Yes No N/A Rule Reference

	17	<ul> <li>Notify BOP within 30 days of initiating or terminating program</li> <li>Receptacle stored in secured location, which is accessible to the public, inside the retail drug outlet, and within the view of the pharmacy counter but NOT behind the pharmacy counter</li> <li>Adequate security measures for proper installation and maintenance of the collection receptable, tracking of liner, documentation and key accountability maintained</li> <li>Appropriate training and accountability provided to all parties involved in maintaining the drug take back disposal box</li> <li>Does the pharmacy sell medications to doctors?</li> </ul>	
		Where are the invoices located?	
	18	Is the pharmacy aware that pseudoephedrine and ephedrine has moved from a Schedule III to a Schedule V Controlled Substance?	OAR 855-080-0026
	19	Is the pharmacy providing nonprescription pseudoephedrine and ephedrine to patients over the counter?	OAR 855-080-0026
		If yes, are the following requirements met:  Store all pseudoephedrine and ephedrine behind the pharmacy counter (inaccessible to the public)  Utilize an electronic system meeting the requirements specified in 2021 HB 2648  Train staff on the requirements of the:  Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177),  Combat Methamphetamine Enhancement Act of 2010, P.L. 111-268, and  Use of the electronic system as described in 2021 HB 2648  Ensure only a pharmacist or pharmacy technician participates in the sale  Ensure that all requirements of sale are met:  Verify purchaser is 18 years or older  Verify identity of purchaser with valid government issued ID  Confirm the purchase is permitted via the electronic system  Document the purchase with required information  All sales are subject to quantity limit restrictions:  No more than 3.6 grams in 24-hour period and 9 grams in a 30-day period  Note: Interns and clerks may not sell nonprescription pseudoephedrine and ephedrine	

Yes No N/A Rule Reference

	20	Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent?	OAR 855-041-1132 ORS 689.564
		If not, what is the anticipated date of compliance?	
		Note: The prescription must bear a label in <b>both</b> English and the language requested.	
	21	Does the pharmacy have signage that provide patient notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels?	OAR 855- 041-1035 (1)(e)(B)
	22	How is the public notified that prescription readers are available at the pharmacy?	OAR 855-041-1131 ORS 689.561
		How does the pharmacy provide prescription readers for visually impaired patients?	
	23	<ul> <li>Effective 1/1/2020, a pharmacy shall electronically include the following notifications to the Oregon Prescription Drug Monitoring Program (PDMP):         <ul> <li>The diagnosis code (ICD-10), if it is provided by the prescriber with the prescription</li> <li>The reason for prescription, if it is provided by the prescriber with the prescription</li> <li>Gabapentin prescriptions dispensed</li> </ul> </li> </ul>	OAR 333-023-0810 ORS 431A.855
		Is the pharmacy, using language provided by the OHA, notifying each patient receiving a controlled substance about the PDMP before or when the controlled substance is dispensed to the patient? The notification shall include that the prescription will be entered into the system.	OAR 333-023-0815
		Note: Per the PDMP, if the ICD-10 and/or reason for Rx are not provided with the prescription, the pharmacist is not responsible to retrieve the missing information (this will not be considered an incomplete record submitted to the PDMP, and will not be rejected/sent back for completion at this time)	
		Note: Pharmacies are required to report naloxone prescriptions to the PDMP, however pursuant to 2019 legislation, the identity of a patient for whom naloxone is prescribed will not be disclosed in PDMP reports. This means that naloxone prescriptions will not appear on PDMP reports.	

#### **Controlled Substances**

Yes No N/A **Rule Reference** Is the pharmacy identifying and CLEARLY DOCUMENTING AND OAR 855-019-24 П П П **EXPLAINING ALL VARIANCES on CII reconciliations?** 0300(5)(e)(h) Note: The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least quarterly. If these records are maintained electronically, they must be accessible and producible at the time of inspection (audit, variances, and explanations). Note: Providing the count at the time of the reconciliation is not sufficient to meet this requirement. Working copies or documentation showing the audit and all variance explanations for all CIIs must be kept and will be requested for review at time of inspection. Where are the records located? Is the PIC/pharmacy reporting the theft or significant loss of a OAR 855-019-0205(6) П П 25 П controlled substance to the Board and DEA within 1 business OAR 855-041-1030 CFR 1306.76(b) day? Are on-hand quantity changes of controlled substances reviewed? 26 If so, how often and by whom? Who is permitted to make on hand changes? Was the controlled substance (CII-V) inventory performed on one OAR 855-080-0070 П 27  $\Box$ П day, within 12 months (367 days) of the last inventory? Date of last annual CII-CV inventory: Note: Inventory includes drugs in LTC e-kits, drugs used for compounding, items in the refrigerator, automated dispensing machines, outdated controlled substances. 24-hour pharmacies must indicate the time frame in which the inventory was completed. Non 24-hour pharmacies must indicate if the inventory was completed before opening or after closing.

Yes	No	N/A			Rule Reference
			28	Is the annual CII inventory filed separately from the CIII-CV inventory and are CII invoices and prescriptions filed separately from other prescriptions and invoices?	21 CFR 1304.04
			29	How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?	OAR 855-041-1020
Secur	ity				
Yes	No	N/A			Rule Reference
			30	When no pharmacist is physically present in the pharmacy, are computers, records and medications properly secured to prevent entry and access to records by non-pharmacist employees?	OAR 855-041-1020(3) OAR 855-041-2100 OAR 855-041-1015(1)
			31	Can technicians process/receive prescriptions or access records before a pharmacist arrives or after the pharmacist leaves?	OAR 855-041-1020(3)
Supp	ort Pe	rsonn	<u>iel</u>		
Yes	No	N/A			Rule Reference
			32	Are pharmacists, interns, technicians, and clerks clearly identified as such to the public?	OAR 855-025-0025(3)
			33	Is there documentation of initial and ongoing technician training?  Where are the records located?	OAR 855-025-0025(6)
			_	Be prepared to retrieve documentation of training for ALL technicians when requested by a Board Compliance Officer.  Do technicians know they cannot communicate with patients in	OAR 855-025-0040(3)(e)
			34	terms of drug class or indication/use (such as when a patient asks for a refill of their "diabetes medication")?  Note: Technicians can only communicate in terms of drug name and prescription number.	<u> </u>

Pharmacists may not allow technicians to counsel, answer a patient's medication related questions, or allow a technician

to relay information on their behalf.

OAR 855-019-0200(2)(3) OAR 855-019-0230

			35	Is each technician under the supervision, direction and control of a pharmacist and does the pharmacist verify work performed by technicians and document this verification?	ORS 689.486(6) OAR 855-025-0025(4)
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### **Pharmacists**

Yes	No	N/A			Rule Reference
			36	Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration?	OAR 855-019-0220(3)
				How is a DUR performed? Please provide the following details:	
				At which point in the process does a pharmacist perform a DUR?	
				Does this process vary depending on the type of fill (new vs refill)?	
				How is a DUR documented?	
				Note: A Pharmacist must perform a DUR on each fill (the computer may assist but does not replace RPH)	
			37	Is the Prescription Drug Monitoring Program (PDMP) utilized when performing a DUR on all controlled substances and gabapentin?	
				If no, why not?	
			38	Does the pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	OAR 855-019-0220(1) OAR 855-041-1165
			39	Does the PIC ensure that policies and procedures are followed to ensure that prescriptions are correctly dispensed?	OAR 855-041-1105
			40	When pharmacists or interns receive a telephone prescription, are they documenting their name, the date and the name of the person transmitting the prescription?	OAR 855-019-0210 OAR 855-041-1105
			41	Does the pharmacist document verification of 'return to stock' medications re-labeled by a technician or intern?	OAR 855-025-0025(4) OAR 855-019-0200

			42	Is a pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?	OAR 855-019-0200(2) OAR 855-041-1130(10)
				Note:  Expiration dates on prescriptions must be the same as that on the original container or one year from the date the drug was originally dispensed and placed in the new container, which ever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.	
			43	Is the Product Identification Label (PIL) on all dispensed medications, including OTCs and compounded medications?	OAR 855-041-1130(1)(k)
			44	Is a pharmacist or intern orally counseling on new and refill prescriptions requiring counseling and including information necessary to promote the safe use of the medication?	OAR 855-019-0230(1)(a) OAR 855-019-0230(2)
				Note: Asking the patient if they have any questions does not fulfill this requirement.	
			45	How is a new prescription identified as requiring counseling?	OAR 855-019-0230
			46	How does a pharmacist identify a prescription <b>refill</b> as requiring counseling?	OAR 855-019-0230
				Note: A pharmacist (not a technician) may indicate that a prescription 'renewal' does not require counseling, only if, after performing a DUR, the <b>pharmacist determines</b> nothing has changed (continuation of therapy (CT) and it is appropriate to release the prescription without speaking to the patient).	
			47	Is the pharmacist/intern (not a patient/clerk/technician or point-of-sale keypad) personally documenting whether counseling is provided or declined on prescriptions that require counseling at the time of the counseling?	OAR 855-019-0230(1)(c)
Drug (	Storag				
Yes	No	N/A			Rule Reference
			48	Does each active cold storage system maintain the temperature of refrigerated products between 2-8°C (35-46°F) and frozen products between -25 to -10°C (-13 to 14°F) or as specified by the manufacturer?	OAR 855-041-1036 (2) (a)(A)

Yes

No

N/A

**Rule Reference** 

N/A **Rule Reference** Yes No Note: An excursion is any temperature outside of these specified parameters. Each excursion requires a detailed written explanation in accordance with the requirements of this rule. Are the thermometers/probes centrally placed, accurate and OAR 855-041-1036(2) 49 calibrated? When is the next calibration (to ensure temperature readings are correct) due? OAR 855-041-1036(2) Is there documented training for ALL pharmacy personnel related 50 to the drug storage monitoring plan? Where are the records located? OAR 855-041-Explanation and documentation of ALL drug storage 51 excursions must include at least all the following: 1036(2)(b) (D-E) The event date & time frame: The name of person(s) involved in response; How long drug(s)/vaccine(s) were out of range; Temperature variances: Pharmacist review of duration and variance; The decision to quarantine for destruction each drug/vaccine affected or that each drug/vaccine affected is safe for continued use; Which pharmacist made the final decision: The information resource used to determine whether drug/vaccine is safe for continued use. Where are the records located? OAR 855-041-1036 Where is the emergency action plan for all refrigerated and frozen 52 medications and vaccines located? **Vaccine Drug Storage** Yes No N/A Rule Reference OAR 855-041-1036(3) Does the pharmacy store vaccines in the temperature stable 53 П П sections of the refrigerator? (a)(A)

Yes No N/A Rule Reference

		Note: Including the central shelves, but not the door or crisper drawers.	
	54	Does each active vaccine storage unit utilize a system of continuous temperature monitoring with automated data logging?	OAR 855-041-1036(3)(d)
	55	Does the pharmacy conduct quarterly <b>validations</b> of <b>EACH</b> <u>vaccine</u> storage unit and their monitoring equipment?  How are quarterly validations conducted?	OAR 855-041-1036(3) (a)(D)
		(Note – Quarterly validations are not the same as the thermometer calibrations)	

## **Vaccine Administration**

Prescriptive Authority is per OHA vaccine protocol

Yes	No	N/A			Rule Reference
			56	Do all immunizing pharmacists/interns have a current CPR card intended for healthcare providers?	OAR 855-019-0270 OAR 855-019-0290(3)
				Note: Online only programs are NOT approved.	
				Is the CPR training applicable for the age of patient's staff are vaccinating?	
			57	Does the pharmacy have required equipment and supplies for managing adverse events and are reviews done to ensure all supplies are readily retrievable and that no medication will expire before the next review?	OAR 855-019-0270
				Note: Regularly check the OHA Oregon Pharmacy Protocols for Immunization for the current Emergency Kit Requirements.	
			58	Does each pharmacist have access to ALERT and utilize it to perform a DUR and forecast potential immunizations?	OAR 855-019-0290
			59	Is the pharmacist/intern who administers any vaccine/immunization recording and maintaining the following information:  • Name, address, gender, date of birth of the patient and phone number when available;  • Date of administration; injection site;  • Vaccine name, dose, manufacturer, lot number and expiration date;	OAR 855-019-0290

		<ul> <li>Identity of administering pharmacist; the date of the publication of the VIS; and the date the VIS was provided?</li> </ul>	
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### **Collaborative Drug Therapy Management (CDTM)**

Yes	No	N/A			Rule Reference
			60	Do pharmacists participate in Collaborative Drug Therapy Management (CDTM) agreements?  Examples: Diabetes management, anti-coagulation, hypertension.	OAR 855-019-0260
			61	Does the written CDTM agreement contain the following:  Identification of the participating pharmacist(s) and practitioner(s)  The name of the principal pharmacist and practitioner who are responsible for development, training, administration, and quality assurance of the arrangement  The types of decisions that the pharmacist is allowed to make and when the pharmacist should initiate communications with the practitioner  Where are the records located?	OAR 855-019-0260 (2)(a-g) and (3)
			62	Are CDTM agreements being reviewed and updated at least every two years?	OAR 855-019-0260(2)(h)
			63	Are the practitioner and pharmacist identified on each prescription order?	OAR 855-019-0260 (2)(a-b)
				Note: The practitioner is the individual who referred the patient for treatment under the CDTM agreement. For a prescription written by a pharmacist under CDTM to be valid, the practitioner must be identified as the prescriber.	

#### Pharmacist Prescriptive Authority: (Public Health & Pharmacy Formulary Advisory Committee)

Yes	No	N/A			Rule Reference
			64	Do pharmacists at this location prescribe and dispense FDA approved drugs and devices included on either the Formulary or Protocol Compendia?	OAR 855-020-0200 OAR 855-020-0300
				Do pharmacists prescribe any drugs or devices to self or immediate family members? (Not allowed)	OAR 855-020-0120
				Please list all Prescriptive Authority Protocols that the outlet's pharmacists are qualified to participate in. Attach a separate page if needed.	
				Space below	

Protocol Page/Location of Policy/Location of Training Record \*\*Be prepared to show these records at the time of inspection. \*\*Please update eGov profiles to include this information. Do policies and procedures include the following? OAR 855-020-0110 65 П П Patient inclusion and exclusion criteria Explicit medical referral criteria Care plan preparation, implementation, and follow-up Prescribing drugs and devices pursuant to the formulary and protocol compendia Patient education: and Provider notification OAR 855-019-0470 For each drug or device prescribed, does the pharmacist: П assess the patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status? Is the pharmacist's patient assessment performed in a face-to-face. П П П in-person interaction and not through electronic means? Is the pharmacist utilizing information obtained in the assessment to П П evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures? Do care plans include appropriate treatment goals, monitoring П П П parameters, and follow-up? Is the patient's PCP or other identified care provider notified within П П П five business days following the prescribing of a Compendia drug or device? Is the pharmacist maintaining all records associated with prescribing and other related activities performed for a minimum of 10 years? Where are these records kept? Are pharmacists aware that they can provide protocol feedback to 66 the Public Health & Pharmacy Formulary Advisory Committee (PHPFAC) at www.oregon.gov/pharmacy/Pages/PFAC.aspx?

Yes

No

N/A

**Rule Reference** 

## **Pharmacist Prescriptive Authority: Contraceptives**

Yes	No	N/A			Rule Reference
			67	Do pharmacists at this location prescribe hormonal contraceptives?  Where are records located? (Including Questionnaire, Visit Summary, prescription, etc.)	OAR 855-019-0425 OAR 855-019-0430 OAR 855-019-0435
				Be prepared to show records at time of inspection. It is recommended to keep these records in a separate file/or log for easy retrieval.  Note: A clinical visit is required every 3 years.	
			68	Is the pharmacist taking the patient's blood pressure (BP)?	OAR 855-019-0425
			00	When the BP is not within range of the protocol (either reading is ≥140/90 for oral contraception or ≥160/100 for Depot Medroxyprogesterone) are pharmacists referring patients to primary care provider, not prescribing the hormonal contraceptive, and documenting the encounter?	
				Note: If the BP is out of range, a second BP reading may be taken and recorded before referring patient.	
		l .			
<u>Pharn</u>	nacist	Pres	cripti	ve Authority: Naloxone	
Pharn Yes	nacist No	Pres	cripti	ve Authority: Naloxone	Rule Reference
			69	Do pharmacists at this location prescribe naloxone?  If yes, does the pharmacy provide written notice about naloxone accessibility in a conspicuous manner?  Where are the records located?  Be prepared to show these records at time of inspection.	Rule Reference  OAR 855-019-0460 OAR 855-041-2340
Yes	No	<b>N/A</b>	69	Do pharmacists at this location prescribe naloxone?  If yes, does the pharmacy provide written notice about naloxone accessibility in a conspicuous manner?  Where are the records located?	OAR 855-019-0460
Yes	No	<b>N/A</b>	69	Do pharmacists at this location prescribe naloxone?  If yes, does the pharmacy provide written notice about naloxone accessibility in a conspicuous manner?  Where are the records located?  Be prepared to show these records at time of inspection.	OAR 855-019-0460

		refills of insulin and associated insulin-related devices and supplies, not including insulin pump devices?
		If so, is the pharmacist ensuring that the person has evidence of a previous prescription from a licensed health care provider and are they prescribing the lesser of a 30-day supply or the smallest available package size, and not more than three emergency refills and supplies in a calendar year?
		Where are the records located?
		Be prepared to show these records at time of inspection.

## **Telework**

Yes	No	N/A			Rule Reference
			71	Do pharmacy staff (Pharmacists, Interns or COPT) work from a location physically outside of the pharmacy (i.e. their home)?  Note: This is considered telework at a telework site by the board.  • If the answer is No to this question, please proceed to the	OAR 855-041-3205
				next section of questions.	
			72	Only OR licensed Pharmacists, Interns, and COPTs (with at least one year of experience) are providing pharmacy services to Oregon patients     All licensees comply with applicable federal and state laws and rules; and     NO DRUGS or DEVICES are permitted at a telework site	OAR 855-041-3215 OAR 855-041-3235
			73	How does the PIC and Pharmacists ensure the supervision, direction, and control of COPTs?	OAR 855-041-3215 OAR 855-041-3220
			74	Does the pharmacy have a written agreement that includes all condition, duties and policies governing the licensee engaged in telework activities?	OAR 855-041-3215 OAR 855-041-3245
			75	Does the pharmacy maintain a continuously updated list of all licensees engaged in telework and the Telework Sites that includes all of the following:  • Address and phone number where telework is performed for each Telework Site?	OAR 855-041-3215 OAR 855-041-3250

Yes No N/A Rule Reference

		<ul> <li>Functions being performed by licensees engaged in telework?</li> <li>The Pharmacist providing supervision, direction, and control for each non-pharmacist licensee?</li> </ul>	
	76	<ul> <li>Are all of the following supervision requirements met?</li> <li>Utilize technology that enables real-time audio and visual connections and interface to allow access to information required to complete assigned duties</li> <li>Ensure telephone audio is recorded, reviewed, and stored, for all patient interactions completed by each Intern and COPT</li> <li>Ensure a pharmacist is supervising, directing and controlling each Intern and COPT and that the continuous audio/visual connection is fully operational</li> <li>Ensure that a pharmacist using professional judgment, determines the frequency of "checkins" for each licensee being supervised via the real-time audio and visual connection with a minimum of at least once per work shift, and documents the interaction</li> <li>Ensure a pharmacist is readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and</li> <li>Ensure the Intern or COPT knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction, and control at all times</li> <li>Provide adequate staff to allow the pharmacist to complete required technician reviews</li> </ul>	OAR 855-041-3220
	77	Are all of the following supervision requirements met by the Pharmacist?  • Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed  • Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request  • Document the following within 48 hours of the review in  • Number of each licensee's patient interactions;  • Number of each licensee's patient interactions pharmacist is reviewing;  • Date and time of licensee patient interaction pharmacist is reviewing;  • Date and time of pharmacist review of licensee's patient interaction; and  • Pharmacist notes of each interaction reviewed; and  • Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 48 hours of discovery and to the board within 10 days	OAR 855-041-3220
	78	How does the pharmacy ensure patient confidentiality?  Space below	OAR 855-041-3225 OAR 855-041-3240
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res	NO	IN/A			Rule Reference
				Note: All computer equipment used at the Telework Site must:  • Establish and maintain a secure connection to the pharmacy and patient information;  • Utilize equipment that prevents unauthorized access to the pharmacy and patient information;  • Be configured so that the pharmacy and patient information is not accessible when  • There is no Pharmacist actively supervising  • There is no licensee at the telework site  • When any component of the real-time audiovisual connection is not functioning	
			79	Is a COPT or Intern able to access the pharmacy and patient information when a pharmacist is not actively supervising?	OAR 855-041-3240
			80	<ul> <li>Are the following technology requirements met?</li> <li>Test the continuous audio and visual connection and document that it operates properly before engaging in telework.</li> <li>Develop, implement, and enforce a plan for responding to and recovering from an interruption of service which prevents a pharmacist from supervising, directing and controlling the Intern and COPT at the Telework Site</li> <li>Ensure access to:         <ul> <li>Appropriate and current pharmaceutical references based on the services offered; and</li> <li>Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters.</li> </ul> </li> <li>Train the Pharmacists, Interns and COPT in the operation of continuous audio and visual connection</li> </ul>	OAR 855-041-3230
			81	If a pharmacist is performing verification via telework, are all of the following requirements met?  • Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each  • Source container including manufacturer, name, strength, lot, and expiration;  • Dispensed product including the imprint and physical characteristics;	OAR 855-041-3230(1)

Yes

N/A

No

**Rule Reference** 

N/A **Rule Reference** Yes No Completed prescription container including the label: and Ancillary document provided to patient at the time of dispensing Does each Pharmacist determine and document how many OAR 855-041-3235 82 П licensed individuals they are capable of supervising, directing, and controlling? Note: When supervising an Intern or COPT working at a Telework Site, the Pharmacist may supervise no more than four licensees among all locations, including the Pharmacy. Are all records maintained with in the requirements of OAR 855-OAR 855-041-3250 83 041-3250? Long Term Care (LTC) / Community Based Care (CBC) Services □ N/A Yes No N/A **Rule Reference** Is the pharmacy or pharmacists assisting in the establishment and OAR 855-041-7060(1) 84 supervision of the policies & procedures for the safe storage. distribution, administration, & disposal of drugs and for professional advice/medication counseling of patients and/or caregivers? Are emergency drug kits provided to any facilities? OAR 855-041-7060(2) 85 Does each facility's license allow them to have an emergency drug kit? If yes, how does a pharmacist verify and document verification of the kit?

Is the pharmacy ensuring that only a licensed nurse is accessing

the emergency drug kit or on-site pharmacy pursuant to OAR 855-

041-6310 AND that there is a practitioner's order to authorize the

If the pharmacy accepts the return of previously dispensed

Does the pharmacy dispense medications that have been

prescriptions, is the facility in compliance with OAR 855-041-

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1045?

removal of medications?

How is this being ensured?

previously dispensed and returned?

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OAR 855-041-7060(2)(b)

OAR 855-041-7060(5)

OAR 855-041-1045

OAR 855-041-1045(3)

Yes	No	N/A			Rule Reference			
				If so, under what circumstances?				
			89	Are prescriptions provided to patients in a Skilled Nursing Facility (SNF) and/or Immediate Care Facility (ICF)?  If yes, what is the outlet's Institutional Drug Outlet Registration #?	OAR 855-041-5005 OAR 855-041-5015 OAR 855-041-7050			
				Registration #:				
			90	Are all partially dispensed CII prescriptions (Note: Valid for up to a maximum of 60 days from the date written) documented with the following?  • "LTCF patient" or "terminally ill"  • Date of partial fill  • Quantity dispensed  • Remaining quantity authorized to be dispensed  • Identification of the dispensing pharmacist for each partial fill	21 CFR 1306.13			
policies	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.							
Printed	d Name	e of PIC	D:	License #:				
Signat	ure of I	PIC:		Date:				

If the pharmacy performs any drug compounding, you are also required to complete the Compounding Pharmacy Self-Inspection form located on the Board website.

If the pharmacy is a Remote Dispensing Site (RDSP) Affiliated Pharmacy for a Remote Dispensing Site Pharmacy (RDSP), please complete the RDSP Self- Inspection form located on the Board Website.

#### 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.

NAME	FULL OREGON LICENSE NUMBER	OREGON LICENSE EXPIRATION DATE

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