

REMOTE DISPENSING SITE PHARMACY (RDSP) SELF-INSPECTION FORM 2024

ATTENTION: PHARMACIST-IN-CHARGE (PIC)

- Failure to complete this form by July 1, 2024, and within 15 days of becoming PIC, may result in disciplinary action (OAR 855-115-0210(1)(h)).
- In order to be a PIC, a pharmacist must have:
 - o Completed at least one year of pharmacy practice; or
 - Completed a board provided PIC training course either before the appointment or within 90 days after the appointment; and
 - Be employed by the outlet (OAR 855-115-0205(1)(a)(b)(c)).
- Effective 7/1/2025, a PIC must complete a board-provided PIC training course at least every five years. (OAR 855-115-0205(3)).

Requirements: Oregon law states the PIC and all pharmacists on duty are responsible for ensuring the pharmacy is compliant with all applicable state and federal laws and rules. This form must be provided to the board upon request and retained in compliance with <u>OAR 855-104-0055</u>.

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, 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 by the PIC, reviewed with all pharmacy staff, and filed in a conspicuous manner (DO NOT SEND to the agency office). It is advisable to create a binder for this form, using tabs to organize and group documents where possible.

Agency Use: Compliance Officers use the self-inspection form as a general guide to assess pharmacy compliance. The PIC and all pharmacy staff should be prepared and able to retrieve this form and locate any auxiliary documents referenced within if requested by a Compliance Officer.

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

2024 REMOTE DISPENSING SITE PHARMACY (RDSP) SELF-INSPECTION FORM

The PIC must complete and sign this inspection form and have available for inspection <u>within 15 days of</u> <u>becoming PIC and by 7/1/2024</u> (as required by <u>OAR 855-115-0210</u>).					
Date PIC completed Self-Inspection:/	/	-			
PIC Name:		PIC Licens	se # RPH:		
PIC Work E-mail:					
RDSP Name:					
Address:					
City:	State:	Zip Code: _			
Telephone: ()		Fax: (_)		
DEA License #:		Exp:	/		
Retail Drug Outlet Registration #:		Exp:	/		
Nonprescription Drug Outlet Registration #:		Exp:	/	/	
Hours of operation:					
RDSP Affiliated Pharmacy Name:					
Address:					
City:	State:	Zip Code: _			
Telephone: ()		Fax: ()		
DEA License #:		Ехр:	/	/	
Retail Drug Outlet Registration #:		Exp:	/	/	
Pharmacist in person physical inspection:					
Name and license # of RPH:					
Dates audits completed:					

Please list where the following items are specifically located inside the pharmacy. Once located, ensure each is compliant, and reflects current practices within the outlet (if an item is not applicable, indicate with N/A). Unless otherwise specified, documents are to be retained for 3 years (the first year must be on site) and must be provided to the Board upon request, as outlined in <u>OAR 855-104-0055</u>.

Policies, Procedures, and Protocols (list # and location):

- o Security:
- o Operation, testing and maintenance of the telepharmacy system:
- o Sanitation:
- o Storage of drugs:
- o Dispensing:
- o Oregon licensed Pharmacist (Pharmacist) supervision, direction, and control of pharmacy technicians:
- o Documenting the identity, function, location, date, and time of the licensees engaging in telepharmacy:
- o Drug and/or device procurement:
- o Receiving of drugs and/or devices:
- o Delivery of drugs and/or devices:
- o Utilization of Pharmacist (e.g. DUR, Counseling):
- o Recordkeeping:
- o Patient confidentiality:
- o On-site inspection by a Pharmacist:
- o Continuous quality improvement:
- o Plan for discontinuing and recovering services if telepharmacy system disruption occurs:
- Training Initial and ongoing:

- o Interpretation, translation, and prescription reader services:
- Non-prescription drugs:
- Non-sterile compounding:
- o Controlled Substances:
- Pseudoephedrine / Ephedrine Sales

Training documents

- o Telepharmacy system training:
- Use of audio-visual connection training:
- o Initial and annual technician training documents:
- o Drug Take-Back Box Training:

Records

- o Patient profiles and records:
- o Prescriptions:
- o Still image capture and store and forward images:
- o Data and telephone audio records:
- o Pharmacist determinations of how many technicians to supervise:
- Date, time, and identification of each individual and activity or function performed, including in the dispensing process:
- o Testing of audio and visual connection:
- o Individual training on audio visual connection:
- o Any errors or irregularities identified by the quality improvement program:

o Completed Pharmacist Physical Inspection Forms:

Security

- o Surveillance Data:
- o <u>Controlled Substances:</u> □ N/A
 - Current written annual controlled substance inventory:
 - 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:
 - Quarterly CII reconciliations with detailed explanations of all variances:

Cold Drug Storage

- Policies and Procedures (to include storage, monitoring, and emergency action plan):
- Temperature Monitoring Data:
- Temperature Excursion Documentation:
- Calibration Certificates:
- Quarterly Validations (for all vaccine storage units):

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.

The term 'Pharmacist' means Oregon licensed pharmacist.

General Requirements

Yes	No			Rule Reference
		1.	Does the RDSP have an RDSP Affiliated Pharmacy?	OAR 855-139-0010(3)
			Note: Regulations do not permit an RDSP to operate without a RDSP Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.	

Yes	No			Rule Reference
		2.	Is the PIC aware that a change in location of the RDSP Affiliated Pharmacy or the location change of the RDSP requires the submission of a new RDSP application within 15 days of occurrence?	OAR 855-139-0020(1)
			Note : Per OAR 855-139-0010, a RDSP must be physically located in Oregon. Per OAR 855-139-0030, an <u>RDSP Affiliated Pharmacy</u> may be located outside of Oregon but must be registered as a Retail Pharmacy Drug Outlet with OBOP.	
		3.	Is the RDSP aware that a change in the RDSP Affiliated Pharmacy ownership or RDSP ownership requires the submission a new RDSP application within 15 days of occurrence?	OAR 855-139-0020(2)
		4.	Is the RDSP aware that discontinuation of operation of the RDSP requires notification to the board at least 15 days prior?	OAR 855-139-0145(2)
		5.	 Are all licensees aware that they must report: Theft or significant loss of a controlled substance to the Board and DEA <u>within 1 business day?</u> Felony arrests OR convictions, misdemeanor convictions, and suspected or known violations of state pharmacy laws and rules to the Board <u>within 10 days?</u> Changes in legal name, name used when in pharmacy, preferred email address, personal phone number, physical address, mailing address, and employer <u>within 15 days?</u> 	OAR 855-104-0010 OAR 855-139-0130 CFR 1301.76(b)
			(Visit <u>mylicense/eGov</u> to update)	
		6.	Is the PIC/pharmacy aware that an RDSP Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination must report the termination to the board within 10 working days?	OAR 855-139-0050(7)
		7.	Are Interns or unlicensed persons utilized at the RDSP? Note : A RDSP is not permitted to utilize Interns or unlicensed personnel.	OAR 855-139-0050(2)
		8.	Is each Pharmacist determining and documenting how many licensed individuals they are capable of supervising, directing, and controlling based on the services being provided?	OAR 855-139-0050(3)(4)(5)
		9.	Does the PIC ensure that Pharmacists and technicians complete a training program on the proper use of the telepharmacy system prior to working at the RDSP?	OAR 855-139-0050(6)
		10.	Does the RDSP and RDSP Affiliated Pharmacy, ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy?	OAR 855-139-0050(5)
		11.	Is the RDSP Affiliated Pharmacy affiliated with more than 2 RDSPs?	OAR 855-139-0200(1)
			Note: An RDSP Affiliated Pharmacy may not be affiliated with more than 2 RDSPs.	
		12.	Is the RDSP less than 120 miles from the RDSP Affiliated Pharmacy?	OAR 855-139-0200(2)
			How many miles?	
			Note: A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.	

Yes	No			Rule Reference
		13.	 Do the RDSP and RDSP Affiliated Pharmacy have the following? Same owner or written contract that specifies the following: The services to be provided by each licensee and registrant; The responsibilities of each licensee and registrant; and The accountabilities of each licensee and registrant; Ensure each prescription is dispensed in compliance with OAR 855-115, OAR 855-025, and OAR 855-139; Designate in writing the Pharmacists and technicians authorized to access the RDSP and operate the telepharmacy system; Train the Oregon licensed Pharmacists and technicians in the operation of the telepharmacy system and RDSP; Develop, implement, and enforce a continuous quality improvement program for dispensing services from a RDSP designed to objectively and systematically; Monitor, evaluate, document the quality and appropriateness of patient care; Improve patient care; and Identify, resolve, and establish the root cause of dispensing and DUR errors and prevent their reoccurrence; Provide a telephone number that a patient, patient's agent, or prescriber may use to contact the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy; Develop, implement, and enforce a process for an in person physical inspection of the RDSP by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed PIC 	<u>OAR 855-139-0200(3)</u>
		14.	Does a Pharmacist from the RDSP Affiliated Pharmacy physically inspect the RDSP at least once every 28 days using the RDSP self- inspection form include a review of temperature recordings and an inventory of controlled substances with reconciliation of discrepancies?	<u>OAR 855-139-0200(3)(i)</u> <u>OAR 855-139-0125(2)(b)(H)</u> <u>OAR 855-139-0225(4)</u>

Minimum Equipment, Procedures and Records

Yes	No			Rule Reference
		15.	 Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet? Items to be addressed: Security Operation, testing and maintenance of the telepharmacy system Sanitation Storage of drugs Dispensing Oregon licensed Pharmacist supervision, direction, and control of PTs Documenting the identity, function, location, date, and time of the licensees engaging in telepharmacy Drug and/or device procurement Receiving of drugs and/or devices Utilization of Oregon licensed Pharmacist (e.g. DUR, Counseling) Recordkeeping Patient confidentiality 	<u>OAR 855-139-0500</u>

Yes	No			Rule Reference
			 On-site inspection by an Oregon licensed Pharmacist Continuous quality improvement Plan for discontinuing and recovering services if telepharmacy system disruption occurs Training: initial and ongoing Interpretation, translation, and prescription reader services Non-prescription drugs (if offered) Non-sterile compounding Controlled Substance: to include date reviewed with staff Note: All RDSP policies and procedures must be reviewed and revised if necessary, every 12 months by the PIC at the RDSP Affiliated Pharmacy.	
		16.	Is the RDSP clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-139-0150(1)(2)
		17.	Does the RDSP report to the appropriate electronic reporting databases (e.g. PDMP, OHA Alert-IIS, etc.) based on the services offered?	OAR 855-139-0155(1)(c)
		18.	Does the RDSP have the proper equipment and supplies to provide services (e.g. drug storage, hot and cold running water, etc)?	OAR 855-139-0155(1)(d)(f)
		19.	 Does the RDSP post signage in a location easily seen by the public that states or provides the following information? "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." Notification of the right to free competent oral interpretation and translation services including translated prescription labels for patients in the 14 required languages per OAR 855-139-0410. Naloxone and necessary medical supplies are available and are provided by the pharmacy per OAR 855-139-0720. "This location is a Remote Dispensing Site Pharmacy, supervised by an Oregon licensed Pharmacist from (insert name of RDSP Affiliated Pharmacy, address, and telephone number)." 	<u>OAR 855-139-</u> 0155(1)(g)(A)(B)(C)(D)
		20.	Does the RDSP quarantine and either destroy or return to the supplier all outdated, adulterated, misbranded, and suspect product? Where does the RDSP keep drugs quarantined, awaiting destruction or disposal? Note: A medication that has previously been dispensed to a patient may not be re-dispensed.	<u>OAR 855-139-0450</u> <u>OAR 855-139-0455</u>
		21.	Is the RDSP registered with the DEA as an authorized collector for drug take back disposal?	OAR 855-139-0460
			 If yes, are the following requirements met? Notify BOP within 30 days of initiating or terminating program Receptacles are stored in a 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 	

Yes	No			Rule Reference
			 Adequate security measures for proper installation and maintenance of the collection receptable are in place that include tracking of liner, documentation, and key accountability Appropriate Training and accountability provided to all parties involved in maintaining the drug take back disposal box Pharmacy stock is not disposed of in a collection receptacle. Liners are retrieved from a locked collection receptacle under the supervision of two employees of the pharmacy. Upon removal, the liner must be immediately sealed, and the pharmacy employees must document their participation in the insertion and removal of each liner from a collection receptacle on a log. Sealed liners must not be opened, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. Sealed liners are directly transferred, or otherwise stored in a secured, locked location in the pharmacy for no longer than 14 days prior to being transferred, by two pharmacy personnel to a registered drug distribution agent (such as registered UPS, FedEx, or USPS) or a reverse wholesaler registered with the DEA and the board. Any tampering with a collection receptacle, liner or theft of deposited drugs must be reported to the board in writing within one day of discovery. 	
		22.	Is the RDSP aware that pseudoephedrine and ephedrine is a Schedule V Controlled Substance?	OAR 855-080-0026
		23.	Is the RDSP providing non-prescription 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 HB 2648 Train staff on the requirements of Combat Methamphetamine Epidemic Act of 2005 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. 	040.955.420.0440
		24.	Are prescription labels available in all 14 languages required by rule and are they made available to the patient if requested by the prescribing practitioner, patient or patient's agent? What is the RDSP's process to ensure that these labels are available at the time of request?	<u>OAR 855-139-0410</u> <u>ORS 689.564</u>

			1
		Note: The prescription must bear a label in both English and the language requested.	
	25.	Does the RDSP have signage easily seen by the public which provides notification of the right to free, competent oral interpretation and translation services (including translated prescription labels) in each of the 14 required languages?	OAR 855-041-1035 (1)(e)(B) OAR 855-041-1133 OAR 855-139-0155(1)(g)
		Dual Language Labeling Sign for Pharmacies	
	26.	Does the RDSP notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request?	OAR 855-139-0405 ORS 689.561
		Does the RDSP provide prescription readers for visually impaired patients?	
		Are prescription readers available and appropriate to address a person's visual impairment?	
	27.	Is the RDSP using the <u>PDMP Notice by Pharmacies to Patients</u> language provided by the OHA to notify each patient receiving a controlled substance about the PDMP before , or when , the controlled substance is dispensed to the patient?	OAR 333-023-0815
		Note: The notification must include that the prescription will be entered into the PDMP.	
	28.	Is the RDSP aware that non-prescription drugs can only be sold when a Pharmacist is immediately available to provide counseling or recommendations involving non-prescription drugs?	OAR 855-139-0220

Yes No

	-		
	29.	Are controlled substances purchased, stored, or dispensed by the RDSP?	OAR 855-139-0225
		 Does the RDSP: Comply with controlled substance regulations? Store <u>all</u> controlled substances in a secure locked cabinet? Maintain an accurate controlled substance perpetual inventory? Ensure Pharmacist conducts a controlled substance inventory at least once every 28 days and reconciles all discrepancies at the time of in person physical inspection? 	
	30.	Is the Pharmacist ensuring that the ALL VARIANCES on quarterly C-II reconciliations are DOCUMENTED, and CLEARLY EXPLAINED? If recorded electronically, it MUST be made available at time of inspection. Note: Providing an on-hand count is not sufficient to meet this requirement. The Board considers a reconciliation to be an accurate accounting of the outlet's true inventory, performed at least every 93 days in a Retail Drug Outlet Pharmacy.	<u>OAR 855-115-0210(1)(i)</u> <u>OAR 855-139-0225</u>

Rule Reference

		If it is determined that no discrepancies are found for any CIIs, provide	
		documentation to show this (i.e., screenshot of computer report that says this or report with expected value vs. actual value).	
	31.	Is the PIC/RDSP reporting the confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance to the Board and DEA within 1 business day?	<u>OAR 855-115-0115</u> <u>OAR 855-139-0130(2)</u> <u>CFR 1301.76(b)</u>
	32.	How often are on-hand quantity changes of controlled substances reviewed?	
		By whom?	
	33.	Was the controlled substance (CII-V) inventory and reconciliation performed on one day, within 12 months (367 days) of the last inventory?	OAR 855-080-0070
		Date of last annual CII-CV inventory: / // Note: Inventory includes compounding supplies, items in the refrigerator. 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.	
	34.	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
	35.	How does the PIC/RDSP maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?	OAR 855-139-0100 OAR 855-139-0225
		Are quarantined controlled substances included in the inventory?	

Security

Yes No

	36.	Does the RDSP utilize physical barriers, including floor to ceiling walls and locked separate entrance, to ensure the security of the area where drugs are stored, possessed, prepared, and compounded?	OAR 855-139-0100(1)
	37.	Are the PIC and supervising Pharmacist aware they are responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs and records for such drugs?	OAR 855-139-0100(2)
	38.	Is the RDSP locked, and the security system armed to prevent entry when:	OAR 855-139-0100(3) OAR 855-139-0100(5)

	 There is no Oregon licensed pharmacist actively supervising the RDSP? There is no technician present at the RDSP? Note: No one may be in the prescription area of the RDSP unless authorized in real-time by a Pharmacist who is supervising the RDSP from the RDSP Affiliated Pharmacy. 	
□ 39	Is a record created and maintained with the name and license number of each person entering the pharmacy area of the RDSP?	OAR 855-139-0100(4)
□ 40	 Are the following in place and properly functioning? Alarm system with an audible alarm at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy Electronic keypad or other electronic entry system that records the: Identification of the Pharmacist authorizing access and securing the RDSP Identification of the technician accessing and securing the RDSP Date and time of each activity Surveillance system that utilizes continuously accessible and recorded audiovisual link between the RDSP Affiliated Pharmacy and the RDSP. The system must provide a clear view of: Dispensing site entrances Preparation areas Drug storage areas Pick up areas Office areas Publicly accessible areas 	<u>OAR 855-139-0100(6)</u>

Supervision

Yes No

Dula	Reference
Rule	Reference

	41.	Are prescriptions only dispensed from the RDSP if a Pharmacist is supervising each technician and the telepharmacy system is fully operational?	OAR 855-139-0210(1)
		Note: Prescriptions may only be dispensed when a Pharmacist is supervising, and the surveillance system is fully operational.	
	42.	Does the RDSP ensure that a Pharmacist supervises, directs, and controls each technician at the RDSP using continuous audio and visual technology which must be recorded, reviewed, and stored?	OAR 855-139-0210(2)
	43.	 Does the Pharmacist who is supervising a technician at the RDSP complete the following? Using reasonable professional judgment, determining the percentage of patient interactions for each licensee that must be observed or reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed Reviewing 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 	<u>OAR 855-139-0210(3)</u>

		 Documenting the following within 24 hours of the review in (3)(b): 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 Pharmacist notes of each interaction reviewed Reporting any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days 	
	44.	Does the RDSP ensure telephone audio is recorded, reviewed, and stored for all patient interactions completed by each technician?	OAR 855-139-0210(5)
	45.	Has the RDSP developed, implemented, and enforced a plan for responding to and recovering from an interruption of service which prevents a Pharmacist from supervising each technician at the RDSP?	<u>OAR 855-139-0210(6)</u>

Technology

Yes No

Rule Reference

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	46.	Does the RDSP and RDSP Affiliated Pharmacy utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to process and fill a prescription drug order?	OAR 855-139-0205(1)
	47.	 Does the RDSP 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? Completed prescription container including the label? and Ancillary document provided to patient at the time of dispensing? 	<u>OAR 855-139-0205(2)</u>
	48.	Does the RDSP test the telepharmacy system and document that it operates properly before providing pharmacy services?	OAR 855-139-0205(4)
	49.	Did the RDSP develop, implement and does it enforce a plan for routine maintenance of the telepharmacy system?	OAR 855-139-0205(5)

Support Personnel (Assisting in the practice of pharmacy)

Yes No

	50.	Are technicians clearly identified in all interactions and	OAR 855-125-0105(3)(i)
	00.	communications (e.g. nametag, phone interactions)	

	51.	and with each policy/procedure update for the practice site?	OAR 855-139-0050(6)
	52.	 Do <u>technicians</u> know they can only <u>assist</u> in the practice of pharmacy as permitted by the Pharmacist who is supervising, directing, and controlling their work, and cannot <u>perform</u> any act that constitutes the practice of pharmacy as defined in ORS 689.005(28) and (29)? This includes, but is not limited to, the following: Counseling DUR Conducting MTM Note: Pharmacists may not allow technicians to counsel, answer a patient's medication related questions, allow a technician to relay information on their behalf or ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist. 	<u>ORS 689.005(28)(29)</u> <u>OAR 855-125-0150(1)(3)</u> <u>OAR 855-139-0600</u>
	53.	Is each technician under the supervision, direction and control of a Pharmacist and does the Pharmacist verify all work performed by technicians and document this verification?	ORS 689.486(6) OAR 855-115-0120(1)(d) OAR 855-125-0105(3)(b)(c)
		 At all times, during any given shift, do ALL: <u>Pharmacists</u> know the identity of each Intern under their supervision, and Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction, and control? 	
		• <u>Technicians</u> know the Pharmacist that is supervising, directing,	

Are technicians trained appropriately prior to performance of tasks

Pharmacists

No

Yes

and controlling them?

Does the RDSP utilize a Pharmacist from the RDSP Affiliated OAR 855-139-0215 П 54. Π Pharmacy to perform the professional tasks of interpretation, OAR 855-115 evaluation, DUR, verification and counseling before the prescription is dispensed? Does a Pharmacist use the real-time audio-visual communication to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed? How does the pharmacist document the interaction? Note: The Pharmacist must personally document whether counseling is provided or declined on prescriptions that require counseling at the time of the counseling.

Yes No

51.

Rule Reference

Rule Reference

OAR 855-125-0105(2)(k)

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	55.	Does the pharmacist perform a DUR for ALL prescriptions prior to dispensing, or preparing for administration?	OAR 855-115-0140
		At which point in the prescription process is a DUR performed?	
		Does this vary depending on the type of fill (new vs. refill)? If so, please explain.	
		If an intervention is required, how is it carried out and documented?	
		Note: A pharmacist must personally perform a DUR on each fill.	
	56.	Does the pharmacist document verification of ' return to stock ' medications re-labeled by a technician or intern if relevant to your practice setting?	<u>OAR 855-125-0135(2)</u> <u>OAR 855-115-0105</u>
	57.	Does a licensee offer, and a pharmacist or intern provide, counseling on all new prescriptions, and refills when determined necessary?	OAR 855-115-0145
	58.	How does the pharmacist denote that a new, or refilled, prescription requires the offer or provision of counseling?	OAR 855-115-0145
	59.	Does counseling include all information necessary to promote safe use of the medication or device?	OAR 855-115-0145
		Note: Using their professional judgment, only a pharmacist can determine the manner and amount of counseling that is reasonable and necessary.	
	60.	Are counseling activities (offer, and provision or declination)	OAR 855-115-0145
		documented in real-time, including identity of the licensee involved and the function they provided (provided counseling vs. accepted declination)?	
	61.	Does the Pharmacist make a reasonable effort to obtain, record, and	OAR 855-115-0130(1)(d)
		maintain in the patient record the elements required in OAR 855-041- 1165 including but not limited to patient demographics, preferred	OAR 855-139-0555
		language for communication, allergies and chronic medical conditions for both new and existing patients?	
	62.	How does the Pharmacist ensure that all prescriptions are correctly dispensed?	OAR 855-139-0300(1)

Yes	No
103	110

Rule Reference

	63.	Is a Pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?	OAR 855-115-0105 OAR 855-139-0400
		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;	
	64.	Is the Product Identification Label (PIL) on all dispensed medications, including non-sterile compounded medications?	OAR 855-139-0400(11)
	65.	How does the Pharmacist ensure that a technician does not ask questions of a patient or patient's agent that may screen and/or limit their interaction with the Pharmacist?	<u>OAR 855-139-0600</u>

Drug Storage

Yes	No			Rule Reference
		66.	Does each active cold storage system maintain the temperature of refrigerated products between 2 to 8°C (35 to 46°F) and frozen products between -25 to -10°C (-13 to 14°F), or as specified by the manufacturer?	<u>OAR 855-139-0125(2)</u> (a)(A)
			Note: ANY temperature outside of these parameters for ANY amount of time IS CONSIDERED AN EXCURSION.	
		67.	Are the thermometers/probes centrally placed, accurate and calibrated?	OAR 855-139-0125(2)(a)(B)
			When is the next <u>calibration</u> (to ensure temperature readings are correct) due? / /	
		68.	Is there documented training for ALL pharmacy personnel related to the drug storage monitoring plan?	OAR 855-139-0125(2)(b)(A)
		69.	 Are <u>ALL</u> excursions documented to include the following? Event date & time frame Name of person(s) involved Pharmacist's review of duration and magnitude Action(s) taken, whether to <u>quarantine</u> product for destruction/return, or <u>keep</u> product if deemed safe for continued use Source of information used Identity of pharmacist who made final decision 	<u>OAR 855-139-0125(2)(b)(D-</u> <u>E)</u>
		70.	Does the outlet have an emergency action plan for all refrigerated and frozen medications and vaccines?	OAR 855-139-0125(2)(F)

Compounding

No

Rule Reference

		Description DDDD as a former as a manual in a D	OAD 055 400 0000
	71.	Does the RDSP perform compounding?	OAR 855-139-0230 OAR 855-139-0600
		Note: ONLY non-sterile compounding is permitted at an RDSP. An RDSP is not permitted to compound sterile preparations.	<u>OAN 855-159-0000</u>
	72.	Does a Pharmacist supervise via real-time audio-visual connection all steps of the compounding AND visually verify and document each item as required in OAR 855-139-0205?	OAR 855-139-0230

Note: If the RDSP performs any drug compounding, you are also required to complete the <u>Compounding</u> <u>Pharmacy Self-Inspection form</u> located on the Board website.

Records

Yes

Yes	No			Rule Reference
		73.	Are all records and documentation required by rules retained for a total of 3 years with records being stored at a minimum on site for 1 year? Note: The RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.	<u>OAR 855-139-0550(1)(2)</u>
		74.	 Do the RDSP and RDSP Affiliated Pharmacy maintain the following records for 3 years? Patient profiles and records; Date, time, and identification of each individual and activity or function performed; If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process; Controlled substance inventory and reconciliation; Oregon licensed Pharmacist physical inspection of RDSP; Audio and visual connection testing and individual training on use of the audio and visual connection; Still image capture and store and forward images Temperature logs Documentation of temperature review Med paks, Drug disposal Patient services records (EPT, naloxone, etc.) Any errors or irregularities identified by the quality improvement program. 	<u>OAR 855-139-0550(3)</u>
		75.	Do the RDSP and RDSP Affiliated Pharmacy maintain the following records for 6 months?	OAR 855-139-0550(3)(h)
			Note: Data, telephone audio and surveillance data must be retained for 6 months	

Yes	No			Rule Reference
		76.	Do Pharmacists at this location allow technicians to participate in "Final Verification" (that is, after prescription information is entered into a pharmacy's electronic system and reviewed by a Pharmacist for accuracy, a <u>physical verification</u> that the drug and drug dosage, device or product selected from a pharmacy's inventory pursuant to the electronic system entry is the prescribed drug and drug dosage, device, or product)? If yes, please print, complete, and attach the <u>Additional Services</u> <u>Self-Inspection Form.</u>	ORS 689.005 OAR 855-005-0006(21) OAR 855-115-0130(3) OAR 855-125-0105(4)

I hereby certify that to the best of my knowledge, this outlet is compliant with all applicable laws and rules, that written policies and procedures reflect current practices, that I have documented training of staff, and that the answers marked on this form are true and correct.

Printed Name of PIC: _____

Signature of PIC: _____

Date: _____ / _____ / _____

PHARMACY PERSONNEL – KEEP CURRENT THROUGHOUT THE YEAR ADDING NEW LICENSEES AND CROSSING OUT ANY WHO NO LONGER WORK AT THIS LOCATION.

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	OREGON LICENSE #	OREGON LICENSE EXPIRATION DATE

RDSP 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	OREGON LICENSE #	OREGON LICENSE EXP DATE