



2022
REMOTE DISPENSING SITE PHARMACY
SELF-INSPECTION FORM

ATTENTION: PHARMACISTS AND PHARMACIST-IN-CHARGE (PIC)

Oregon law holds the pharmacist-in-charge (PIC) and all pharmacists on duty responsible for ensuring Remote Dispensing Site Pharmacy (RDSP) compliance with all state and federal laws governing the practice of pharmacy. 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.

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 (RPH) and Certified Oregon Pharmacy Technicians (COPT), and 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 the outlet is in compliance. Please review Board regulations and take the time to personally verify that compliance exists. Email all Compliance related questions to pharmacy.compliance@bop.oregon.gov. (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
REMOTE DISPENSING SITE PHARMACY (RDSP)
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 and within 15 days of becoming PIC (as required by OAR 855-019-0300).

Date PIC Inspection was performed: _____

PIC Name & License #: _____

PIC e-mail: _____

RDSP Name: _____

Telephone: _____ Fax: _____

Address: _____

City/State/Zip Code: _____

DEA #: _____ Exp: _____

Retail Drug Outlet Registration #: _____

RDSP Affiliated Pharmacy Name: _____

Telephone: _____ Fax: _____

Address: _____

City/State/Zip Code: _____

DEA #: _____ Exp: _____

Affiliated Pharmacy Retail Drug Outlet Registration #: _____

Monthly Audits:

Name and license # of RPH: _____

Dates completed monthly audits: _____

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

PIC Annual Self Inspection Report: _____

Pharmacist physical inspections of the RDSP: _____

Policies and Procedures:

Security: _____

Operation, testing and maintenance of the telepharmacy system: _____

Sanitation: _____

Storage of drugs: _____

Dispensing: _____

Oregon licensed pharmacist supervision, direction and control of pharmacy technicians: _____

Date: _____
In person or Virtual Inspection (circle)
Compliance Officer: _____
RPh or COPT present for inspection: _____
Result: _____
Comments: _____

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; _____

Delivery of drugs and/or devices; _____

Utilization of Oregon licensed Pharmacist (e.g. DUR, Counseling); _____

Recordkeeping; _____

Patient confidentiality; _____

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: _____

Non- sterile compounding: _____

Controlled Substance: _____

Training documents:

Telepharmacy system training: _____

Use of audio-visual connection training: _____

Initial and annual Certified Oregon Pharmacy Technician training documents: _____

Records:

Patient profiles and records: _____

Prescriptions: _____

Still image capture and store and forward images: _____

Data and telephone audio records: _____

RPH determinations of how many technicians to supervise: _____

Date, time, and identification of each individual and activity or function performed, including in the dispensing process:

Testing of audio and visual connection: _____

Individual training on audio visual connection: _____

Any errors or irregularities identified by the quality improvement program: _____

Monthly RPH Physical Inspection: _____

Security:

Surveillance Data: _____

Controlled Substances: (if applicable)

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: _____

Pharmacist Quarterly CII reconciliations with detailed explanations of all variances: _____

Cold Drug Storage:

Policies and procedures: _____

Temperature logs: _____

Thermometer calibration records: _____

Quarterly validation records: _____

Emergency action plan: _____

Public Health Emergency (PHE) and COVID

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1	Are staff aware that Division 7 rules are ONLY in effect during a Public Health Emergency declared by the Governor?	OAR 855- 007
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	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? 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	https://osha.oregon.gov/covid19/Pages/default.aspx

General Requirements

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5	Does the RDSP have an RDSP Affiliated Pharmacy?	OAR 855-139-0100(3)

Yes	No	N/A			Rule Reference
				Note: Regulations do not permit an RDSP to operate without a RDSP Affiliated Pharmacy.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6	Is the PIC aware that a change in location of the RDSP Affiliated Pharmacy or the location change of the RDSP requires the submission a new RDSP application within 15 days of occurrence? Note: An RDSP must be physically located in Oregon. An RDSP Affiliated Pharmacy may be located outside of Oregon and must be registered as a Retail Pharmacy Drug Outlet with OBOP.	OAR 855-139-0020(1) OAR 855-139-0030
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7	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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8	Is the RDSP aware that discontinuation of operation of the RDSP requires notification to the board at least 15 days prior?	OAR 855-139-0025(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9	Are Pharmacists and Certified Oregon Pharmacy Technicians (COPTs) 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 confirmed significant drug loss or any loss related to suspected drug theft must be reported to the board within one 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 855-139-0130 21 CFR 1301.76(b)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10	Is the PIC/pharmacy reporting all employment terminations or resignations in lieu of termination of licensees' employment to the Board within 10 days?	OAR 855-139-0050(9)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11	Are Interns, Pharmacy Technicians, or unlicensed persons utilized at the RDSP? Note: A RDSP is not permitted to utilize Interns, Pharmacy Technicians or unlicensed personnel.	OAR 855-139-0050(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12	Are the Oregon licensed Pharmacists determining and documenting how many licensed individuals they are capable of supervising, directing, and controlling based on the services being provided? Note: The Oregon licensed Pharmacist may not supervise more than four licensed pharmacy technicians (COPTs and PTs) among all locations, including the RDSP Affiliated Pharmacy.	OAR 855-139-0050(4)(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13	Does the PIC ensure that Oregon licensed Pharmacists and COPTs complete a training program on the proper use of the telepharmacy system, prior to working at the RDSP?	OAR 855-139-0050(8)

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14	Do both Drug Outlets, RDSP and RDSP Affiliated Pharmacy, ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy?	OAR 855-139-0050(7)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	15	Is the RDSP Affiliated Pharmacy affiliated with more than 2 RDSPs? NOTE: A RDSP Affiliated Pharmacy may not be affiliated with more than 2 RDSPs.	OAR 855-139-0200(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	16	Is the RDSP less than 120 miles from the RDSP Affiliated Pharmacy? How many miles? Note: A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP.	OAR 855-139-0200(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	17	Does the RDSP and RDSP Affiliated Pharmacy have the following? <ul style="list-style-type: none"> • Same owner or written contract that specifies the following: <ul style="list-style-type: none"> ○ 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 855-019, OAR 855-025 and OAR 855-139; • Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system • Train the Oregon licensed Pharmacists and COPTs 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 <ul style="list-style-type: none"> • 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 	OAR 855-139-0200(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	18	Does an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy physically inspect the RDSP at least once every 28 days using the RDSP self-inspection form?	OAR 855-139-0200(3)(i)

Minimum Equipment, Procedures and Records

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	19 Are Drug Outlet Procedures compliant with Oregon laws and rules, and do they reflect the current practice at the outlet? Items to be addressed: <ul style="list-style-type: none"> • Security • Operation, testing and maintenance of the telepharmacy system • Sanitation • Storage of drugs • Dispensing • Oregon licensed Pharmacist supervision, direction, and control of COPTs: • 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; • Delivery of drugs and/or devices; • Utilization of Oregon licensed Pharmacist (e.g. DUR, Counseling) • Recordkeeping; • Patient confidentiality; • 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; and • Controlled Substance: to include date reviewed with staff: <p>Note: All RDSP policies and procedures must be reviewed and revised if necessary, every 12 months by the Pharmacist at the RDSP Affiliated Pharmacy.</p>	OAR 855-139-0500
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	20 Is the RDSP clean (refrigerator, sink, reconstitution equipment, ventilation ducts, etc.)?	OAR 855-139-0150(1)(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	21 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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	22 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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	23 Does the RDSP post signage in a location easily seen by the public that states or provides the following information? <ul style="list-style-type: none"> • “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.” 	OAR 855-139-0155(1)(g)(A)(B)(C)

				<ul style="list-style-type: none"> • 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)." 	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	24	<p>Does the RDSP quarantine and either destroy or return to the supplier all outdated, adulterated, misbranded, and suspect product?</p> <p>Where does the RDSP keep drugs quarantined, awaiting destruction or disposal?</p> <p>Note: A medication that has previously been dispensed to a patient cannot be re-dispensed. It is considered adulterated and must be destroyed or returned to the supplier.</p>	OAR 855-139-0450 OAR 855-139-0455
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	25	<p>Is the RDSP aware that a Drug Take Back Box may be requested free of charge?</p>	https://www.oregon.gov/deq/Hazards-and-Cleanup/hw/Pages/drugtakeback.aspx
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	26	<p>Is the RDSP registered with the DEA as an authorized collector for drug take back disposal?</p> <p>If yes, are the following requirements met?</p> <ul style="list-style-type: none"> • 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 • Adequate security measures for proper installation and maintenance of the collection receptacle 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 	OAR 855-139-0460

				<p>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.</p> <ul style="list-style-type: none"> 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. 	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	27	<p>Is the RDSP aware that pseudoephedrine and ephedrine has moved from a Schedule III to a Schedule V Controlled Substance?</p>	OAR 855-080-0026
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	28	<p>Is the RDSP providing non-prescription pseudoephedrine and ephedrine to patients over the counter?</p> <p>If yes, are the following requirements met:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 	OAR 855-080-0026
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	29	<p>Are prescription labels available in all of the 14 languages required, if requested by the patient or patient's agent?</p> <p>If not, what is the anticipated date of compliance?</p> <p>Note: The prescription must bear a label in both English and the language requested.</p>	OAR 855-139-0410 ORS 689.564
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	30	<p>Does the RDSP provide prescription readers for visually impaired patients? Are prescription readers available and appropriate to address a person's visual impairment?</p>	OAR 855-139-0405 ORS 689.561

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	31	<p>Effective 1/1/2020, a pharmacy shall electronically include the following notifications to the Oregon Prescription Drug Monitoring Program (PDMP):</p> <ul style="list-style-type: none"> The diagnosis code (ICD-10), if it is provided by the prescriber with the prescription The reason for prescription, if it is provided by the prescriber with the prescription Gabapentin prescriptions dispensed <p>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.</p> <p><i>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)</i></p> <p><i>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.</i></p>	OAR 333-023-0810 ORS 431A.855 OAR 333-023-0815
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	32	Is the RDSP aware that it is not permitted to deliver or mail prescriptions to patients?	OAR 855-139-0600(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	33	Is the RDSP aware that non-prescription drugs can only be sold when RDSP Affiliated Pharmacy and RDSP are both open?	OAR 855-139-0220 OAR 855-139-0600

Controlled Substances

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	34	<p>Are controlled substances purchased, stored, or dispensed by the RDSP?</p> <p>Does the RDSP:</p> <ul style="list-style-type: none"> Comply with controlled substance regulations? Store all controlled substances in a secure locked cabinet? Maintain an accurate controlled substance perpetual inventory? Ensure an Oregon licensed Pharmacist conducts a controlled substance inventory at least once every 28 days and reconciles all discrepancies at the time of in person physical inspection? 	OAR 855-139-0225
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	35	<p>Is the pharmacist identifying and CLEARLY DOCUMENTING AND EXPLAINING ALL VARIANCES on CII reconciliations?</p> <p><u>Note: The Board considers a reconciliation to be an accurate accounting of the true inventory, performed at least quarterly.</u></p>	OAR 855-019-0300(5)(e)(h)

				<p>If these records are maintained electronically, they must be accessible and producible at the time of inspection (audit, variances and explanations).</p> <p><u>Working copies</u> showing the audit and all variance explanations for all CII must be kept and will be requested for review at time of inspection.</p> <p>Where are the records located?</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	36	<p>Is the PIC/pharmacy 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?</p>	<p>OAR 855-019-0205(6) OAR 855-139-0130(2) CFR 1306.76(b)</p>
			37	<p>How often are on-hand quantity changes of controlled substances reviewed?</p> <p>By whom?</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	38	<p>Was the controlled substance (CII-V) inventory performed on one day, within 12 months (365 days) of the last inventory?</p> <p>Date of last annual CII-CV inventory:</p> <p>Note: Inventory includes compounding supplies, items in the refrigerator. 24-hour pharmacies must indicate the time frame in which the inventory was completed. Non24-hour pharmacies must indicate if the inventory was completed before opening or after closing.</p>	<p>OAR 855-080-0070</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	39	<p>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?</p>	<p>21 CFR 1304.04</p>
	<input type="checkbox"/>	<input type="checkbox"/>	40	<p>How does the PIC/pharmacy maintain the security of controlled substances that have been quarantined (outdated, adulterated, misbranded or is a suspect product)?</p> <p>Are quarantined controlled substances included in the inventory?</p>	

Security

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	41	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, compounded?	OAR 855-139-0100(1)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	42	Are the PIC and supervising Oregon licensed 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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	43	Is the RDSP locked, and the security system armed to prevent entry when: <ul style="list-style-type: none"> • There is no Oregon licensed pharmacist actively supervising the RDSP? • There is no COPT present at the RDSP? <p>Note: No one may be in the prescription area of the RDSP unless authorized in real-time by an Oregon licensed pharmacist who is supervising the RDSP from the RDSP Affiliated Pharmacy.</p>	OAR 855-139-0100(3) OAR 855-139-0100(5)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	44	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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	45	Are the following in place and properly functioning? <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Identification of the Oregon licensed pharmacist authorizing access and securing the RDSP ○ Identification of the COPT 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: <ul style="list-style-type: none"> ○ Dispensing site entrances ○ Preparation areas ○ Drug storage areas ○ Pick up areas ○ Office areas ○ Publicly accessible areas 	OAR 855-139-0100(6)

Supervision

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	46	Are prescriptions only dispensed from the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician, and the telepharmacy system is fully operational?	OAR 855-139-0210(1)

Yes	No	N/A			Rule Reference
				Note: Prescriptions may only be dispensed when a pharmacist is supervising, and the surveillance system is fully operational.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	47	Does the RDSP ensure that an Oregon licensed Pharmacist supervises, directs, and controls each COPT at the RDSP using continuous audio and visual technology which must be recorded, reviewed and stored?	OAR 855-139-0210(2)
			48	Does the Oregon licensed Pharmacist who is supervising a COPT at the RDSP complete the following? <ul style="list-style-type: none"> • Using professional judgment, determine 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 • 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 24 hours of the review in (3)(b): <ul style="list-style-type: none"> ○ 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 • Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days 	OAR 855-139-0210(3)
			49	Does the RDSP ensure telephone audio is recorded, reviewed, and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician?	OAR 855-139-0210(5)
			50	Has the RDSP developed, implemented, and enforced a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a COPT at the RDSP?	OAR 855-139-0210(6)

Technology

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	51	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)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	52	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: <ul style="list-style-type: none"> • Source container including manufacturer, name, strength, lot, and expiration? 	OAR 855-139-0205(2)

Yes	No	N/A			Rule Reference
				<ul style="list-style-type: none"> 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? 	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	53	Does the RDSP test the telepharmacy system and document that it operates properly before providing pharmacy services?	OAR 855-139-0205(4)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	54	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	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	55	Are only COPTs that have 1 year of experience working at an Oregon registered Retail Drug Outlet Pharmacy during the 3 years preceding the date they begin work at the RDSP?	OAR 855-139-0050(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	56	Are COPTs clearly identified as such to the public?	OAR 855-025-0025(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	57	Is there documentation of COPT training? Be prepared to retrieve documentation of training for ALL COPTs when requested by a Board Compliance Officer.	OAR 855-025-0025(6) OAR 855-139-0050(8)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	58	Do technicians know they cannot communicate with patients in 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. 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.	OAR 855-025-0040(3)(e) OAR 855-019-0200(2)(3) OAR 855-019-0230 OAR 855-139-0600
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	59	Is each COPT 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 855-025-0025(4)

Pharmacists

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	60	Does the RDSP utilize an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed?	OAR 855-139-0215 OAR 855-019-0230(1)(c)

Yes	No	N/A		Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>Does 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?</p> <p>How does the pharmacist document the interaction?</p> <p>Note: The Pharmacist must personally document whether counseling is provided or declined on prescriptions that require counseling at the time of the counseling.</p>	
			<p>61 How does a pharmacist identify a prescription refill as requiring counseling?</p> <p>Note: A pharmacist (not a technician) may indicate that a prescription "renewal" does not require counseling, only if, after performing a DUR, the pharmacist determines <u>nothing</u> has changed (continuation of therapy (CT) and it is appropriate to release the prescription without speaking to the patient).</p>	<p>OAR 855-019-0230</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>62 Is a pharmacist orally counseling on new and refill prescriptions requiring counseling and including information necessary to promote the safe use of the medication?</p> <p>Note: Asking the patient if they have any questions does not fulfill this requirement.</p>	<p>OAR 855-019-0230(1)(a) OAR 855-019-0230(2)</p>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<p>63 Does the pharmacist perform a DUR for all prescriptions (new and refilled) prior to dispensing or preparing for administration?</p> <p>How is DUR performed? Please provide the following details:</p> <p>At which point in the process does a pharmacist perform DUR?</p> <p>Does this process vary depending on the type of fill (new vs refill)?</p>	<p>OAR 855-019-0220(3)</p>

Yes No N/A

Rule Reference

				<p>How is a DUR documented?</p> <p>Note: A Pharmacist must perform DUR on each fill (the computer may assist but does not replace RPH)</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	64	<p>Is the Prescription Drug Monitoring Program (PDMP) utilized when performing a DUR on controlled substances?</p> <p>If no, why not?</p>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	65	Does the Pharmacist capture and maintain allergies and chronic medical conditions for new and existing patients?	OAR 855-019-0220(1) OAR 855-139-0555
			66	How does the Pharmacist ensure that all prescriptions are correctly dispensed?	OAR 855-139-0315
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	67	When a pharmacist receives a telephone prescription, are they documenting their name, the date and the name of the person transmitting the prescription?	OAR 855-019-0210 OAR 855-139-0300
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	68	<p>Does the pharmacist document verification of 'return to stock' medications re-labeled by a COPT?</p> <p>How?</p>	OAR 855-025-0025(4) OAR 855-019-0200
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	69	<p>Is a pharmacist verifying the expiration date on the prescription label is not greater than the manufacturer's expiration date?</p> <p>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;</p>	OAR 855-019-0200(2) OAR 855-139-0400
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	70	Is the Product Identification Label (PIL) on all dispensed medications, including compounded medications?	OAR 855-139-0400(11)

Yes	No	N/A			Rule Reference
			71	How does the pharmacist ensure that a COPT does not ask questions of a patient or patient's agent that may screen and/or limit their interaction with the Pharmacist?	OAR 855-139-0600
			72	Does an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy perform and in person inspection at the RDSP at least once every 28 days that includes a review of temperature recordings and an inventory of controlled substances with reconciliation of discrepancies?	OAR 855-139-0200(3)(i) OAR 855-139-0125(2)(b)(H) OAR 855-139-0225(4)

Drug Storage

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	73	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) <u>or as specified by the manufacturer?</u> 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.	OAR 855-139-0125(2)(a)(A)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	74	Are the thermometers/probes centrally placed, accurate and calibrated? When is the next <u>calibration</u> (to ensure temperature readings are correct) due?	OAR 855-139-0125(2)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	75	Is there documented training for ALL pharmacy personnel related to the drug storage monitoring plan? Where are the records located?	OAR 855-139-0125(2)

Yes	No	N/A		Rule Reference	
			76	<p>Explanation and documentation of ALL drug storage excursions must include at least all the following:</p> <ul style="list-style-type: none"> • 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. <p>Where are the records located?</p>	OAR 855-139-0125(2)(b)(D-E)
			77	Where is the emergency action plan for all refrigerated and frozen medications and vaccines located?	OAR 855-139-0125(2)(F)

Compounding

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	78	<p>Does the RDSP perform compounding?</p> <p>Note: ONLY non-sterile compounding is permitted at an RDSP. An RDSP is not permitted to compound Sterile preparations.</p>	OAR 855-139-0230 OAR 855-139-0600
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	79	Does an Oregon licensed 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

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

Records

Yes	No	N/A		Rule Reference	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	80	<p>Are all records and documentation required by rules retained for a total of 3 years, records being stored at a minimum on site for 1 year?</p> <p>Note: The RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.</p>	OAR 855-139-0550(1)(2)

Yes No N/A

Rule Reference

Yes	No	N/A			Rule Reference
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	81	Does the RDSP and RDSP Affiliated Pharmacy maintain the following records for 3 years? <ul style="list-style-type: none">• 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• Pharmacist determination of adequate staff for completion of audio record review• Med paks,• Drug disposal• Patient services records (EPT, naloxone, etc.)• Any errors or irregularities identified by the quality improvement program.	OAR 855-139-0550(3)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	82	Does the RDSP and RDSP Affiliated Pharmacy maintain the following records for 6 months? Note: Data, telephone audio and surveillance data must be retained for 6 months	OAR 855-139-0550(3)(h)

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 Name of PIC:

License #:

Signature of PIC:

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	FULL OREGON LICENSE NUMBER	OREGON LICENSE EXPIRATION DATE	LICENSEE'S SIGNATURE (*Signature indicates attestation that I have read and understand the elements of this form*)