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CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: 2021 SB 629 allows use of telepharmacy to deliver pharmacy services at a remote location

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RULES:
855-019-0300, 855-139-0001, 855-139-0005, 855-139-0010, 855-139-0015, 855-139-0020, 855-139-0025, 855-139-0030, 855-139-0050, 855-139-0100, 855-139-0120, 855-139-0125, 855-139-0130, 855-139-0150, 855-139-0155, 855-139-0200, 855-139-0205, 855-139-0210, 855-139-0215, 855-139-0220, 855-139-0225, 855-139-0230, 855-139-0300, 855-139-0305, 855-139-0310, 855-139-0315, 855-139-0320, 855-139-0325, 855-139-0350, 855-139-0355, 855-139-0400, 855-139-0405, 855-139-0410, 855-139-0450, 855-139-0455, 855-139-0460, 855-139-0500, 855-139-0550, 855-139-0555, 855-139-0600, 855-139-0602, 855-139-0650, 855-139-0710, 855-139-0715, 855-139-0720, 855-139-0725, 855-139-0730

AMEND: 855-019-0300

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-019-0300
Duties of a Pharmacist-in-Charge ¶

(1) In accordance with Division 41 of this chapter of rules, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) employed on a regular basis.¶
(2) In order to be a PIC, a pharmacist must have:¶
(a) Completed at least one year of pharmacy practice; or¶
(b) Completed a board approved PIC training course either before the appointment or within 30 days after the appointment. With the approval of the board, this course may be employer provided and may qualify for continuing education credit.¶
(3) A pharmacist may not be designated PIC of more than ~~two~~three pharmacies without prior written approval by the board. If such approval is given, the pharmacist must comply with the requirements in sub-section (4)(e) of this rule.¶
(4) The PIC must perform the following the duties and responsibilities:¶
(a) When a change of PIC occurs, both outgoing and incoming PICs must report the change to the board within 15 days of the occurrence, on a form provided by the board;¶

(b) The new PIC must complete an inspection on the PIC Annual Self-Inspection Form, within 15 days of becoming PIC;¶
(c) The PIC may not authorize non-pharmacist employees to have unsupervised access to the pharmacy, except in the case of hospitals that do not have a 24-hour pharmacy where access may be granted as specified in OAR 855-041-0120;¶
(d) In a hospital only, the PIC is responsible for providing education and training to the nurse supervisor who has been designated to have access to the pharmacy department in the absence of a pharmacist;¶
(e) A pharmacist designated as PIC for more than one pharmacy must personally conduct and document a quarterly compliance audit at each location. This audit must be on the Quarterly PIC Compliance Audit Form provided by the board;¶
(f) If a discrepancy is noted on a board inspection, the PIC must submit a plan of correction within 30 days of receiving notice.¶
(g) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.¶
(5) The PIC is responsible for ensuring that the following activities are correctly completed:¶
(a) An inventory of all controlled substances must be taken within 15 days before or after the effective date of change of PIC, and must be dated and signed by the new PIC. This inventory must be maintained in the pharmacy for three years and in accordance with all federal laws and regulations;¶
(b) Verifying, on employment and as appropriate, but not less than annually, the licensure of all pharmacy personnel who are required to be licensed by the board;¶
(c) Conducting an annual inspection of the pharmacy using the PIC Annual Self-Inspection Form provided by the board, by February 1 each year. The completed self-inspection forms must be signed and dated by the PIC and maintained for three years from the date of completion;¶
(d) Conducting an annual inventory of all controlled drugs as required by OAR 855-080;¶
(e) Performing a quarterly inventory reconciliation of all Schedule II controlled drugs.¶
(f) Ensuring that all pharmacy staff have been trained appropriately for the practice site. Such training should include an annual review of the PIC Self-Inspection Report;¶
(g) Implementing a quality assurance plan for the pharmacy.¶
(h) The records and forms required by this section must be filed in the pharmacy, made available to the board for inspection upon request, and must be retained for three years.¶
(6) The PIC, along with other licensed pharmacy personnel, must ensure that the pharmacy is in compliance with all state and federal laws and rules governing the practice of pharmacy and that all controlled substance records and inventories are maintained in accordance with all state and federal laws and rules.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-139-0001

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0001
Purpose and Scope
The purpose of OAR 855-139 is to provide minimum requirements for the locations where telepharmacy services are conducted.
Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0005

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0005
Definitions
The following words and terms, when used in OAR 855-139, have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section has the definition set out in OAR 855-006.¶
(1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.¶
(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 USC 262(k)(3)(A)(i) (12/01/2021).¶
(3) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 USC 262(k)(4) (12/01/2021).¶
(4) "RDSP Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system. ¶
(5) "Reference biological product" means the biological product licensed pursuant to 42 USC 262(a) (12/01/2021) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.¶
(6) "Remote Dispensing Site Pharmacy" or "RDSP" means an Oregon location registered as a Retail Drug Outlet Remote Dispensing Site Pharmacy staffed by a Certified Oregon Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system.¶
(7) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug. ¶
(8) "Still image capture" means a specific image captured electronically from a video or other image capture device.¶
(9) "Store and forward" means a video or still image record which is saved electronically for future review.¶
(10) "Telepharmacy" means the delivery of pharmacy services by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician.¶
(11) "Telepharmacy system" means a system of telecommunications technologies that enables monitoring, documenting and recording of the delivery of pharmacy services at a remote location by an electronic method which must include the use of audio and video, still image capture, and store and forward.
Statutory/Other Authority: ORS 689.205, ORS 689.522, 2021 SB 629
Statutes/Other Implemented: ORS 689.522, ORS 689.564, 2021 SB 629

ADOPT: 855-139-0010

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0010
Registration: General
(1) A location in Oregon where the practice of pharmacy occurs by an Oregon licensed Pharmacist through the use of a telepharmacy system to a patient at a remote location staffed by a Certified Oregon Pharmacy Technician must be registered by the board in Oregon as a Retail Drug Outlet RDSP. ¶
(2) If controlled substances are stored in the RDSP, the RDSP must have an active Controlled Substance Registration Certificate with the board and Drug Enforcement Administration (DEA).¶
(3) A Retail Drug Outlet RDSP application must specify the RDSP Affiliated Pharmacy and cannot operate without a RDSP Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.¶
(4) All registration renewal applications must be accompanied by the annual fee and must contain the same information required in OAR 855-139-0011(3) and (4).¶
(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.¶
(6) Retail Drug Outlet RDSP registration expires March 31, annually. If the annual registration fee referred to in OAR 855-110 is not paid by March 31 of the current year, a late fee as set out in OAR 855-110 must be included with the application for registration renewal.¶
(7) The registration is not transferable and the registration fee cannot be prorated.¶
(8) No RDSP may be operated until a certificate of registration has been ¶
issued to the pharmacy by the board.
Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, 2021 SB 629

ADOPT: 855-139-0015

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0015
Registration: Application
(1) An application for registration of a new RDSP must be accompanied by a floor plan drawn to scale and must be approved by the board prior to opening.¶
(2) The application must specify the location of the RDSP and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:¶
(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;¶
(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests must be indicated on the application.¶
(3) Upon request by the board, the applicant must furnish such information as required by the board regarding the partners, stockholders, or other persons not named in the application.¶
(4) A certificate of registration will be issued upon board approval of the application.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0020

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0020
Registration: Change of Owner, Location, or RDSP Affiliated Pharmacy
(1) A change of location of the RDSP Affiliated Pharmacy or location of the Retail Drug Outlet RDSP requires:¶
(a) Submission of a new Retail Drug Outlet RDSP application 15 days prior to occurrence; ¶
(b) Registration fee;¶
(c) Approval of the board; and¶
(d) New certificate of registration. ¶
(2) A change in the RDSP Affiliated Pharmacy or ownership of the Retail Drug Outlet RDSP requires:¶
(a) Submission of a new Retail Drug Outlet RDSP application 15 days prior to occurrence; ¶
(b) Registration fee;¶
(c) Approval of the board; and¶
(d) New certificate of registration. ¶
(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.¶
(4) A certificate of registration will be issued upon board approval of the application.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0025

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0025
Registration: Change of Business Name or Closure
(1) A RDSP Affiliated Pharmacy must notify the board 15 days prior to any change of business name of a Retail Drug Outlet RDSP. The change must be reported by filing a new application for which no fee is required. ¶
(2) A RDSP Affiliated Pharmacy must notify the board 15 days prior to discontinuing operation of a Retail Drug Outlet RDSP. Notification must include the: ¶
(a) Final disposition of drugs stored in the Retail Drug Outlet RDSP including:¶
(A) Name and location where the drugs are transferred; ¶
(B) Name and location where destruction occurred; and¶
(C) Name and location of the site that will store all records;¶
(c) Transfer all Schedule II medications on DEA 222 forms, and Schedule III, IV and V by invoice;¶
(d) Provide the board with:¶
(A) Oregon Board of Pharmacy state license(s); and¶
(B) Signed statement giving the effective date of closure; and¶
(e) Comply with the requirements of 21 CFR 1301.52 (04/01/2021).
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0030

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0030
Non-Resident Pharmacies
(1) For the purpose of these rules, a non-resident pharmacy includes a RDSP Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet RDSP located in Oregon.¶
(2) Each non-resident RDSP Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.¶
(3) To qualify for registration under these rules, every non-resident RDSP Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.¶
(4) Each out-of-state non-resident RDSP Affiliated Pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of the RDSP. To qualify for this designation, the person must:¶
(a) Hold a license to practice pharmacy in the resident state;¶
(b) Be normally working for the RDSP Affiliated Pharmacy a minimum of 20 hours per week;¶
(c) Complete the annual RDSP PIC self-inspection report prior to February 1 each year; and¶
(d) Provide the PIC self-inspection report as requested by the board.¶
(5) Every non-resident RDSP Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in Oregon prior to initial registration of the RDSP.¶
(6) The PIC must comply with the requirements of OAR 855-019-0300.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225

ADOPT: 855-139-0050

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0050
Personnel
(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy is responsible for all operations at the RDSP including responsibility for the telepharmacy system and enforcing policies and procedures.¶
(2) A RDSP may not utilize Interns, Pharmacy Technicians, or unlicensed personnel. ¶
(3) A Certified Oregon Pharmacy Technician working at a RDSP is required to have at least one year experience working at an Oregon registered Retail Drug Outlet Pharmacy during the three years preceding the date the Certified Oregon Pharmacy Technician begins working at the RDSP.¶
(4) The Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy who is supervising a RDSP must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided. ¶
(5) When supervising a Certified Oregon Pharmacy Technician working at a RDSP, the Oregon licensed Pharmacist may supervise no more than four licensed pharmacy technicians among all locations, including the RDSP Affiliated Pharmacy. ¶
(6) The RDSP Affiliated Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.¶
(7) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy. ¶
(8) Prior to working at a RDSP, the Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the RDSP must have completed a training program on the proper use of the telepharmacy system.¶
(9) A RDSP Affiliated Pharmacy that terminates or allows a board licensee to resign in lieu of termination must report the termination or resignation to the board within 10 working days.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

ADOPT: 855-139-0100

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0100
Security
(1) The area in a registered RDSP where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.¶
(2) The RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the RDSP is 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.¶
(3) The RDSP must be locked and the security system armed to prevent entry when:¶
(a) There is no Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy actively supervising the RDSP; or¶
(b) There is no Certified Oregon Pharmacy Technician present in the RDSP.¶
(4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.¶
(5) No one may be in the prescription area of a RDSP unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the RDSP and from the RDSP Affiliated Pharmacy.¶
(6) Minimum security methods must include a properly functioning:¶
(a) Alarm system with an audible alarm at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy;¶
(b) Electronic keypad or other electronic entry system that records the:¶
(A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;¶
(B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the RDSP; and¶
(C) Date and time of each activity. ¶
(c) 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:¶
(A) Dispensing site entrances;¶
(B) Preparation areas;¶
(C) Drug storage areas;¶
(D) Pick up areas;¶
(E) Office areas; and¶
(F) Publicly accessible areas.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0120

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0120
Drug: Procurement
RDSP may only receive drugs from an Oregon Registered Drug Outlet (i.e. Wholesaler, Manufacturer or Pharmacy).
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0125

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0125
Drug: Storage
(1) A RDSP must maintain proper storage of all drugs. This includes, but is not limited to the following:¶
(a) All drugs must be stored according to manufacturer's published or USP guidelines.¶
(b) All drugs must be stored in appropriate conditions of temperature, light, humidity, sanitation, ventilation, and space.¶
(c) Appropriate storage conditions must be provided for, including during transfers between facilities and to patients.¶
(d) A RDSP must quarantine drugs which are outdated, adulterated, misbranded or suspect. Cold Storage and Monitoring.¶
(2) A RDSP must store all drugs at the proper temperature according to manufacturer's published guidelines (pursuant to FDA package insert or USP guidelines).¶
(a) All drug refrigeration systems must:¶
(A) Maintain refrigerated products between 2 to 8 □C (35 to 46 □F); frozen products between -25 to -10 □C (-13 to 14 □F); or as specified by the manufacturer.¶
(B) Utilize a centrally placed, accurate, and calibrated thermometer;¶
(C) Be dedicated to pharmaceuticals only;¶
(D) Be measured continuously and documented either manually twice daily to include minimum, maximum and current temperatures; or with an automated system capable of creating a producible history of temperature readings. ¶
(b) A RDSP must adhere to a monitoring plan, which includes, but is not limited to:¶
(A) Documentation of training of all personnel;¶
(B) Maintenance of manufacturer recommended calibration of thermometers;¶
(C) Maintenance of records of temperature logs for a minimum of three years;¶
(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;¶
(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;¶
(F) A written emergency action plan; ¶
(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and¶
(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.¶
(3) Vaccine Drug Storage:¶
(a) A RDSP that stores vaccines must comply with section two of this rule and the following:¶
(A) Vaccines must be stored in the temperature stable sections of the refrigerator;¶
(B) A centrally placed and accurate buffered probe thermometer, such as glycol or glass beads, calibrated within a plus or minus 0.5 □C variance must be utilized;¶
(C) Each freezer and refrigerator compartment must have its own exterior door and independent thermostat control;¶
(D) A system of continuous temperature monitoring with automated data logging and physical confirmation must be utilized. Documentation of the temperature of each active storage unit must be logged at least twice daily, data must be downloaded weekly, and system validations must be conducted quarterly; and¶
(E) Must adhere to a written quality assurance process to avoid temperature excursions.¶
(4) A retail drug outlet may store drugs in another location that is registered as a Drug Room and meets all Pharmacy drug storage and security requirements.
Statutory/Other Authority: ORS 689.205, ORS 689.325
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0130

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0130
Drug: Loss
A RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Ensure that disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs or devices are reported to the board immediately.¶
(2) Ensure that confirmed significant drug loss or any loss related to suspected drug theft of a controlled substance is reported to the board within one business day. ¶
(3) Ensure that a Report of Theft or Loss of Controlled Substances (DEA Form 106) or Report of Theft or Loss of Listed Chemicals (DEA Form 107) is sent to the Drug Enforcement Administration, a copy is sent to the board at the same time.
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.315
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0150

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0150
Outlet: Sanitation
A RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Ensure the RDSP is kept clean.¶
(2) Ensure the Certified Oregon Pharmacy Technician working in the RDSP practices appropriate infection control.
Statutory/Other Authority: ORS 689.305
Statutes/Other Implemented: ORS 689.305

ADOPT: 855-139-0155

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0155
Outlet: Minimum Equipment Requirements
(1) Each Oregon Retail Drug Outlet RDSP must have the following:¶
(a) Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) services offered by the outlet; ¶
(b) 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;¶
(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based on the services offered by the outlet;¶
(d) Appropriate equipment to maintain the proper storage of drugs;¶
(e) Appropriate equipment and supplies as required by Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;¶
(f) A sink with running hot and cold water;¶
(g) Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶
(A) Stating "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." The printing on this sign must be in block letters not less than one inch in height. ¶
(B) Providing notification in each of the languages required in OAR 855-139-0062 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy dispenses prescriptions for a patient's self-administration;¶
(C) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services are provided by the pharmacy per OAR 855-139-0215; and¶
(D) Stating "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)." The printing on the sign must be in block letters not less than one inch in height; and¶
(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.¶
(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0200

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0200
Outlet: General Requirements
(1) A RDSP Affiliated Pharmacy may not be affiliated with more than two Remote Dispensing Site Pharmacies.¶
(2) A RDSP Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the RDSP. ¶
(3) A RDSP and its RDSP Affiliated Pharmacy must:¶
(a) Have the same owner; or¶
(b) Have a written contract that specifies:¶
(A) The services to be provided by each licensee and registrant;¶
(B) The responsibilities of each licensee and registrant; and¶
(C) The accountabilities of each licensee and registrant;¶
(c) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025 and OAR 855-139;¶
(d) Comply with all applicable federal and state laws and rules;¶
(e) Designate in writing the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;¶
(f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians in the operation of the telepharmacy system and RDSP;¶
(g) Develop, implement and enforce a continuous quality improvement program for dispensing services from a RDSP designed to objectively and systematically:¶
(A) Monitor, evaluate, document the quality and appropriateness of patient care; ¶
(B) Improve patient care; and¶
(C) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence;¶
(h) 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; and¶
(i) 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 Pharmacist-in-charge of the RDSP Affiliated Pharmacy. The inspection must utilize the RDSP self-inspection form, be documented and records retained.
Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: 2021 SB 629, ORS 689.155

ADOPT: 855-139-0205

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0205
Outlet: Technology
A RDSP and its RDSP Affiliated Pharmacy must:¶
(1) 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;¶
(2) 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 Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy can visually identify each:¶
(a) Source container including manufacturer, name, strength, lot, and expiration;¶
(b) Source ingredient including the imprint and physical characteristics if compounding; ¶
(c) Dispensed product including the imprint and physical characteristics; ¶
(d) Completed prescription container including the label; and ¶
(e) Ancillary document provided to patient at the time of dispensing.¶
(3) Utilize barcode, radio-frequency identification or quick response code technology to record information in (2) if available;¶
(4) Test the telepharmacy system and document that it operates properly before providing pharmacy services; and¶
(5) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system.
Statutory/Other Authority: ORS 689.205, 2021 SB 629
Statutes/Other Implemented: 2021 SB 629, ORS 689.155

ADOPT: 855-139-0210

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0210
Outlet: Supervision
A RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician, and the telepharmacy system is fully operational;¶
(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician at the RDSP using continuous audio and visual technology which must be recorded, reviewed and stored;¶
(3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a RDSP must:¶
(a) 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 10% of patient interactions observed or reviewed; ¶
(b) 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;¶
(c) Document the following within 24 hours of the review in (3)(b):¶
(A) Number of each licensee's patient interactions;¶
(B) Number of each licensee's patient interactions pharmacist is reviewing; ¶
(C) Date and time of licensee patient interaction pharmacist is reviewing; ¶
(D) Date and time of pharmacist review of licensee's patient interaction; and¶
(E) Pharmacist notes of each interaction reviewed; and¶
(d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days. ¶
(4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.¶
(5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician.¶
(6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the RDSP.
Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

ADOPT: 855-139-0215

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0215
Outlet: Pharmacist Utilization
A RDSP and its RDSP Affiliated Pharmacy must:¶
(1) 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; and¶
(2) Utilize an Oregon licensed Pharmacist and 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 when counseling is required under OAR 855-019-0230 and when requested and document the interaction.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0220

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0220
Outlet: Non-Prescription Drugs
If non-prescription drugs are offered for sale at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Ensure that the Certified Oregon Pharmacy Technician does not provide advice, information that requires judgment, or recommendations involving non-prescription drugs; and¶
(2) Ensure that an Oregon-licensed Pharmacist is immediately available to provide counseling or¶ recommendations involving non-prescription drugs.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0225

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0225
Outlet: Controlled Substances
If controlled substances are at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Comply with controlled substance regulations; ¶
(2) Store all controlled substances in a secure locked cabinet;¶
(3) Maintain an accurate controlled substance perpetual inventory; and¶
(4) 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.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0230

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0230
Outlet: Non-Sterile Compounding
If non-sterile preparations are compounded at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:¶
(1) Adhere to the requirements of OAR 855-045;¶
(2) Ensure an Oregon licensed Pharmacist:¶
(a) Supervises via a real-time audio-visual connection all steps of the compounding; and¶
(b) Documents and visually verifies each item required in OAR 855-139-0041.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0300

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0300
Prescription: General Requirements
(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, it must be transmitted to the Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy and both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.¶
(2) Each RDSP must document the following information for each prescription:¶
(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal.¶
(b) If for an animal, the name of the patient, name the owner and the species of the animal.¶
(c) The full name, address, and contact phone number of the practitioner. If for a controlled substance, the Drug Enforcement Administration registration number of the practitioner and other number as authorized under rules adopted by reference under rule OAR 855-080-0085;¶
(d) The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;¶
(e) The directions for use, if given by the practitioner; and¶
(f) The date of filling, and the total number of refills authorized by the prescribing practitioner.¶
(3) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.¶
(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any one of the following phrases or notations:¶
(A) No substitution;¶
(B) N.S.;¶
(C) Brand medically necessary;¶
(D) Brand necessary;¶
(E) Medically necessary;¶
(F) D.A.W. (Dispense As Written); or¶
(G) Words with similar meaning.¶
(b) For an electronically transmitted prescription, the prescriber or prescriber's agent must clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.¶
(c) Such instructions must not be default values on the prescription.¶
(4) A RDSP or Oregon licensed Pharmacist filling a prescription or order for a biological product may not substitute a biosimilar product for the prescribed biological product unless:¶
(a) The biosimilar product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;¶
(b) The prescribing practitioner has not designated on the prescription that substitution is prohibited;¶
(c) The patient for whom the biological product is prescribed is informed of the substitution prior to dispensing the biosimilar product;¶
(d) The RDSP or Oregon licensed Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and¶
(5) The RDSP must dispense prescriptions accurately and to the correct party.
Statutory/Other Authority: ORS 689.205, ORS 689.522
Statutes/Other Implemented: ORS 689.505, ORS 689.515, ORS 689.522

ADOPT: 855-139-0305

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0305
Prescription: Tamper-resistant
When the use of a tamper-resistant prescription is required by any federal or state law or rule, the term "tamper-resistant" has the meaning as defined in OAR 855-006-0015.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0310

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0310
Prescription: Verification of Authenticity
Alteration of a written prescription, other than by an Oregon licensed Pharmacist's or practitioner's authorization, in any manner constitutes an invalid order unless verified with the prescriber.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

ADOPT: 855-139-0315

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0315
Prescription: Refills
(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III, IV and V are limited to five refills or six months from date of issue, whichever comes first.¶
(2) If the practitioner is not available and in the professional judgment of the Oregon licensed Pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the Oregon licensed Pharmacist may authorize the Certified Oregon Pharmacy Technician to prepare for pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner must be promptly notified of the emergency refill.¶
(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include;¶
(a) The identity of the Certified Oregon Pharmacy Technician and responsible Oregon licensed Pharmacist;¶
(b) Name of the patient;¶
(c) Name of the medication;¶
(d) Date of refill; and¶
(e) Quantity dispensed.¶
(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.¶
(5) A retail pharmacy may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required, unless the requested fill or refill is part of an auto-refill program and is a continuation of therapy.¶
(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.¶
(7) Auto-Refill Programs. A mail order or retail pharmacy, excluding cycle-fill for long term care, may use a program that automatically refills non-controlled prescription medications, that have existing refills available and are consistent with the patient's current medication therapy only when the following conditions are met:¶
(a) A patient or patient's agent must enroll each prescription medication in an auto-refill program before a pharmacy can include the prescription medication as part of the auto-refill program; ¶
(b) The prescription is not a controlled substance; ¶
(c) The pharmacy must discontinue auto-refill program enrollment when requested by the patient or patient's agent; ¶
(d) Pick-up notification to a patient or patient's agent may be generated upon completion of a prescription refill; and¶
(e) When an auto-refill prescription is returned to stock or when delivery is refused that prescription medication is removed from the auto-refill program for that patient.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515

ADOPT: 855-139-0320

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0320
Prescription: Expiration
This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.¶
(1) After one year from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.¶
(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.¶
(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.¶
(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed one year.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515

ADOPT: 855-139-0325

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0325
Prescription: Transfers
(1) Prescriptions may be transferred between pharmacies for the purpose of refill dispensing provided that:¶
(a) The prescription is invalidated at the sending pharmacy; and¶
(b) The receiving pharmacy obtains all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability.¶
(2) Prescriptions for controlled substances can only be transferred one time.¶
(3) Pharmacies using the same electronic prescription database are not required to transfer prescriptions for dispensing purposes.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0350

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0350
Dispensing: Containers
Each pharmacy must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (04/01/2021), 16 CFR 1701 (04/01/2021), and 16 CFR 1702 (04/01/2021). ¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0355

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0355
Dispensing: Customized Patient Medication Packages
In lieu of dispensing two or more prescribed drug products in separate containers, an Oregon licensed Pharmacist may, with the consent of the patient, the patient's caregiver, or a prescriber, provide a customized patient medication package (patient med pak). A patient med pak is a package prepared by a Certified Oregon Pharmacy Technician and verified by a pharmacist for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms. The patient med pak is so designed for each container is so labeled as to indicate the day and time, or period of time, that the contents within each container are to be taken:¶
(1) Label:¶
(a) The patient med pak must bear a label stating:¶
(A) The name of the patient;¶
(B) A serial number for each patient med pak itself and a separate identifying serial number for each of the prescription orders for each of the drug products contained therein;¶
(C) The name, strength, physical description or identification, and total quantity of each drug product contained therein;¶
(D) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;¶
(E) Any storage instructions or cautionary statements required by the official compendia;¶
(F) The name of the prescriber of each drug product;¶
(G) The date of preparation of the patient med pak and the beyond-use date assigned to the patient med pak (such beyond-use date must be no later than 60 days from the date of preparation);¶
(H) The name, address, and telephone number of the dispenser and the dispenser's registration number where necessary; and¶
(I) Any other information, statements, or warnings required for any of the drug products contained therein.¶
(b) If the patient med pak allows for the removal or separation of the intact containers therefrom, each individual container must bear a label identifying each of the drug products contained therein.¶
(2) Labeling: The patient med pak must be accompanied by a patient package insert, in the event that any medication therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the RDSP for the total patient med pak.¶
(3) Packaging:¶
(a) In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med pak must comply with the moisture permeation requirements for a Class B single-unit or unit-dose container. Each container must be either not reclosable or so designed as to show evidence of having been opened;¶
(b) There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus the patient med pak, if it does not meet child-resistant standards must be placed in an outer package that does comply, or the necessary consent of the purchaser or physician, to dispense in a container not intended to be child-resistant, must be obtained.¶
(4) Guidelines: It is the responsibility of the dispenser, when preparing a patient med pak, to take into account any applicable compendia requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the medications. In this regard, pharmacists are encouraged to report to USP headquarters any observed or report incompatibilities.¶
(5) Recordkeeping: In addition to any individual prescription filing requirements, a record of each patient med pak must be made and filed. Each record must contain, as a minimum:¶
(a) The name and address of the patient;¶
(b) The serial number of the prescription order for each drug product contained therein;¶
(c) The name of the manufacturer or labeler and lot number for each drug product contained therein;¶
(d) Information identifying or describing the design, characteristics, or specifications of the patient med pak sufficient to allow subsequent preparation of an identical patient med pak for the patient;¶

(e) The date of preparation of the patient med pak and the beyond-use date that was assigned;¶
(f) Any special labeling instructions; and¶
(g) The name or initials of the Certified Oregon Pharmacy Technician who prepared the med pak and the Oregon licensed Pharmacist who verified the patient med pak.¶
(6) Ensure an Oregon licensed Pharmacist visually verifies and documents each item required in OAR 855-139-0041 for each individual dosage unit in the med pak.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0400

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0400
Labeling: General Requirements
Prescriptions must be labeled with the following information:¶
(1) Name, address and telephone number of the RDSP;¶
(2) Date;¶
(3) Identifying number;¶
(4) Name of patient;¶
(5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶
(6) Directions for use by the patient;¶
(7) Name of practitioner;¶
(8) Required precautionary information regarding controlled substances;¶
(9) Such other and further accessory cautionary information as required for patient safety;¶
(10) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the Oregon licensed Pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date must not be dispensed beyond the said expiration date of the drug; ¶
(11) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, must be labeled with its physical description, including any identification code that may appear on tablets and capsules; and¶
(12) Address and telephone number of the RDSP Affiliated Pharmacy.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515

ADOPT: 855-139-0405

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0405
Labeling: Prescription Reader Accessibility
(1) A pharmacy must notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request; a prescription reader is a device designed to audibly convey labeling information. ¶
(2) If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy must provide to the person a prescription reader that is available to the person for at least the duration of the prescription, must confirm it is appropriate to address the person's visual impairment, and must ensure that prescription labels are compatible with the prescription reader. This requirement does not apply to an institutional drug outlet, dispensing a drug intended for administration by a healthcare provider. ¶
(3) The pharmacy must ensure an Oregon licensed Pharmacist verifies and documents that the correct electronic label was placed on each prescription container and that the audio information produced by the prescription reader is accurate prior to dispensing the prescription.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.561

ADOPT: 855-139-0410

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0410
Labeling: Limited English Proficiency and Accessibility
1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.¶
(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in both English and one of the following languages: ¶
(a) Spanish;¶
(b) Russian;¶
(c) Somali;¶
(d) Arabic;¶
(e) Chinese (simplified);¶
(f) Vietnamese;¶
(g) Farsi;¶
(h) Korean;¶
(i) Romanian;¶
(j) Swahili;¶
(k) Burmese;¶
(l) Nepali;¶
(m) Amharic; and¶
(n) Pashtu.¶
(3) The board must reassess and update (2) as necessary and at least every ten years.
Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205

ADOPT: 855-139-0450

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0450
Drugs and Devices: Disposal
Drugs and devices that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0455

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0455
Drug and Devices: Return
A Certified Oregon Pharmacy Technician may accept the return of a drug or device as defined by ORS 689.005 once the drug or device have been dispensed from the pharmacy if they were dispensed in error, were defective, adulterated, misbranded, dispensed beyond their expiration date, or are subject of a drug or device recall only if:¶
(1) An Oregon licensed Pharmacist has approved the return; ¶
(2) The drugs or devices are accepted for destruction or disposal; and ¶
(3) An Oregon licensed Pharmacist verifies the destruction or disposal.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305

ADOPT: 855-139-0460

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0460
Drugs and Devices: Take-back Program
(1) A RDSP that operates a drug take-back collection program or that participates in a drug take-back program under ORS 459A.200 to ORS 459A.266 as an authorized collector must be registered with the DEA as an authorized collector to collect controlled and non-controlled drugs for destruction.¶
(2) A RDSP that operates as a Drug Enforcement Agency (DEA) authorized collector must notify the board within 30 days of initiating or terminating the program and must establish and enforce policies and procedures, including but not limited to:¶
(a) Provision of a secure location of the collection receptacle inside the retail drug outlet, which is accessible to the public, within view of the pharmacy counter and must not be located behind the pharmacy counter; and¶
(b) Provision of adequate security measures, including proper installation and maintenance of the collection receptacle, tracking of liners, documentation and key accountability; and¶
(c) Personnel training and accountability.¶
(3) A RDSP must inform consumers to directly deposit drugs into the collection receptacle. Pharmacy personnel must not count, sort, inventory, or otherwise handle drugs collected.¶
(4) A RDSP must not dispose of drugs from pharmacy stock in a collection receptacle.¶
(5) The liner must be inserted and removed from a locked collection receptacle only by or 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.¶
(6) Liners that have been removed from a collection receptacle and immediately sealed must be 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.¶
(7) 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.¶
(8) A RDSP must maintain all drug disposal records for a minimum of 3 years.¶
(9) Authorized collectors are required to comply with the following federal and state laws: ¶
(a) ORS 459A.200, ORS 459A.203, ORS 459A.206, ORS 459A.209, ORS 459A.212, ORS 459A.215, ORS 459A.218, ORS 459A.221, ORS 459A.224, ORS 459A.227, ORS 459A.230, ORS 459A.233, ORS 459A.236, ORS 459A.239, ORS 459A.242, ORS 459A.245, ORS 459A.248, ORS 459A.251, ORS 459A.254, ORS 459A.257, ORS 459A.260, ORS 459A.263, and ORS 459A.266;¶
(b) OAR 340-098-0000, OAR 340-098-0010, OAR 340-098-0300, OAR 340-098-0350, OAR 340-098-0370, and OAR 340-098-0390;¶
(c) 21 CFR 1317.30 (04/01/2020), 21 CFR 1317.35 (04/01/2020), 21 CFR 1317.40 (04/01/2020), 21 CFR 1317.55 (04/01/2020), 21 CFR 1317.60 (04/01/2020), 21 CFR 1317.65 (04/01/2020), 21 CFR 1317.70 (04/01/2020), 21 CFR 1317.75 (04/01/2020), 21 CFR 1317.80 (04/01/2020), and 21 CFR 1317.85 (04/01/2020); and¶
(d) 21 USC 822 (04/01/2021), 21 USC 822a (04/01/2021).
Statutory/Other Authority: ORS 689.205, ORS 459A.266
Statutes/Other Implemented: ORS 689.305, ORS 459A.203, ORS 459A.215, ORS 495A.218

ADOPT: 855-139-0500

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0500
Policies and Procedures
(1) The Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and the RDSP Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the RDSP. The written policies and procedures must be maintained at the RDSP Affiliated Pharmacy and the RDSP and must be available to the board upon request. ¶
(2) The written policies and procedures must include at a minimum the responsibilities of the RDSP Affiliated Pharmacy and each RDSP including;¶
(a) Security;¶
(b) Operation, testing and maintenance of the telepharmacy system;¶
(c) Sanitation;¶
(d) Storage of drugs;¶
(e) Dispensing;¶
(f) Oregon licensed Pharmacist supervision, direction and control of pharmacy technicians;¶
(g) Documenting the identity, function, location, date and time of the licensees engaging in telepharmacy;¶
(h) Drug and/or device procurement;¶
(i) Receiving of drugs and/or devices;¶
(j) Delivery of drugs and/or devices; ¶
(k) Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);¶
(l) Recordkeeping;¶
(m) Patient confidentiality;¶
(n) On-site inspection by an Oregon licensed Pharmacist;¶
(o) Continuous quality improvement;¶
(p) Plan for discontinuing and recovering services if telepharmacy system disruption occurs;¶
(q) Training: initial and ongoing; and¶
(r) Interpretation, translation and prescription reader services.¶
(3) If non-prescription drugs are offered for sale at the RDSP, the policies and procedures must outline the process for the Oregon licensed Pharmacist counseling and advice.¶
(4) If non-sterile preparations are compounded at the RDSP, the policies and procedures must meet the requirements of OAR 855-045.¶
(5) If controlled substances are stored at the RDSP, the policies and procedures must include the following processes:¶
(a) Reviewing of controlled substance prescriptions for unauthorized alterations and inspected for legitimacy by the Oregon licensed Pharmacist during inspection visits;¶
(b) Maintaining an accurate controlled substance perpetual inventory for all controlled substances that are stocked at the RDSP; and¶
(c) Conducting and reconciling the controlled substance inventory.¶
(6) A RDSP Affiliated Pharmacy that provides remote pharmacy services through a telepharmacy system at a RDSP must review its written policies and procedures every 12 months, revise them if necessary, and document the review.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0550

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0550
Records: General Requirements
(1) The recordkeeping requirements OAR 855-139 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.¶
(2) The RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.¶
(3) Records retained by the Drug Outlet must include, but are not limited to:¶
(a) Patient profiles and records;¶
(b) Date, time and identification of each individual and activity or function performed;¶
(c) 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;¶
(d) Controlled substance inventory and reconciliation;¶
(e) Oregon licensed Pharmacist physical inspection of RDSP;¶
(f) Audio and visual connection testing and individual training on use of the audio and visual connection; ¶
(g) Still image capture and store and forward images must be retained according to (1); ¶
(h) Data, telephone audio and surveillance data must be retained for 6 months; and¶
(i) Any errors or irregularities identified by the quality improvement program.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.508

ADOPT: 855-139-0555

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0555
Records: Patient
A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The pharmacist must make a reasonable effort to obtain, record, and maintain the following information:¶
(1) Full name of the patient for whom the drug is intended;¶
(2) Address and telephone number of the patient;¶
(3) Patient's age or date of birth;¶
(4) Patient's gender;¶
(5) Chronic medical conditions;¶
(6) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;¶
(7) Known allergies, drug reactions, and drug idiosyncrasies; and¶
(8) If deemed relevant in the Oregon licensed Pharmacist's professional judgment:¶
(a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and¶
(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508

ADOPT: 855-139-0600

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0600
Prohibited Practices: General
A Retail Drug Outlet RDSP may not:¶
(1) Allow a Certified Oregon Pharmacy Technician to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;¶
(2) Advertise or otherwise purport to operate as a pharmacy or to advertise or purport to provide pharmacy services unless the person is registered with the board pursuant to ORS 689.305.¶
(3) Deliver a prescription;¶
(4) Compound sterile preparations; or¶
(5) Repackage drugs.
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0602

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0602
Prohibited Practices: Disclosure of Patient Information
A Retail Drug Outlet RDSP may not:¶
(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule.¶
(2) A licensee may disclose patient information:¶
(a) To the board;¶
(b) To a practitioner, Oregon licensed Pharmacist, Intern, Pharmacy Technician, or Certified Oregon Pharmacy Technician, if disclosure is authorized by an Oregon-licensed Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or well-being; or¶
(c) To a third-party when disclosure is authorized or required by law; or¶
(d) As permitted pursuant to federal and state patient confidentiality laws; or¶
(e) To the patient or to persons as authorized by the patient.¶
(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.
Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0650

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0650
Grounds for Discipline
The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:¶
(1) Unprofessional conduct as defined in OAR 855-006-0020;¶
(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:¶
(a) Is false, fraudulent, deceptive, or misleading; or¶
(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.¶
(3) Failure to provide a working environment that protects the health, safety and welfare of a patient which includes but is not limited to:¶
(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with an Oregon licensed Pharmacist's ability to practice with reasonable competency and safety.¶
(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.¶
(c) Adequate time for an Oregon licensed Pharmacist to complete professional duties and responsibilities including, but not limited to:¶
(A) Drug Utilization Review;¶
(B) Verification of the accuracy of a prescription; ¶
(C) Counseling; and¶
(D) All other duties and responsibilities of an Oregon licensed Pharmacist as specified in OAR 855-019.¶
(4) Introducing external factors such as productivity or production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.¶
(5) Incenting or inducing the transfer of a prescription absent professional rationale.
Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-139-0710

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0710
Service: Epinephrine- Definitions
The following words and terms, when used in OAR 855-139-0210 through OAR 855-139-0211 have the following meanings, unless the context clearly indicates otherwise.¶
(1) "Allergic reaction" means a medical condition caused by exposure to an allergen, with physical symptoms that may be life threatening, ranging from localized itching to severe anaphylactic shock and death.¶
(2) "Authorization to Obtain Epinephrine" means a certificate that contains the name, signature, and license number of the supervising professional authorizing the dispensing of epinephrine to the individual whose name appears on the certificate. Additionally, the certificate contains a record of the number of epinephrine orders filled to date.¶
(3) "Statement of Completion" means a certificate that states the specific type of emergency the trainee was trained to respond to, the trainee's name and address, the name of the authorized trainer and the date that the training was completed.¶
(4) "Trainee" means an individual who has attended and successfully completed the formal training pursuant to the protocols and criteria established by the Oregon Health Authority, Public Health Division.
Statutory/Other Authority: ORS 689.205, ORS 689.681
Statutes/Other Implemented: ORS 689.681, ORS 689.155

ADOPT: 855-139-0715

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0715
Service: Epinephrine- General Requirements
(1) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification an order for epinephrine to be used by trainees to treat an anaphylactic reaction. Trainees must be 18 years of age or older and must have responsibility for or contact with at least one (1) other person as a result of the trainee's occupation or volunteer status, such as, but not limited to, a camp counselor, scout leader, forest ranger, school employee, tour guide or chaperone.¶
(2) Individuals must successfully complete a training program approved by the Oregon Health Authority, Public Health Division. Upon successful completion, the trainee will receive the following certificates:¶
(a) Statement of Completion; and¶
(b) Authorization to Obtain Epinephrine.¶
(3) Acquisition of epinephrine from a pharmacy to be used for the treatment of allergic emergencies may occur in the following manners:¶
(a) An Oregon licensed Pharmacist may dispense epinephrine to a trainee upon presentation of the Statement of Completion and Authorization to Obtain Epinephrine certificate to a pharmacy when:¶
(A) An Oregon licensed Pharmacist may generate a prescription for and dispense an emergency supply of epinephrine for not more than one adult and one child dose package, as specified by the supervising professional whose name, signature, and license number appear on the Authorization to Obtain Epinephrine certificate.¶
(B) The Oregon licensed Pharmacist who generates the hardcopy prescription for epinephrine in this manner must reduce the prescription to writing and file the prescription in a manner appropriate for a non-controlled substance.¶
(C) Once the Oregon licensed Pharmacist generates the epinephrine prescription, the Certified Oregon Pharmacy Technician must write in the appropriate space provided on the Authorization to Obtain Epinephrine certificate the date and the number of doses dispensed, the Oregon licensed Pharmacist must verify the accuracy of data written on the certificate and the Certified Oregon Pharmacy Technician must return the completed certificate to the trainee.¶
(D) The Statement of Completion and the Authorization to Obtain Epinephrine certificate may be used to obtain epinephrine up to four (4) times within three (3) years from the date of the initial training.¶
(E) Both the Statement of Completion and the Authorization to Obtain Epinephrine certificate expire three (3) years from the date of the trainee's last Oregon Health Authority approved allergy response training.¶
(F) Upon completion of the training, the trainee will receive a new Statement of Completion and Authorization to Obtain Epinephrine certificate, with a valid duration of three (3) years.¶
(b) A Certified Oregon Pharmacy Technician may prepare for Oregon licensed Pharmacist verification epinephrine to be dispensed to an entity when:¶
(A) The epinephrine is acquired by a valid prescription presented to the pharmacy;¶
(B) The prescription identifies the entity as the patient for the purpose of prescribing and labeling the prescription.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 433.825

ADOPT: 855-139-0720

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RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0720
Service: Naloxone- General Requirements
Pharmacies providing naloxone services must establish, maintain and enforce written procedures including, but not limited to:¶
(1) Providing a workflow process and physical location that maintains confidentiality and is not susceptible to distraction; ¶
(2) Documentation and recordkeeping: and¶
(3) Provide written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.305, ORS 689.681, ORS 689.682

ADOPT: 855-139-0725

NOTICE FILED DATE: 10/25/2021

RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0725
Service: Expedited Partner Therapy (EPT)- Purpose
(1) There is substantial evidence that rates of re-infection with certain sexually transmitted diseases can be reduced by treating all sexual partners for the disease, even when the treating clinician has not examined those partners. This practice is known as Expedited Partner Therapy.¶
(2) Because of the important public health implications, the 2009 Oregon Legislature passed HB 3022 authorizing this practice. This law permits health professional regulatory boards to adopt rules permitting practitioners to practice Expedited Partner Therapy.¶
(3) The law specifies that a prescription issued in the practice of Expedited Partner Therapy is valid, even if the name of the patient the prescription is intended for is not on the prescription.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505

ADOPT: 855-139-0730

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RULE SUMMARY: Revision to Divisions 019 and creation of Division 139 is necessary to allow for provision of pharmacy services via telepharmacy to a patient at a remote location allowed by 2021 SB 629.

CHANGES TO RULE:

855-139-0730
Service: Expedited Partner Therapy (EPT) - Procedures
(1) "Expedited Partner Therapy (EPT)" means the practice of prescribing or dispensing an antibiotic drug for the treatment of a sexually transmitted disease to the partner of a patient without first examining that partner.¶
(2) Notwithstanding any other rules in this division that mandate requirements for a valid prescription and for labeling, when a prescription is marked EPT or a similar notation by the prescribing practitioner, this rule govern.¶
(3) An EPT prescription may only be dispensed for a drug that has been determined by the Oregon Health Authority (OHA) to be appropriately used for EPT.¶
Prescription¶
(4) An EPT treatment protocol must conform to the following:¶
(a) It must include a prescription for each named or unnamed partner of the patient;¶
(b) It must contain a handwritten or electronic signature of the prescribing practitioner;¶
(c) The practitioner must identify the prescription in the following manner:¶
(A) Write "for EPT," or a similar notation, on the face of the prescription;¶
(B) For a verbal order, the practitioner must identify the prescription as an "EPT Prescription," or similar identification;¶
(C) The practitioner must identify the prescription for each partner either by including the name of the patient, such as "John Doe - Partner 1" or by labeling the prescription as "EPT Partner"¶
(d) An EPT Prescription expires 30 days after the date written;¶
(e) An EPT Prescription may not be refilled;¶
(f) If any component of the prescription is missing, the Oregon licensed Pharmacist must contact the prescriber or the prescriber's agent and must record the additional information on the prescription.¶
(5) A patient may give the prescription to each unnamed partner for that person to fill at a pharmacy of their choice; or the patient may give all prescriptions to one pharmacy and then give the dispensed drugs to each unnamed partner.¶
Labeling¶
(6) The Certified Oregon Pharmacy Technician must label the drug for the named patient in accordance with normal procedures as specified in the other rules of this division, however when either the patient or partner is unnamed, the pharmacy may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.¶
(7) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identity this number on each corresponding prescription label.¶
Counseling¶
(8) The Oregon licensed Pharmacist is not required to obtain an EPT patient's or partner's name, address, or demographics; however, the Oregon licensed Pharmacist must:¶
(a) Provide counseling in the form of written patient information to accompany each prescription for each partner and ask the patient about any known allergies or other drugs being taken by each partner. The Oregon licensed Pharmacist should advise the patient to encourage each partner to call the pharmacist before taking the drug if they have experienced any adverse effect from a drug in the past or if they are taking other drugs;¶
(b) Document counseling.¶
Records¶
(9) All documentation required by this rule must be attached to the prescription and must be referenced to each partner's prescription. Such documentation must be retained in accordance with the other rules in this division and must be made available to the board upon request.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505