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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/26/2022 2:44 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Removes certain personnel and ratio requirements for Remote Dispensing Site Pharmacies

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Portland, OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 05/24/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Proposed amendments include adding 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician', removing requirement for similar work experience and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2022 HB 4034 <https://olis.oregonlegislature.gov/liz/2022R1/Downloads/MeasureDocument/HB4034/Enrolled>

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

There are racial and ethnic disparities in geographic access to pharmacies. Remote Dispensing Site Pharmacies are an option to add pharmacy access in current pharmacy deserts. Given the critical role of prescription medications in the prevention and treatment of chronic conditions, ensuring access to pharmacies has implications for population health and health disparities. By permitting both Pharmacy Technicians and Certified Oregon Pharmacy Technicians to work in a RSDP, removing the work experience and ratio requirements for this setting, more RDSPs may be able to open, and Oregonians may have increased access to pharmacy services.

FISCAL AND ECONOMIC IMPACT:

Pharmacies are not required to operate a Remote Dispensing Site Pharmacy. No fiscal impact is anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the Oregon Board of Pharmacy, small businesses, or members of the public. If a pharmacy chooses to operate a Remote Dispensing Site Pharmacy via telepharmacy, the pharmacy will be required to apply and pay a registration fee for the Remote Dispensing Site Pharmacy as well as required to comply with all Oregon Administrative Rules and Oregon Revised Statutes.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of the proposed amendments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

Proposed amendments are directives of 2022 HB 4034.

RULES PROPOSED:

855-139-0005, 855-139-0010, 855-139-0050, 855-139-0100, 855-139-0150, 855-139-0200, 855-139-0210, 855-139-0220, 855-139-0315, 855-139-0355, 855-139-0455, 855-139-0600, 855-139-0715, 855-139-0730

AMEND: 855-139-0005

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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) "RDSP Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon where an Oregon licensed Pharmacist provides pharmacy services through a telepharmacy system. ¶

(2) "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 or Pharmacy Technician under the supervision, direction and control of an Oregon licensed Pharmacist using a telepharmacy system. ¶

(3) "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 or

Pharmacy Technician.¶

(4) "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~~ ORS 689.700, 2022 HB 4034

Statutes/Other Implemented: ORS 689.522, ORS 689.564, ~~2021 SB 629~~ ORS 689.700, 2022 HB 4034

AMEND: 855-139-0010

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 or 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) AThe 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)~~(2).¶

(5) The initial and annual registration fee for pharmacies is set out in OAR 855-110.¶

(6) The 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~~ORS 689.700, 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ~~2021 SB 629~~ORS 689.700, 2022 HB 4034

AMEND: 855-139-0050

RULE SUMMARY: Amends (2) by removing 'Pharmacy Technicians' and adds 'may not perform any pharmacy services' after 'Unlicensed Personnel'. Amends (4) by removing 'the RDSP', adds 'or Pharmacy Technician' after Certified Oregon Pharmacy Technician, adds 'adequately trained to perform their duties and' and removes experience requirements and pharmacist to technician ratio pursuant to directives of 2022 HB 4034.

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 Phar. Unlicensed personnel macy 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. not perform any pharmacy services.¶¶~~

~~(43) The Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy who is supervising a RDSP must determine and document how many licensed individuals the pPharmacist is capable of supervising, directing and controlling based on the services being provided.¶¶~~

~~(54) WWhen 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 RDSP Affiliated Pharmacy and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are required to comply with the pPharmacist's determination in (43) and retain records.¶¶~~

~~(75) The RDSP and RDSP Affiliated Pharmacy must ensure adequate staffing at both the RDSP and RDSP Affiliated Pharmacy.¶¶~~

~~(86) Prior to working at a RDSP, the Certified Oregon RDSP Affiliated Pharmacy, and the Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy are responsible for ensuring the Certified Oregon Pharmacy Technician or Pharmacy Technician and the Oregon licensed Pharmacist supervising the RDSP must are adequately trained to perform their duties and have completed a training program on the proper use of the telepharmacy system.¶¶~~

~~(97) 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305, 2022 HB 4034

AMEND: 855-139-0100

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 alarm system armed to prevent, deter and detect 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 or Pharmacy Technician present in the RDSP; or¶
 - (c) Any component of the surveillance system is not functioning.¶
- (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 at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy if unauthorized access occurs;¶
 - (b) Electronic entry system that is controlled by an Oregon licensed Pharmacist and records the:¶
 - (A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;¶
 - (B) Identification of the Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the RDSP; and¶
 - (C) Date and time of each activity. ¶
 - (c) Surveillance system that utilizes continuously accessible and recorded video 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-139-0150

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 or Pharmacy Technician working in the RDSP practices appropriate infection control.

Statutory/Other Authority: ORS 689.305, 2022 HB 4034

Statutes/Other Implemented: ORS 689.305, 2022 HB 4034

AMEND: 855-139-0200

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 or Pharmacy Technicians authorized to access the RDSP and operate the telepharmacy system;¶¶
 - (f) Train the Oregon licensed Pharmacists and Certified Oregon Pharmacy Technicians or 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~~ ORS 689.700, 2022 HB 4034

Statutes/Other Implemented: ~~2021 SB 629, ORS 689.155~~ ORS 689.155, ORS 689.700, 2022 HB 4034

AMEND: 855-139-0210

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' and pursuant to directives of 2022 HB 4034. Adds 'reasonable' to (3)(a) before 'professional judgment.'

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 or Pharmacy Technician, and the surveillance system is fully operational;¶

(2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician or Pharmacy Technician at the RDSP using an audiovisual communication system. All patient interactions must be recorded, reviewed and stored;¶

(3) The Oregon licensed Pharmacist who is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician at a RDSP must:¶

(a) Using reasonable 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 phPharmacist 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 phPharmacist is reviewing; ¶

(C) Date and time of licensee patient interaction phPharmacist is reviewing; ¶

(D) Date and time of phPharmacist 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 phPharmacist'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 or 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 or Pharmacy Technician at the RDSP.

Statutory/Other Authority: ORS 689.205, ORS 689.225, 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305, 2022 HB 4034

AMEND: 855-139-0220

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 or 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-139-0315

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034. Adds 'reasonable' to (2) before 'professional judgment'.

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 reasonable 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 or 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 or 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.505, ORS 689.515, 2022 HB 4034

AMEND: 855-139-0355

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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 or 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 or 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 855-139-0041-205 for each individual dosage unit in the med pak.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-139-0455

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

CHANGES TO RULE:

855-139-0455

Drug and Devices: Return

A Certified Oregon Pharmacy Technician or 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.305, 2022 HB 4034

AMEND: 855-139-0600

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

CHANGES TO RULE:

855-139-0600

Prohibited Practices: General

A Retail Drug Outlet RDSP may not:¶

- (1) Allow a Certified Oregon Pharmacy Technician or 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-139-0715

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

CHANGES TO RULE:

855-139-0715

Service: Epinephrine- General Requirements

(1) A Certified Oregon Pharmacy Technician or 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 or 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 or 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 or 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, ORS 433.825, 2022 HB 4034

AMEND: 855-139-0730

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034.

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.¶

(4) Prescription;¶

(4a) An EPT treatment protocol must conform to the following:¶

(aA) It must include a prescription for each named or unnamed partner of the patient;¶

(bB) It must contain a handwritten or electronic signature of the prescribing practitioner;¶

(cC) 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.¶

(5) Labeling;¶

(6a) The Certified Oregon Pharmacy Technician or 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.¶

(7b) The Oregon licensed Pharmacist must assign a separate and unique identifier to each prescription and clearly identify this number on each corresponding prescription label.¶

(6) 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.¶

(7) 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.505, 2022 HB 4034