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## NOTICE OF PROPOSED RULEMAKING INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855  
BOARD OF PHARMACY

FILED

10/21/2022 11:13 AM

ARCHIVES DIVISION

SECRETARY OF STATE

FILING CAPTION: Pharmacy Prescription Kiosk; Establishes new Division 141 and new registration type

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/22/2022 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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971-673-0001

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800 NE Oregon St., Suite 150

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: 11/22/2022

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](http://www.oregon.gov/pharmacy/pages/rulemaking-information) or email your contact information to [pharmacy.rulemaking@bop.oregon.gov](mailto: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:

146 611 440#

for audio only.

You must submit written comments before 4:30PM on November 22, 2022. Email written comments to [pharmacy.rulemaking@bop.oregon.gov](mailto:pharmacy.rulemaking@bop.oregon.gov).

### NEED FOR THE RULE(S)

Proposed rules would establish a new registration type for Pharmacy Prescription Kiosk. Adds new Division 141 which contains requirements for the operation of a Pharmacy Prescription Kiosk by a PPK Affiliated Pharmacy.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2022-2026 Strategic Plan [https://www.oregon.gov/pharmacy/Documents/OBOP\\_Strategic\\_Plan\\_2022-2026.pdf](https://www.oregon.gov/pharmacy/Documents/OBOP_Strategic_Plan_2022-2026.pdf)

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

The proposed rules may positively impact Oregonian's ability to access and pick up prescriptions without having to physically visit an open pharmacy.

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## FISCAL AND ECONOMIC IMPACT:

On 9/6/2022 the agency sent out a fiscal impact request for estimated costs associated with compliance, implementation and operation of a PPK. The request was sent via GovDelivery to 5,004 Drug Outlet, PIC and Pharmacy email addresses and to 2,813 board meeting/rulemaking interested party email addresses. The agency received 1 response from MedAvail who stated that their pricing is proprietary and based on project size and scope.

Pharmacies are not required to operate a PPK. If a pharmacy chooses to operate a PPK, the PPK Affiliated Pharmacy will be required to apply and pay a registration fee of \$225 for the PPK and be required to comply with all Oregon Administrative Rules and Oregon Revised Statutes. We do anticipate that licensed drug outlets may be financially impacted in order to comply with the proposed rules.

Pharmacies that choose to deploy kiosks will generate revenue from prescription and over-the-counter drug sales to help offset the cost of compliance with these proposed rules. Presumably, Pharmacy Prescription Kiosk owners will achieve revenues in excess of expenses in the deployment of this technology.

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## 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).

OBOP- Fiscal impact is estimated to be minimal for the agency and limited to administrative and compliance costs. There is no anticipated fiscal impact to other state agencies, units of local government or the public. There are approximately 113 small business drug outlet pharmacies registered with the board. It is not anticipated that the cost of compliance for small business would be different from that of a non-small business.

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

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

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

The board held a technology forum during the August 2020 board meeting where vendors presented information and resources for the board's consideration prior to drafting proposed rules.

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## RULES PROPOSED:

855-019-0300, 855-141-0001, 855-141-0005, 855-141-0010, 855-141-0015, 855-141-0020, 855-141-0030, 855-141-0050, 855-141-0100, 855-141-0120, 855-141-0125, 855-141-0130, 855-141-0145, 855-141-0150, 855-141-0155, 855-141-0200, 855-141-0205, 855-141-0210, 855-141-0215, 855-141-0225, 855-141-0300, 855-141-0305, 855-141-0310, 855-141-0315, 855-141-0320, 855-141-0325, 855-141-0345, 855-141-0350, 855-141-0400, 855-141-0405, 855-141-0410, 855-141-0450, 855-141-0455, 855-141-0500, 855-141-0550, 855-141-0555, 855-141-0600, 855-141-0602, 855-141-0650

AMEND: 855-019-0300

RULE SUMMARY: Proposed amendments adds "Pharmacy Prescription Kiosks in OAR 855-141" to (3), amends (4)(f) by adding "the time allowed by the board." and removes (4)(f)(A)(B) language related to number of days when a PIC must submit a plan of correction upon receiving a deficiency or non-compliance notice.

CHANGES TO RULE:

855-019-0300

Duties of a Pharmacist-in-Charge ¶

- (1) In accordance with OAR 855-041 and OAR 855-139, a pharmacy must, at all times have one Pharmacist-in-Charge (PIC) who is normally present in the pharmacy 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 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. A Pharmacy Prescription Kiosks in OAR 855-141 and Pharmacy Prescription Lockers in OAR 855-143 does not count toward this limit.¶
- (4) The PIC must perform the following the duties and responsibilities:¶
- (a) When a change of PIC occurs, both the 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:¶
- (A) 15 days of receiving a deficiency notice; or¶
- (B) 30 days of receiving a non-compliance notice the time allowed by the board.¶
- (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: 855-141-0001

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

**855-141-0001**

**Purpose and Scope**

The purpose of OAR 855-141 is to provide minimum requirements for the operation of a Pharmacy Prescription Kiosk (PPK) by a PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0005

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0005

Definitions

The following words and terms, when used in OAR 855-141, 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) "Pharmacy Prescription Kiosk Affiliated Pharmacy" or "PPK Affiliated Pharmacy" means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Kiosk.¶

(2) "Pharmacy Prescription Kiosk" or "PPK" means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Kiosk using a mechanical system that stores and dispenses patient-specific prescription and non-prescription drugs, devices, and related supplies.¶

(3) "Telepharmacy system" means a system of telecommunications technologies that enables documenting and recording of the delivery of pharmacy services at a remote location by an electronic method.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0010

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0010

Registration: General

- (1) Each PPK located in Oregon must be registered as a Retail Drug Outlet PPK.¶
- (2) A controlled substance registration will not be issued for a Retail Drug Outlet PPK.¶
- (3) A Retail Drug Outlet PPK application must specify the PPK Affiliated Pharmacy and cannot operate without a PPK Affiliated Pharmacy that is registered by the board as a Retail Drug Outlet Pharmacy.¶
- (4) Each registration renewal application must be accompanied by the annual fee and must contain the same information required in OAR 855-141-0015(2) and additional information requested by the board.¶
- (5) The initial and annual registration fee for a PPK is set out in OAR 855-110.¶
- (6) A Retail Drug Outlet PPK registration expires March 31, annually. If the annual registration fee 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.¶
- (8) The registration fee cannot be prorated.¶
- (9) A PPK must not operate until a certificate of registration has been issued by the board.¶
- (10) The PPK Affiliated Pharmacy registration and the PPK registration must be on display at both the PPK Affiliated Pharmacy and at the PPK.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0015

Registration: Application

- (1) An application for registration of a PPK may be accessed on the board website.¶
- (2) The board may issue a license to a qualified applicant after the receipt of:¶
- (a) A completed application including:¶
- (A) Payment of the fee prescribed in OAR 855-110;¶
- (B) A floor plan drawn to scale with the location of the:¶
- (i) PPK within the building; ¶
- (ii) Surveillance system cameras; and¶
- (iii) Alarm system panel; and¶
- (C) A detailed explanation and supporting documentation relating to the PPK Affiliated Pharmacy regarding all conduct that is required to be disclosed; ¶
- (b) The PPK Affiliated Pharmacy name, Retail Drug Outlet registration number and Pharmacist-in-Charge; and¶
- (c) 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; and¶
- (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, if applicable, 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 registration may be denied for any of the following:¶
- (a) Failure to completely and accurately answer all questions on the application for registration or renewal of registration;¶
- (b) Failure to disclose any requested information on the application or requests resulting from the application; or ¶
- (c) Any other grounds found in ORS 689.405.¶
- (5) An application submitted to the board that is not complete within 90 days from applicant submission will be expired. Once expired, an applicant who wishes to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees. While a new application and documentation is required, the board may still consider information that was provided in previous applications.¶
- (6) The certificate of registration for a PPK must be issued prior to opening.¶
- (7) The registration for a PPK expires March 31 in each year and may be renewed annually.
- Statutory/Other Authority: ORS 475.035, ORS 689.205
- Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-141-0020

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0020

Registration: Change of Physical Address or Location

(1) A change of physical address of the PPK requires: ¶

(a) Submission of a new PPK application a minimum of 15 days prior to occurrence; ¶

(b) Registration fee; ¶

(c) Approval of the board; and ¶

(d) Issuance of a new certificate of registration. ¶

(2) A change of location at the same physical address of the PPK requires the submission of an updated floor plan drawn to scale a minimum of 15 days prior to the change with the new location of the: ¶

(a) PPK within the building; ¶

(b) Surveillance system cameras; and ¶

(c) Alarm system panel.

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-141-0030

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0030

Non-Resident PPK Affiliated Pharmacies

(1) For the purpose of these rules, a non-resident pharmacy includes a PPK Affiliated Pharmacy located outside of Oregon and providing pharmacy services under OAR 855-141 with a PPK located in Oregon.¶

(2) Each non-resident PPK Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy as a Retail Drug Outlet Pharmacy.¶

(3) To qualify for registration under these rules, every non-resident PPK Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.¶

(4) The Pharmacist-in-Charge (PIC) of the non-resident PPK Affiliated Pharmacy is the PIC for each PPK.¶

(5) The PIC is responsible for ensuring that the PPK PIC self-inspection form is correctly completed prior to February 1 each year.¶

(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, ORS 689.527

ADOPT: 855-141-0050

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0050

Personnel

(1) A PPK must have a PIC at all times. ¶

(2) Prior to utilizing a PPK, a Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPK.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0100

Security

(1) The PPK Affiliated Pharmacy, the PPK, PIC of the PPK Affiliated Pharmacy and each Pharmacist supervising the PPK is responsible for the security of the PPK including provisions for adequate safeguards against loss, theft or diversion of prescription and non-prescription drugs, devices, and related supplies, and records for such drugs, devices and related supplies.¶

(2) The PPK Affiliated Pharmacy must ensure the PPK:¶

(a) Is placed in a secure indoor location that is climate controlled and protected from the elements;¶

(b) Is securely fastened to a permanent structure so that it cannot be removed;¶

(c) Stores prescription and non-prescription drugs, devices, and related supplies in compliance with the provisions of OAR 855-141-0125;¶

(3) The PPK must be secured to prevent access when:¶

(a) There is no Pharmacist supervising and authorizing access in real-time to the PPK; or¶

(b) There is no Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician employed by the PPK Affiliated Pharmacy present at the PPK; or¶

(c) Any component of the PPK is not functioning.¶

(4) A record must be maintained with the name and Oregon license number of each person accessing the PPK.¶

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician must only access the PPK when a Pharmacist is supervising the licensee and has authorized access to the PPK in real-time.¶

(6) Unlicensed personnel (e.g. service or repair personnel) must only access the PPK when escorted and continuously observed by a licensee who is authorized by the Pharmacist who is supervising and authorizing access to the PPK in real-time.¶

(7) Minimum security methods must include a properly functioning:¶

(a) Alarm system at the PPK and real-time notification to a Pharmacist from the PPK Affiliated Pharmacy if unauthorized access occurs;¶

(b) Electronic entry system that is controlled by a Pharmacist and records the:¶

(A) Identification of the Pharmacist authorizing each access and securing the PPK;¶

(B) Identification of the Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician accessing and securing the PPK; and¶

(C) Date and time of each activity; and¶

(c) Surveillance system that utilizes continuously accessible and recorded video between the PPK Affiliated Pharmacy and the PPK. The system must provide a clear view of the entire PPK including its access points.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0120

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0120

Drug: Procurement

A PPK must only receive prescription and non-prescription drugs, devices, and related supplies from the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0125

Drug: Storage

- (1) A PPK 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 PPK must quarantine drugs which are outdated, adulterated, misbranded or suspect.  
(2) A PPK 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 (35.6 to 46.4°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 PPK 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 a 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 Pharmacist at the time of in person physical inspection.

Statutory/Other Authority: ORS 689.205, ORS 689.325

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0130

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0130

Drug: Loss

A PPK and its PPK 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 is reported to the board within one business day.

Statutory/Other Authority: ORS 689.205, ORS 689.305, ORS 689.315

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0145

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0145

Outlet: Closure

A PPK Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPK.

Notification must include the:

(1) Final disposition of drugs stored in the PPK 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;

(2) Provide the board with:

(a) Oregon Board of Pharmacy state license(s); and

(b) Signed statement giving the effective date of closure.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-141-0150

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0150

Outlet: Sanitation

A PPK and its PPK Affiliated Pharmacy must ensure the PPK is kept clean.

Statutory/Other Authority: ORS 689.305, ORS 689.527

Statutes/Other Implemented: ORS 689.305

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0155

Outlet: Minimum Equipment Requirements

(1) Each Oregon PPK must have the following:¶

(a) 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 PPK outlet;¶

(b) Appropriate equipment to maintain the proper storage of drugs;¶

(c) Signage in a location easily seen by the public at the PPK where prescription and non-prescription drugs, devices, and related supplies are dispensed;¶

(A) Stating "The (insert name of PPK Affiliated 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 855-141-0410 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) Stating "This location is a Pharmacy Prescription Kiosk, supervised by a Pharmacist from (insert name of PPK Affiliated Pharmacy, address, and telephone number)." The printing on the sign must be in block letters not less than one inch in height; and¶

(D) Providing notification of accurate hours of operation at the PPK; and¶

(d) Additional equipment and supplies that are determined as necessary by the PPK Affiliated Pharmacy or PIC.¶

(e) As an alternative to posting the required signage, PPK's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPK may display the information required by sub-paragraphs (1)(c)(A) - (D) electronically.¶

(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).

Statutory/Other Authority: ORS 689.205, ORS 689.654

Statutes/Other Implemented: ORS 689.155, ORS 689.515, ORS 689.654, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0200

Outlet: General Requirements

- (1) The PPK Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPK.
  - (2) A PPK Affiliated Pharmacy may operate more than one PPK.
  - (3) A PPK Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPK.
  - (4) A PPK and its PPK 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 prescription and non-prescription drugs, devices, and related supplies are dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, OAR 855-041 and OAR 855-141;
    - (d) Ensure that the PPK Affiliated Pharmacy prevents duplicate dispensing of a prescription;
    - (e) Comply with all applicable federal and state laws and rules;
    - (f) Ensure that there is an PIC who is responsible for all operations and enforcing all policies and procedures of the PPK;
    - (g) Designate in writing the Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians authorized to access the PPK;
    - (h) Utilize complete chain of custody tracking;
    - (i) Train the Pharmacists, Interns, Certified Oregon Pharmacy Technicians and Pharmacy Technicians in the operation of the telepharmacy system and PPK and document the training;
    - (j) Develop, implement and enforce a continuous quality improvement program for dispensing services from a PPK 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;
    - (k) Provide a telephone number that a patient, patient's agent or prescriber may use to contact the Pharmacist from the PPK Affiliated Pharmacy; and
    - (l) Develop, implement and enforce a process for an in person physical inspection of the PPK by a Pharmacist at least once every 28 days or more frequently as deemed necessary by the PIC of the PPK Affiliated Pharmacy. The inspection must utilize the PPK self-inspection form, be documented, and records retained.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0205

Outlet: Technology

A PPK and its PPK Affiliated Pharmacy must:¶

- (1) Utilize a shared telepharmacy system and have appropriate technology or interface to allow access to information required to dispense prescription and non-prescription drugs, devices, and related supplies and counsel the patient or patient's agent.¶
- (2) Utilize barcode, radio-frequency identification or quick response code technology for stocking, destocking and dispensing at the PPK.¶
- (3) Test the telepharmacy system and PPK and verify the unit is operable and functioning in all aspects in accordance with minimum acceptable system or unit design specifications before dispensing prescription and non-prescription drugs, devices, and related supplies and after an upgrade or change is made to the system. The PPK Affiliated Pharmacy must make the results of such testing available to the board upon request; and¶
- (4) Develop, implement and enforce a plan for routine maintenance of the telepharmacy system and PPK.¶
- (5) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the PPK is not fully operational and functioning.¶
- (6) For verification of prescriptions, use still image capture or store and forward with a camera that is of sufficient quality and resolution so that the Pharmacist from the PPK Affiliated Pharmacy can visually identify each:¶
  - (a) Source container including manufacturer, name, strength, lot, and expiration;¶
  - (c) Dispensed product including the imprint and physical characteristics if applicable;¶
  - (d) Completed prescription container including the label; and¶
- (7) Utilize barcode, radio-frequency identification or quick response code technology to record information in (6) if available.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0210

Outlet: Supervision

A PPK and its PPK Affiliated Pharmacy must:

(1) Ensure prescription and non-prescription drugs, devices, and related supplies are only dispensed at the PPK if a Pharmacist is available for patient consultation and the PPK is fully operational.

(2) Ensure that stocking and destocking of prescription and non-prescription drugs, devices, and related supplies in a PPK is completed under the supervision, direction, and control of a Pharmacist.

(3) Ensure that a Pharmacist verifies and documents that:

(a) All prescription and non-prescription drugs, devices, and related supplies were correctly stocked into the PPK;

(b) All prescription and non-prescription drugs, devices, and related supplies destocked from the PPK were returned to the PPK Affiliated Pharmacy;

(c) Proper storage conditions were maintained during transfer per OAR 855-141-0125; and

(d) Records are maintained per OAR 855-141-0550.

(4) Drugs and devices destocked from a PPK that satisfy the requirements of this section may be returned to stock at the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205, ORS 689.225

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-141-0215

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0215

Outlet: Pharmacist Utilization

A PPK and its PPK Affiliated Pharmacy must ensure that a prescription drug or device is not released from the PPK until the Pharmacist or Intern has:

(1) Provided counseling when required under OAR 855-019-0230 or when requested by the patient or patient's agent; and

(2) Documented the interaction.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0225

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0225

Outlet: Controlled Substances

Controlled substances must not be stored in the PPK.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0300

Prescription: General Requirements

- (1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization.¶
- (2) Each PPK Affiliated Pharmacy 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.¶
- (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 must use 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 PPK or Pharmacist filling a prescription or order for a biological product must 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 PPK Affiliated Pharmacy or Pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three business days of dispensing the biosimilar product; and¶
- (5) The PPK 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: 855-141-0305

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0305

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: 855-141-0310

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0310

Prescription: Verification of Authenticity

Alteration of a written prescription, other than by a 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

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0315

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.¶

(2) If the practitioner is not available and in the reasonable professional judgment of the Pharmacist from the PPK Affiliated Pharmacy an emergency need for the refill of a prescription drug has been demonstrated, the Pharmacist may authorize the PPK to prepare for Pharmacist verification a sufficient quantity of the drug consistent with the dosage regimen, 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 by the PPK Affiliated Pharmacy. This record must include:¶

(a) Date, time and identification of each individual and activity or function performed;¶

(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 psychotherapeutic drug and the prescriber is notified of the change.¶

(5) A PPK may only dispense a prescription refill upon request of the patient or patient's agent. A request specific to each prescription medication is required.¶

(6) A prescription must be refilled in context with the approximate dosage schedule unless specifically authorized by the prescriber.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.505, ORS 689.515

ADOPT: 855-141-0320

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0320

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 "PRN" is used as a prescription refill designation:¶

(a) The abbreviation means that the prescription can be refilled in proper context for a period of one year.¶

(b) In conjunction with a definite time period, or a specific number of refills, the prescription 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: 855-141-0325

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0325

Prescription: Transfers

(1) Prescriptions may be transferred between pharmacies for the purpose of an initial or 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.¶

(4) An Oregon registered pharmacy must transfer a prescription.¶

(a) To a pharmacy requesting a transfer on behalf of the patient or patient's agent unless the transfer would compromise patient safety or violate state or federal laws or rules; and¶

(b) By the end of the next business day of the request.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

ADOPT: 855-141-0345

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0345

Dispensing: General Requirements

The PPK Affiliated Pharmacy must:

(1) Ensure each prescription, prescription refill, and drug order is correctly dispensed from the PPK in accordance with the prescribing practitioner's authorization; and

(2) Ensure the PPK dispenses prescriptions accurately and to the correct party.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0350

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0350

Dispensing: Containers

Each PPK must dispense a drug in a new container that complies with the current provisions of the Poison Prevention Packaging Act in 16 CFR 1700 (01/01/2021), 16 CFR 1701 (01/01/2021), and 16 CFR 1702 (01/01/2021). ¶

[Publications: Publications referenced are available from the agency.]

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0400

Labeling: General Requirements

Prescriptions must be labeled with the following information:¶

(1) Name and address of the PPK;¶

(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) Such other and further accessory cautionary information as required for patient safety;¶

(9) 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 or one year from the date the drug was originally dispensed and placed in the new container, whichever date is earlier. Any drug expiring before the expected length of time for course of therapy must not be dispensed.¶

(10) 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¶

(11) Name, address and telephone number of the PPK Affiliated Pharmacy.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.505, ORS 689.515

ADOPT: 855-141-0405

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0405

Labeling: Prescription Reader Accessibility

- (1) A PPK 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 PPK Affiliated 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 PPK Affiliated Pharmacy must ensure a 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

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0410

Labeling: Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by the PPK 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), the PPK 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: 855-141-0450

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0450

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: 855-141-0455

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0455

Drug and Devices: Return

A PPK or PPK Affiliated Pharmacy 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 PPK 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) A Pharmacist has approved the return; ¶
- (2) The drugs or devices are accepted for destruction or disposal; and ¶
- (3) A Pharmacist verifies the destruction or disposal.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.305

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0500

Policies and Procedures

(1) The PIC of the PPK Affiliated Pharmacy and the PPK Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPK. The written policies and procedures must be maintained at the PPK Affiliated Pharmacy and must be available to the board upon request.

¶

(2) The written policies and procedures must include at a minimum the responsibilities of the PPK Affiliated Pharmacy and each PPK including:

(a) Security;

(b) Operation, testing and maintenance of the telepharmacy system and the PPK;

(c) Sanitation and cleaning;

(d) Storage of drugs;

(e) Stocking and destocking;

(f) Dispensing;

(g) Preventing duplicate dispensing;

(h) Pharmacist supervision, direction and control of and licensed personnel accessing the PPK;

(i) Documenting the identity, function, location, date and time of licensees engaging in telepharmacy and licensed personnel accessing the PPK;

(j) Utilization of Interns, Certified Oregon Pharmacy Technicians or Pharmacy Technicians;

(k) Utilization of Pharmacist (e.g. Counseling);

(l) Drug and/or device procurement;

(m) Receiving of drugs and/or devices;

(n) Delivery of drugs and/or devices;

(o) Recordkeeping;

(p) Patient confidentiality;

(q) On-site inspection by a Pharmacist;

(r) Continuous quality improvement;

(s) Plan for discontinuing and recovering services if PPK disruption occurs;

(t) Training: initial and ongoing; and

(u) Interpretation, translation and prescription reader services.

(3) A PPK Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and related supplies through a PPK 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, ORS 689.527

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0550

Records: General Requirements

(1) The recordkeeping requirements OAR 855-141 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.<sup>¶</sup>

(2) All required records for the PPK must be maintained by the PPK Affiliated Pharmacy.<sup>¶</sup>

(3) Records retained by the PPK Affiliated Pharmacy must include, but are not limited to:<sup>¶</sup>

(a) Date, time and identification of each individual and activity or function performed via the PPK;<sup>¶</sup>

(b) Pharmacist physical inspection of the PPK;<sup>¶</sup>

(c) Telepharmacy system testing;<sup>¶</sup>

(d) Licensee training on the proper use of the PPK;<sup>¶</sup>

(e) Still image capture and store and forward images must be retained according to (1);<sup>¶</sup>

(f) Data and surveillance system data must be retained for 6 months; and<sup>¶</sup>

(g) Any errors or irregularities identified by the quality improvement program.<sup>¶</sup>

(4) Records of dispensing from a PPK must include the:<sup>¶</sup>

(a) Physical location of the PPK;<sup>¶</sup>

(b) Identification of the patient or patient's agent retrieving the prescription, non-prescription drugs, and supplies;<sup>¶</sup>

(c) A digital image of the individual to whom the prescription was dispensed.<sup>¶</sup>

(d) Date and time of transaction;<sup>¶</sup>

(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;<sup>¶</sup>

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and<sup>¶</sup>

(g) Name of Pharmacist or Intern who provided counseling to the patient or patient's agent, if required, documentation that the counseling was performed or that the Pharmacist or Intern accepted the patient or patient's agent request not to be counseled.<sup>¶</sup>

(5) Records of stocking and destocking of prescriptions into or from a PPK must include the:<sup>¶</sup>

(a) Date and time;<sup>¶</sup>

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;<sup>¶</sup>

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;<sup>¶</sup>

(d) Name and Oregon license number of the person stocking or destocking prescription, non-prescription drugs and supplies from the system; and<sup>¶</sup>

(e) Identity of the Pharmacist who verifies that the system has been accurately stocked or destocked.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508, ORS 689.527

ADOPT: 855-141-0555

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

855-141-0555

Records: Patient

A patient record system must be maintained by the PPK Affiliated Pharmacy for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing 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) Patient's preferred language for communication and prescription labeling;  
¶

(6) Chronic medical conditions;  
¶

(7) 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;  
¶

(8) Known allergies, drug reactions, and drug idiosyncrasies; and  
¶

(9) If deemed relevant in the Pharmacist's reasonable professional judgment:  
¶

(a) 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: 855-141-0600

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

**855-141-0600**

**Prohibited Practices: General**

**A PPK must not:**

- (1) Allow unlicensed personnel, Certified Oregon Pharmacy Technicians or Pharmacy Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with the Pharmacist; ¶**
- (2) Utilize a person to dispense or deliver a prescription and non-prescription drug, device, and any related supply directly to the patient from the PPK; ¶**
- (3) Dispense drugs that require further manipulation prior to administration or dispensing (e.g. reconstitution, compounding, vaccines); and ¶**
- (4) Store or dispense controlled substances.**

**Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315**

**Statutes/Other Implemented: ORS 689.155, ORS 689.527**

ADOPT: 855-141-0602

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

**855-141-0602**

**Prohibited Practices: Disclosure of Patient Information**

A PPK must 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 (a)-(e) of this rule. A licensee can disclose patient information:¶

(a) To the board:¶

(b) To a practitioner, Pharmacist, Intern, Certified Oregon Pharmacy Technician or Pharmacy Technician, if disclosure is authorized by a Pharmacist who reasonably believes that disclosure is necessary to protect the patient's health or wellbeing; 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.¶

(2) 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 except as provided in (1)(a)-(e) of this rule.

Statutory/Other Authority: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315

Statutes/Other Implemented: ORS 689.155, ORS 689.527

ADOPT: 855-141-0650

RULE SUMMARY: Proposed rules establish a new drug outlet type of Pharmacy Prescription Kiosks (PPK) and permit a pharmacy to operate a PPK by a PPK Affiliated Pharmacy. Creates new Division 141.

CHANGES TO RULE:

**855-141-0650**

**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:<sup>¶</sup>

(1) Any of the grounds listed in ORS 689.405.<sup>¶</sup>

(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:<sup>¶</sup>

(a) Is false, fraudulent, deceptive, or misleading; or<sup>¶</sup>

(b) Makes any claim regarding a professional service or product or the cost or price thereof which cannot be substantiated by the licensee.

Statutory/Other Authority: ORS 689.151, ORS 689.155, ORS 689.205, ORS 689.225

Statutes/Other Implemented: ORS 689.155, ORS 689.405, ORS 689.527