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CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Establishes new registration for Pharmacy Prescription Lockers (PPLs)

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RULES:
855-143-0001, 855-143-0005, 855-143-0010, 855-143-0015, 855-143-0020, 855-143-0025, 855-143-0030, 855-143-0050, 855-143-0100, 855-143-0120, 855-143-0125, 855-143-0130, 855-143-0150, 855-143-0155, 855-143-0200, 855-143-0205, 855-143-0210, 855-143-0215, 855-143-0220, 855-143-0225, 855-143-0345, 855-143-0500, 855-143-0550, 855-143-0600, 855-143-0602, 855-143-0650

ADOPT: 855-143-0001

RULE TITLE: Purpose and Scope

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL.

RULE TEXT:
The purpose of OAR 855-143 is to provide minimum requirements for the operation of a Pharmacy Prescription Locker (PPL) by a PPL Affiliated Pharmacy.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0005

RULE TITLE: Definitions

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds definitions related to PPL and PPL Affiliated Pharmacy.

RULE TEXT:

The following words and terms, when used in OAR 855-143, 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 Locker Affiliated Pharmacy” or “PPL Affiliated Pharmacy” means a Retail Drug Outlet Pharmacy registered in Oregon that operates a Pharmacy Prescription Locker.

(2) “Pharmacy Prescription Locker” or “PPL” means an Oregon location registered as a Retail Drug Outlet Pharmacy Prescription Locker using a mechanical system that securely stores completed patient-specific prescription and non-prescription drugs, devices, and related supplies for pick up.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0010

RULE TITLE: Registration: General

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Includes information and requirements for general registration of a PPL.

RULE TEXT:

(1) Each PPL located in Oregon must be registered as a Retail Drug Outlet PPL.

(2) A controlled substance registration will not be issued for a Retail Drug Outlet PPL.

(3) A Retail Drug Outlet PPL application must specify the PPL Affiliated Pharmacy and cannot operate without a PPL 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 855-143-0015(2) and additional information requested by the board.

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

(6) A Retail Drug Outlet PPL 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.

(8) The registration fee cannot be prorated.

(9) A PPL may not operate until a certificate of registration has been issued by the board.

(10) The PPL Affiliated Pharmacy registration and PPL registration must be on display at both the PPL Affiliated Pharmacy and at the PPL.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.151, ORS 689.155, ORS 689.225, ORS 689.305, ORS 689.527

ADOPT: 855-143-0015

RULE TITLE: Registration: Application

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to an application for registration of a PPL.

RULE TEXT:

(1) An application for registration of a new PPL must include a floor plan drawn to scale with the location of the:

(a) PPL at the facility;

(b) Surveillance system cameras; and

(c) Alarm system panel.

(2) The certificate of registration for a PPL must be issued prior to opening.

(3) The application must specify the location of the PPL and must indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application must indicate the owner and the applicant's affiliation with the owner:

(a) If the owner is a partnership or other multiple owners, the names of the partners or persons holding the five largest interests must be indicated on the application;

(b) If the owner is a corporation, the name filed must be the same as filed with the Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders, if applicable, who own the five largest interests must be indicated on the application.

(4) 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.

STATUTORY/OTHER AUTHORITY: ORS 475.035, ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-143-0020

RULE TITLE: Registration: Change of Owner, Location, or PPL Affiliated Pharmacy

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to registration for change of ownership, change of location or change of PPL Affiliated Pharmacy.

RULE TEXT:

(1) A change of location of the PPL Affiliated Pharmacy or location of the PPL requires:

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

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(2) A change in the PPL Affiliated Pharmacy or ownership of the PPL requires:

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

(b) Registration fee;

(c) Approval of the board; and

(d) New certificate of registration.

(3) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(4) A certificate of registration will be issued upon board approval of the application.

(5) A PPL that has changed location or ownership must not operate until the new certificate of registration has been approved and issued.

STATUTORY/OTHER AUTHORITY: ORS 475.035, ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.305, ORS 689.527

ADOPT: 855-143-0025

RULE TITLE: Registration: Closure

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to closing a PPL.

RULE TEXT:
A PPL Affiliated Pharmacy must notify the board a minimum of 15 days prior to discontinuing operation of a PPL. Notification must include the:
(1) Final disposition of drugs stored in the PPL 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: 855-143-0030

RULE TITLE: Non-Resident PPL Affiliated Pharmacies

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to Non-Resident PPL Affiliated Pharmacies.

RULE TEXT:

(1) For the purpose of these rules, a non-resident pharmacy includes a PPL Affiliated Pharmacy located outside of Oregon and providing pharmacy services to a PPL located in Oregon.

(2) Each non-resident PPL 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 PPL Affiliated Pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence.

(4) The Oregon licensed Pharmacist-in-Charge (PIC) of the non-resident PPL Affiliated Pharmacy is the PIC for each PPL.

(5) The PIC is responsible for ensuring that the PPL PIC self-inspection form is 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: 855-143-0050

RULE TITLE: Personnel

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to personnel.

RULE TEXT:
(1) A PPL must have an Oregon licensed PIC at all times.
(2) Prior to utilizing a PPL, the Oregon licensed Pharmacist, Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician must have completed a training program on the proper use of the PPL.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.151, ORS 689.155, ORS 689.527

ADOPT: 855-143-0100

RULE TITLE: Security

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to security.

RULE TEXT:

(1) The PPL Affiliated Pharmacy, the PPL, Oregon licensed PIC of the PPL Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the PPL is responsible for the security of the PPL 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 PPL Affiliated Pharmacy must ensure the PPL:

(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 855-143-0125;

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

(a) There is no Oregon licensed Pharmacist supervising and authorizing access in real-time to the PPL; or

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

(c) Any component of the PPL is not functioning.

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

(5) An Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician may only access the PPL when an Oregon licensed Pharmacist is supervising the licensee and has authorized access to the PPL in real-time.

(6) Unlicensed personnel (e.g. vendor) may only access the PPL when escorted and continuously observed by a licensee who is authorized by the Oregon licensed Pharmacist who is supervising and authorizing access to the PPL in real-time.

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

(a) Alarm system at the PPL and real-time notification to an Oregon licensed Pharmacist of the PPL 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 PPL;

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

(C) Date and time of each activity; and

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

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0120

RULE TITLE: Drug: Procurement

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to drug procurement.

RULE TEXT:
A PPL may only receive prescription, non-prescription drugs, devices, and related supplies from the PPL Affiliated Pharmacy.

STATUTORY/OTHER AUTHORITY: ORS 475.035, ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0125

RULE TITLE: Drug: Storage

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to drug storage.

RULE TEXT:

(1) A PPL 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 PPL must quarantine drugs which are outdated, adulterated, misbranded or suspect.

(2) A PPL 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 PPL must adhere to a monitoring plan, which includes, but is not limited to:

(A) Documentation of training of all personnel;

(B) Maintenance of manufacturer recommended calibration of thermometers;

(C) Maintenance of records of temperature logs for a minimum of three years;

(D) Documentation of excursion detail, including, but not limited to, event date and name of persons(s) involved in excursion responses;

(E) Documentation of action(s) taken, including decision to quarantine product for destruction, or determination by an Oregon licensed Pharmacist that it is safe for continued use. This documentation must include details of the information source;

(F) A written emergency action plan;

(G) Routine preventative maintenance and evaluation of refrigeration equipment and monitoring equipment; and

(H) Documentation and review of temperature recordings at least once every 28 days by the Oregon licensed Pharmacist at the time of in person physical inspection.

STATUTORY/OTHER AUTHORITY: ORS 689.205, ORS 689.325

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0130

RULE TITLE: Drug: Loss

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to drug loss.

RULE TEXT:

A PPL and its PPL 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: 855-143-0150

RULE TITLE: Outlet: Sanitation

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds sanitation requirements for a PPL and PPL Affiliated Pharmacy.

RULE TEXT:
A PPL and its PPL Affiliated Pharmacy must ensure the PPL is kept clean.

STATUTORY/OTHER AUTHORITY: ORS 689.305

STATUTES/OTHER IMPLEMENTED: ORS 689.305, ORS 689.527

ADOPT: 855-143-0155

RULE TITLE: Outlet: Minimum Equipment Requirements

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds minimum equipment requirements.

RULE TEXT:

(1) Each Oregon PPL 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 PPL outlet;

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

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

(A) Stating “The (insert name of PPL 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 855-143-0410 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 Locker, supervised by an Oregon licensed Pharmacist from (insert name of PPL 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 PPL; and

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

(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

ADOPT: 855-143-0200

RULE TITLE: Outlet: General Requirements

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to general requirements.

RULE TEXT:
(1) The PPL Affiliated Pharmacy and its PIC are responsible for all operations and enforcing all policies and procedures of the PPL.
(2) A PPL Affiliated Pharmacy may operate more than one PPL.
(3) A PPL Affiliated Pharmacy must be less than 120 miles apart via the shortest surface street route from the PPL.
(4) A PPL and its PPL 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 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 855-143;
(d) Ensure that the PPL Affiliated Pharmacy prevents duplicate dispensing of a prescription;
(e) Comply with all applicable federal and state laws and rules;
(f) Ensure that PPL Affiliated Pharmacy has received and documented consent by the patient or patient's agent for the patient’s prescription and non-prescription drugs, devices, and related supplies to be placed in the PPL;
(g) Ensure that there is an Oregon licensed PIC who is responsible for all operations and enforcing all policies and procedures of the PPL;
(h) Designate in writing the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians authorized to access the PPL;
(i) Utilize complete chain of custody tracking;
(j) Train the Oregon licensed Pharmacists, Interns, Pharmacy Technicians and Certified Oregon Pharmacy Technicians in the operation of the PPL and document the training;
(k) Develop, implement and enforce a continuous quality improvement program for dispensing services from a PPL 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;
(l) Provide a telephone number that a patient, patient’s agent or prescriber may use to contact the Oregon licensed Pharmacist from the PPL Affiliated Pharmacy; and
(m) Develop, implement and enforce a process for an in person physical inspection of the PPL by an Oregon licensed Pharmacist at least once every 28 days or more frequently as deemed necessary by the Oregon licensed PIC of the PPL Affiliated Pharmacy. The inspection must utilize the PPL self-inspection form, be documented, and records retained.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0205

RULE TITLE: Outlet: Technology

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to technology.

RULE TEXT:

A PPL and its PPL Affiliated Pharmacy must:

(1) Utilize a shared computer 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 PPL;

(3) Test the PPL 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 PPL 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 PPL.

(5) Develop, implement and enforce a plan for responding to and recovering from an interruption of service where the PPL is not fully operational and functioning.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0210

RULE TITLE: Outlet: Supervision

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to supervision.

RULE TEXT:

A PPL and its PPL Affiliated Pharmacy must:

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

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

(3) Ensure that an Oregon licensed Pharmacist verifies and documents that:

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

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

(c) Proper storage conditions were maintained during transfer per OAR 855-143-0125; and

(d) Records are maintained per OAR 855-143-0550.

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: 855-143-0215

RULE TITLE: Outlet: Pharmacist Utilization

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to pharmacist utilization.

RULE TEXT:
A PPL and its PPL Affiliated Pharmacy must ensure that a prescription drug or device is not released from the PPL until the Oregon licensed 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: 855-143-0220

RULE TITLE: Outlet: Non-Prescription Drugs and Supplies

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to non-prescription drugs and supplies.

RULE TEXT:
If non-prescription drugs and related supplies are placed in the PPL, the PPL and its PPL Affiliated Pharmacy must ensure that only an Oregon licensed Pharmacist verifies non-prescription drugs and related supplies that will be placed in the PPL.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0225

RULE TITLE: Outlet: Controlled Substances

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to controlled substances.

RULE TEXT:
Controlled substances may not be stored in the PPL.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0345

RULE TITLE: Dispensing: General Requirements

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and general requirements related to dispensing.

RULE TEXT:

The PPL Affiliated Pharmacy must:

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

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

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0500

RULE TITLE: Policies and Procedures

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to policies and procedures.

RULE TEXT:
(1) The Oregon licensed PIC of the PPL Affiliated Pharmacy and the PPL Affiliated Pharmacy drug outlet is accountable for establishing, maintaining, and enforcing written policies and procedures for the PPL. The written policies and procedures must be maintained at the PPL 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 PPL Affiliated Pharmacy and each PPL including;
(a) Security;
(b) Operation, testing and maintenance of the PPL;
(c) Sanitation and cleaning;
(d) Storage of drugs;
(e) Stocking and destocking;
(f) Dispensing;
(g) Preventing duplicate dispensing;
(h) Oregon licensed Pharmacist supervision, direction and control of and licensed personnel accessing the PPL;
(i) Documenting the identity, function, location, date and time of the licensed personnel accessing the PPL;
(j) Utilization of Oregon licensed Pharmacist (i.e. Counseling);
(k) Recordkeeping;
(l) Patient consent and confidentiality;
(m) On-site inspection by an Oregon licensed Pharmacist;
(n) Continuous quality improvement;
(o) Plan for discontinuing and recovering services if PPL disruption occurs;
(p) Training: initial and ongoing; and
(q) Interpretation, translation and prescription reader services.
(3) If compounded preparations are compounded at the PPL Affiliated Pharmacy and placed in the PPL the policies and procedures must meet the requirements of OAR 855-045.
(4) A PPL Affiliated Pharmacy that provides prescription and non-prescription drugs, devices, and related supplies through a PPL 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

ADOPT: 855-143-0550

RULE TITLE: Records: General Requirements

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and general requirements related to records.

RULE TEXT:

(1) The recordkeeping requirements OAR 855-143 are in addition to the requirements of other recordkeeping rules of the board. Unless otherwise specified, all records and documentation required by these rules, must be retained for three years and made available to the board for inspection upon request. Records must be stored onsite for at least one year and may be stored, after one year, in a secured off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two.

(2) All required records for the Drug Outlet PPL must be maintained by the PPL Affiliated Pharmacy.

(3) Records retained by the PPL Affiliated Pharmacy must include, but are not limited to:

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

(b) Oregon licensed Pharmacist physical inspection of the PPL;

(c) Audiovisual communication system testing;

(d) Licensee training on the proper use of the PPL;

(e) Still image capture and store and forward images must be retained according to (1);

(f) Data and surveillance system data must be retained for 6 months; and

(g) Any errors or irregularities identified by the quality improvement program.

(4) Records of dispensing from a PPL must include the:

(a) Physical location of the PPL;

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

(c) A digital image of the individual to whom the prescription was dispensed.

(d) Date and time of transaction;

(e) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(f) Each non-prescription drug and supply name, UPC or NDC number, and quantity; and

(g) Name of Oregon licensed Pharmacist or Oregon licensed 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.

(5) Records of stocking and destocking of prescriptions into or from a PPL must include the:

(a) Date and time;

(b) Each prescription number, patient name, prescriber name, drug name, strength, dosage form and quantity;

(c) Each non-prescription drug and supply name, UPC or NDC number, and quantity;

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

(e) Identity of the Oregon licensed 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: 855-143-0600

RULE TITLE: Prohibited Practices: General

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to prohibited practices.

RULE TEXT:

A PPL may not:

(1) Allow unlicensed personnel, Oregon licensed Pharmacy Technicians or Certified Oregon Pharmacy Technicians to ask questions of a patient or patient's agent which screen and/or limit interaction with the Oregon licensed Pharmacist;

(2) Utilize a person to dispense or deliver a prescription and non-prescription drugs, devices, and related supplies directly to the patient;

(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: 855-143-0602

RULE TITLE: Prohibited Practices: Disclosure of Patient Information

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements for prohibited practices related to disclosing patient information.

RULE TEXT:

A Retail Drug Outlet PPL may not:

(1) Allow a licensee or registrant of the board who obtains any patient information to disclose that information to a third party without the consent of the patient except as provided in (2) of this rule.

(2) A licensee may disclose patient information:

(a) To the board;

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

(c) To a third-party when disclosure is authorized or required by law; or

(d) As permitted pursuant to federal and state patient confidentiality laws; or

(e) To the patient or to persons as authorized by the patient.

(3) Allow a licensee or registrant of the board to access or obtain any patient information unless it is accessed or obtained for the purpose of patient care.

STATUTORY/OTHER AUTHORITY: ORS 475.035, ORS 689.205, ORS 689.305, ORS 689.315

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.527

ADOPT: 855-143-0650

RULE TITLE: Grounds for Discipline

NOTICE FILED DATE: 02/23/2022

RULE SUMMARY: Rules establish a new drug outlet type of Pharmacy Prescription Lockers (PPLs) and permit a pharmacy to operate a PPL. Adds information and requirements related to grounds for discipline.

RULE TEXT:

The State Board of Pharmacy may impose one or more of the following penalties which includes: suspend, revoke, or restrict the license of an outlet or may impose a civil penalty upon the outlet upon the following grounds:

(1) Any of the grounds listed in ORS 689.405.

(2) Advertising or soliciting that may jeopardize the health, safety, or welfare of the patient including, but not be limited to, advertising or soliciting that:

(a) Is false, fraudulent, deceptive, or misleading; or

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

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