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# PERMANENT ADMINISTRATIVE ORDER

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CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Pharmacy Prescription Lockers proactive procedural rule review amendments pursuant to public testimony

EFFECTIVE DATE: 06/16/2022

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RULES:
855-019-0300, 855-143-0155, 855-143-0210, 855-143-0550

AMEND: 855-019-0300

RULE TITLE: Duties of a Pharmacist-in-Charge

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Proactive procedural rule review. Amendments include revising language related to duties of a Pharmacist-in-charge. Adds 'OAR 855-041 and OAR 855-139' and 'who is normally present in the pharmacy' in (1). Adds 'A Pharmacy Prescription Locker in OAR 855-143 does not count toward this limit' in (3). Adds '15 days of receiving a deficiency notice; or in (3)(A) and 'non-compliance' in (3)(B).

RULE TEXT:
(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 Locker 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.
(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

AMEND: 855-143-0155

RULE TITLE: Outlet: Minimum Equipment Requirements

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Procedural rule review. Amendments add 'As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPL may display the information required by sub-paragraphs (1)(c)(A) – (D) electronically.' to (1)(e).

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.

(e) As an alternative to posting the required signage, PPL's that utilize an electronic video monitor that the patient is required to acknowledge prior to retrieving medication from the PPL 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 689.527, ORS 689.654

AMEND: 855-143-0210

RULE TITLE: Outlet: Supervision

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Procedural rule review. Amendments add 'Drugs and devices destocked from a PPL that satisfy the requirements of this section may be returned to stock at the PPL Affiliated Pharmacy.' in (4).

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.

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

AMEND: 855-143-0550

RULE TITLE: Records: General Requirements

NOTICE FILED DATE: 04/26/2022

RULE SUMMARY: Proactive procedural rule review. Amendments add '30 days except when a PPL Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the PPL Affiliated Pharmacy must retain the data related to that incident for 6 months from the date of review'.

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 30 days except when a PPL Affiliated Pharmacy becomes aware of an incident that requires review of surveillance data, the PPL Affiliated Pharmacy must retain the data related to that incident for 6 months from the date of review; 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