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CHAPTER 855
BOARD OF PHARMACY

FILING CAPTION: Annual Self-Inspection Form completion deadline

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RULES:
855-019-0300, 855-041-1060, 855-043-0560, 855-045-0220, 855-080-0100, 855-139-0030, 855-141-0030, 855-143-0030

AMEND: 855-019-0300

RULE TITLE: Duties of a Pharmacist-in-Charge

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amends the annual self-inspection due date from "February 1" to "July 1" each year.

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 must 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. Pharmacy Prescription Kiosks in OAR 855-141 and Pharmacy Prescription Lockers in OAR 855-143 do 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 must 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 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 self-inspection of the pharmacy using the annual Self-Inspection Form provided by the board, by July 1 each year. The completed self-inspection forms must be signed and dated by the PIC and retained 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 Form;
(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: 855-041-1060

RULE TITLE: Non-Resident Pharmacies

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amendments include adding "Annually complete a self-inspection using the board's Non-Resident Retail Drug Outlet Self-Inspection Form" and changes the due date from "February 1 to July 1".

RULE TEXT:

(1) For the purpose of these rules, a non-resident pharmacy is any establishment located out of Oregon that engages in the dispensing, delivery or distribution of drugs to Oregon. A non-resident pharmacy also includes entities that provide pharmacy services to Oregon, such as drugless/consulting outlets, even if the entity is not dispensing, delivering or distributing drugs into Oregon.

(2) Every non-resident pharmacy that provides drugs, devices or services to a resident in this state must be registered with the Oregon Board of Pharmacy.

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

(4) Every out-of-state non-resident pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who must be responsible for all pharmacy services provided to residents in Oregon, and to provide supervision and control in the pharmacy. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally present in the pharmacy for a minimum of 20 hours per week;

(c) Annually complete a self-inspection form using the board's Non-Resident Retail Drug Outlet Self-Inspection Form prior to July 1; and

(d) Provide the PIC Self-Inspection Form as requested by the board.

(5) Every non-resident pharmacy will have a pharmacist-in-charge (PIC) who is licensed in Oregon within four months of initial licensure of the pharmacy.

(6) When a change of Pharmacist-in-Charge (PIC) occurs, the non-resident pharmacy will notify the board within ten business days and identify a contact person. The pharmacy will have an Oregon licensed PIC employed within 90 days. The contact person must be a licensed pharmacist in the pharmacy’s state of residence and is responsible for the following:

(a) Supervision of pharmacy staff and ensuring compliance with laws and rules; and

(b) Responding to board correspondence and inquiries.

(7) A new Pharmacist-in-Charge must be appointed, and communication made to the board within 90 days, or the non-resident pharmacy will cease drug distribution and provision of pharmacy services in Oregon.

STATUTORY/OTHER AUTHORITY: ORS 689.205

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

AMEND: 855-043-0560

RULE TITLE: Dispensing Practitioner Drug Outlets - Inspections

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amends the self-inspection form due date from "February 1 to July 1".

RULE TEXT:

(1) The DPDO must annually complete a self-inspection using the board's DPDO Self-Inspection Form by July1 and retain for board inspection.

(2) Each DPDO will be inspected per OAR 855-001-0040 on a routine basis and must be scheduled in advance with the DPDO, to occur during normal business hours.

(3) The inspection must focus on the acquisition, storage, labeling and recordkeeping of drugs intended for dispensing and any violation will apply to the DPDO registration and not to the practitioner.

(4) The Board of Pharmacy must notify the practitioner’s licensing board of any disciplinary action taken against a DPDO.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155, ORS 689.305

AMEND: 855-045-0220

RULE TITLE: Personnel and Responsibilities

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amends (3) by adding that the Pharmacist-in-Charge must annually complete a self-inspection using the board provided Compounding Self-Inspection Form by July 1 and retain it for board inspection.

RULE TEXT:

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.

(2) The Pharmacist-in-Charge (PIC) and the drug outlet must establish, maintain and enforce policies and procedures in accordance with the standards required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and must include written procedures for:

(a) Personnel qualifications, to include training, evaluation and requalification;

(b) Hand hygiene;

(c) Garbing;

(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;

(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;

(f) Components, to include selection, handling, and storage;

(g) Creating master formulation records, with documented pharmacist approval;

(h) Creating compounding records;

(i) Establishing beyond-use dates (BUDs);

(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;

(k) Completed compounded preparations, to include handling, packaging, storage and transport;

(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the board within 10 working days in the event of a patient-level recall of a compounded drug.

(3) The Pharmacist-in-Charge (PIC) must annually complete a self-inspection using the board's Compounding Self-Inspection Form by July 1 and retain for board inspection.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.155

AMEND: 855-080-0100

RULE TITLE: Animal Euthanasia

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amendments add requirement to complete an inspection form annually, using the board's Animal Euthanasia Self-Inspection Form and revises the due date from "February 1 to July 1".

RULE TEXT:

(1) The following requirements shall be met in order for a humane society or animal control agency to be registered or registration renewed to allow the purchase, possession and administration of sodium pentobarbital and sedative and analgesic medications for euthanizing injured, sick, homeless or unwanted domestic pets and other animals:

(a) Registration. Registration as an animal euthanasia drug outlet is limited to animal control agencies and humane societies for the purpose of purchasing, possessing, or administering sodium pentobarbital and sedative and analgesic medications to euthanize animals. The outlet must identify and provide to the Oregon Board of Pharmacy via application, a designated representative who will serve as the primary contact person responsible for managing the outlet operations. The outlet shall notify the Board within 15 days of any change in designated representative. Registration requires submission of an application, and a certificate of registration will be issued upon approval. All registrations and renewals shall be accompanied by an annual fee defined in Division 110 of this Chapter.

(b) Drug Storage. All supplies of sodium pentobarbital and sedative and analgesic medications shall be acquired from an Oregon registered distributor and kept in a locked cabinet. An assigned person designated in writing shall be responsible for the security of the sodium pentobarbital and sedative and analgesic medications. Such designated person shall allow access to and withdrawal of the drug only to a person certified by the Oregon State Veterinary Medical Examining Board to administer sodium pentobarbital and sedative and analgesic medications;

(c) Records. The following records shall be made at the time of the occurrence and shall be maintained for a minimum of three years, available for inspection by the Board of Pharmacy and its agents:

(A) A record of the withdrawal of sodium pentobarbital and sedative and analgesic medications, signed by the person who takes possession of the sodium pentobarbital and sedative and analgesic medications for administration;

(B) A record of the weight, species of animal and dosage of each drug administered for euthanasia signed by the person who administers the drug and by the designated person responsible for security;

(C) A record of all wastage of each drug signed by the person administering each drug and the designated person responsible for security; and

(D) A weekly record of verification of the amount of each drug on hand, minus the amounts withdrawn for administration, signed by the designated person responsible for security;

(E) A record of disposal of any expired or unwanted sodium pentobarbital and sedative and analgesic medications. Disposal shall be in conformance with federal regulations.

(F) Annually complete a self-inspection using the board's Animal Euthanasia Self-Inspection Form by July 1 and retain for board inspection.

(d) Audits. The registrant shall submit to random audits of records and analysis of prepared solutions by the Drug Enforcement Administration (DEA), and Board of Pharmacy or its agents.

(2) The outlet shall notify the Board of Pharmacy in the event of a significant drug loss or violation related to drug theft within one (1) business day.

(3) At the time a Report of Theft or Loss of Controlled Substances (DEA Form 106) is sent to the DEA, a copy shall be sent to the Board of Pharmacy.

(4) The Board of Pharmacy will suspend or revoke the registration of an animal euthanasia drug outlet which allows a person to administer sodium pentobarbital or sedative and analgesic medications who is not certified by the Oregon State Veterinary Medical Examining Board to administer such drug.

STATUTORY/OTHER AUTHORITY: ORS 475.095, ORS 475.190, ORS 689.205

STATUTES/OTHER IMPLEMENTED: ORS 689.151, ORS 689.155

AMEND: 855-139-0030

RULE TITLE: Non-Resident Affiliated Pharmacies

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amendments include revising (4)(c) to read "Annually complete a self-inspection using the board's RDSP Self-Inspection Form prior to July 1", removes "report" and adds "Form" in (4)(d).

RULE TEXT:

(1) For the purpose of these rules, a non-resident pharmacy includes a RDSP Affiliated Pharmacy located outside of Oregon and providing pharmacy services through a telepharmacy system to a Retail Drug Outlet RDSP located in Oregon.

(2) Each non-resident RDSP Affiliated Pharmacy must be registered with the Oregon Board of Pharmacy.

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

(4) Each out-of-state non-resident RDSP Affiliated Pharmacy must designate an Oregon licensed Pharmacist-in-Charge (PIC), who is responsible for all pharmacy services and to provide supervision and control of the RDSP. To qualify for this designation, the person must:

(a) Hold a license to practice pharmacy in the resident state;

(b) Be normally working for the RDSP Affiliated Pharmacy a minimum of 20 hours per week;

(c) Annually complete a self-inspection using the board's RDSP Self-Inspection Form prior to July 1; and

(d) Provide the Self-Inspection Form as requested by the board.

(5) Every non-resident RDSP Affiliated Pharmacy will have a Pharmacist-in-Charge (PIC) who is licensed in Oregon prior to initial registration of the RDSP.

(6) The PIC must comply with the requirements of OAR 855-019-0300.

STATUTORY/OTHER AUTHORITY: ORS 689.205

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

AMEND: 855-141-0030

RULE TITLE: Non-Resident PPK Affiliated Pharmacies

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amendments add that the PIC is responsible for annually completing a self-inspection using the board's PPK Self-Inspection Form prior to July 1 instead of February 1.

RULE TEXT:

(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 annually completing a self-inspection using the board's PPK Self-Inspection Form prior to July 1.

(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

AMEND: 855-143-0030

RULE TITLE: Non-Resident PPL Affiliated Pharmacies

NOTICE FILED DATE: 04/19/2023

RULE SUMMARY: Amendments include adding that the PIC is responsible for annually completing a self-inspection using the board's PPL Self-Inspection Form prior to July 1, instead of February 1.

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 annually completing a self-inspection using the board's PPL Self-Inspection Form prior to July 1.
(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