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ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

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FILING CAPTION: Drug Outlet Pharmacy requirements

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CONTACT: Rachel Melvin
971-673-0001
pharmacy.rulemaking@bop.oregon.gov

800 NE Oregon St., Suite 150
Portland,OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

RULES:
855-041-1010, 855-041-1018, 855-041-1060, 855-041-1105, 855-041-1190, 855-041-2115

AMEND: 855-041-1010

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends rule by adding Pharmacist-in-Charge personnel requirements for a Drug Outlet.

CHANGES TO RULE:

855-041-1010
Outlet (~~RP & IP~~Both Retail and Institutional Drug Outlets): Personnel ¶

Each Drug Outlet Pharmacy must:¶
(1) Have one Pharmacist-in-charge (PIC) employed on a regular basis at that location who shall be responsible for the daily operation of the pharmacy. The Pharmacist-in-charge shall be indicated on the application for a new or relocated pharmacy and for pharmacy renewal registration.¶
(2) Ensure the PIC is qualified per OAR 855-115-0205 and complies with OAR 855-115-0210.¶
(3) Report a change in PIC within 15 days of occurrence in the registrant's electronic licensing record with the board.¶
(4) Report terminating or allowing a board licensee to resign in lieu of termination to the board within 10 working days.~~¶~~
~~(3) Ensure that it is in compliance with all state and federal laws and rules governing the practice of pharmacy~~ The report must include the name of licensee, license number, the date, and the reason for the termination.¶
(4~~5~~) Provide a working environment that protects the health, safety and welfare of a patient which includes but not limited to:¶
(a) Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety.¶
(b) Appropriate opportunities for uninterrupted rest periods and meal breaks.¶
(c) Adequate time for a Pharmacist to complete professional duties and responsibilities as specified in OAR 855-~~019~~115; ¶
(d) Ensure there is sufficient staff to provide services in a safe manner. The outlet must abide by the Pharmacist-on-duty's decision to temporarily shut down a service or services and must respond substantively to a Pharmacist who has identified staffing concerns.

Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

AMEND: 855-041-1018

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Proposed amendments include adding rule references, compliance requirements for dispensing drugs including controlled substances, compounded preparations and radiopharmaceutical, adds licensed and non-licensed personnel requirements, and adds that drug outlet written procedures are to be established and maintained.

CHANGES TO RULE:

855-041-1018
Outlet: General Requirements
A ~~d~~Drug ~~o~~Outlet ~~p~~Pharmacy must:¶
(1) Ensure each ~~p~~:¶
(a) Prescription is dispensed in compliance with OAR 855-0~~19, OAR 855-025, OAR 855-031 and OAR 855-041;~~41, OAR 855-115, OAR 855-120, OAR 855-125, OAR 855-139, OAR 855-141 and OAR 855-143;¶
(b) Controlled substance is dispensed in compliance with OAR 855-080; ¶
(c) Compounded preparation is dispensed in compliance with OAR 855-045; and¶
(d) Radiopharmaceutical is dispensed in compliance with OAR 855-042.¶
(2) Comply with all applicable federal and state laws and rules;¶
(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy.¶
(4) Ensure ~~and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians a~~each licensed and non-licensed individual only perform duties they are licensed and trained to perform.¶
(5) Be responsible for the actions of each licensed and non-licensed individual.¶
(6) Establish, maintain and enforce the drug outlet written procedures required ~~by~~in OAR 855-0~~25-0035;~~41-1040.¶
(~~5~~7) Comply with the Pharmacist's determination in OAR 855-~~019-020~~115-0120(41)(~~e~~).k);¶
(~~6~~8) Develop, implement and enforce a continuous quality improvement program for dispensing services from a ~~d~~Drug ~~o~~Outlet ~~p~~Pharmacy 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.
Statutory/Other Authority: ORS 689.205~~, 2022 HB 4034~~
Statutes/Other Implemented: ORS 689.151,~~ 2022 HB 4034, ORS 689.508,~~ ORS 689.155

AMEND: 855-041-1060

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends rule by modifying PIC requirements for out of state pharmacies that dispense, deliver or distribute drugs into Oregon. Removes requirement for outlet to be in “good standing” in state where pharmacy is physically located. Requires pharmacies to follow Oregon standards for practice of pharmacy in OAR 855-115.

CHANGES TO RULE:

855-041-1060
Non-Resident Pharmacies ¶

(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~~person in Oregon 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~~state where the pharmacy is physically located. ¶
(4) Every 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: 855-041-1105

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends rule by adding dispensing requirements for a Drug Outlet and relocates and revises existing language from OAR 855-019-0210(4)-(7) pertaining to required information for a prescription.

CHANGES TO RULE:

855-041-1105
~~Requirements for Prescriptions~~ Prescriptions: General Requirements ¶

Each Drug Outlet Pharmacy must ensure that:¶
(1) Prescriptions, prescription refills, and drug orders ~~must be correctly dispensed i~~are dispensed:¶
(a) Accurately;¶
(b) To the correct party;¶
(c) Pursuant to a valid prescription; ¶
(d) Pursuant to a valid patient-practitioner relationship; ¶
(e) For a legitimate medical purpose; and¶
(f) In accordance with the prescribing practitioner's authorization. ~~When a prescription is transmitt~~¶
(2) The following information is required for~~ally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.¶~~
~~(2) Each pharmacy must document the following information:¶~~
~~(a) T~~ each new or refilled prescription drug or device: ¶
(a) The name and date of birth of the patient for whom the drug is prescribed, unless for an animal. If for an animal, the name of the patient ~~for whom~~, name or~~f~~ the owner ~~of the animal~~ and the species of the animal ~~for which the drug is dispensed;¶~~
~~(b) The full name;¶~~
(b) The full name and contact phone number of the prescriber and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner ~~or other number as authorized under rules adopted by reference under rule OAR 855-080-0085~~;¶
(c) The name, strength, dosage form~~s~~ of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;¶
(d) The directions for use~~, if given by the practitioner; and~~; ¶
(e) The date of issuance and, if different from the date of issuance, the date of filling;¶
(f) The total number of refills authorized by the prescribing practitioner;¶
(g) A valid signature:¶
(A) For non-controlled substances:¶
(~~e~~i) ~~The date of filling, and the total number of refills authorized by~~Received by the pharmacy via a hard-copy written prescription, the prescribing practitioner or practitioner's agent manual signature. ¶
(ii) Received by the pharmacy via facsimile, the prescribing practitioner or practitioner's agent manual or electronic signature. ¶
(iii) Received by the pharmacy electronically, the prescribing practitioner's or practitioner's agent electronic signature.¶
(B) For controlled substances: ¶
(i) Received by the pharmacy via hard-copy written prescription, the prescription must have an original manually signed signature from the prescribing practitioner. ¶
(ii) Received by the pharmacy via facsimile, the prescription must have an original manually signed signature from 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~~iii) Received by the pharmacy electronically, the prescribing practitioner's digital signature that complies with the rules adopted by reference in OAR 855-080.¶
(C) In (g), manually signed specifically excludes a signature stamp or any form of electronic or digital signature unless permitted under federal regulations; and¶
(h) Any other information required for controlled substances pursuant to federal regulations.¶
(3) An oral prescription must be promptly reduced to writing or entered into an electronic record system and must include: ¶
(a) The name, initials or electronic identifier of the licensee receiving the prescription;¶
(b) The name of the person transmitting the prescription. ¶
(4) The prescription contains all of the information specified in (2) and for controlled substances in OAR 855-080-

0085.¶
(5) In accordance with ORS 689.515(3) and ORS 689.522, the pharmacy dispenses the prescription pursuant to the prescribing practitioner's request that there may be no substitution for the specified brand name ~~drug in a prescription~~of a drug.¶
(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, instruction may use any 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 ~~shall~~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 ~~shall~~must not be default values on the prescription.¶
(46) ~~A pharmacy or pharmacist filling a prescription or order for a biological product may 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 th~~The written or electronic record of each prescription must be ~~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 pharmacy or pharmacist provides written, electronic or telephonic notification of the substitution to the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and¶~~
~~(e) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three (3) years.¶~~
~~(5) Upon written requ~~tained on file as required by OAR 855-041-1160, and in the case of controlled substances, under rulest ~~and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing~~dopted by reference in OAR 855-080.
Statutory/Other Authority: ORS 689.205, ~~2013 OL Ch. 34~~ORS 689.522
Statutes/Other Implemented: ORS 689.505, ORS 689.515, ~~2013 OL Ch. 34~~ORS 689.522

ADOPT: 855-041-1190

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Adds new rule related to requirements for operating a laboratory in a Drug Outlet pharmacy.

CHANGES TO RULE:

855-041-1190
Operation of a Laboratory in Drug Outlet Pharmacy ¶
¶

(1) A Drug Outlet pharmacy may perform a laboratory test when:¶
(a) The Drug Outlet pharmacy possesses a valid laboratory license, including a certificate of a 42 CFR 493.35 waiver;¶
(b) The laboratory test is permitted under the laboratory license; and¶
(c) Requested by a physician, dentist, pharmacist or other person authorized by law to use the findings of laboratory examinations or without a practitioner order as permitted in ORS 438.010, ORS 438.030, ORS 438.040, ORS 438.050, ORS 438.055, ORS 438.060, ORS 438.070, ORS 438.110, ORS 438.120, ORS 438.130, ORS 438.140, ORS 438.150, ORS 438.160, ORS 438.210, ORS 438.220, ORS 438.310, ORS 438.320, ORS 438.420, ORS 438.430, ORS 438.435, ORS 438.440, ORS 438.450, 438.510.¶
(2) The Drug Outlet pharmacy must:¶
(a) Display the laboratory license in a prominent place in view of the public; and¶
(b) Report, to the local health department or state, reportable conditions as required in OAR 333-018.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.661

AMEND: 855-041-2115

NOTICE FILED DATE: 10/19/2023

RULE SUMMARY: Amends rule by adding requirements for prescription transfers, relocates and revises existing language from OAR 855-019-0210.

CHANGES TO RULE:

855-041-2115
~~Transfer of Prescription Information Between Pharmacies~~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 unless otherwise permitted or forbidden by federal regulation.¶
(3) ~~P~~A pharmac~~ies using the same electronic prescription databas~~y that transmits or receives prescription information to or from another pharmacy electronically must ensure as appropriate:¶
(a) The accurate transfer of prescription information between pharmacies;¶
(b) The ~~a~~cre~~ not required to transfer prescriptions for dispensing purposes~~ation of an original prescription or image of an original prescription containing all the information constituting the prescription and its relevant refill history in a manner that ensures accuracy and accountability and that the pharmacist will use in verifying the prescription;¶
(c) The prescription is invalidated at the sending pharmacy; and¶
(d) For controlled substances, complies with the rules adopted by reference in OAR 855-080.¶
(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