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

CHAPTER 855  
BOARD OF PHARMACY

**FILED**

10/19/2023 5:01 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Drug Outlet Pharmacy requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/21/2023 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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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: 11/21/2023

TIME: 9:30 AM

OFFICER: Rachel Melvin

HEARING LOCATION

ADDRESS: Oregon Board of Pharmacy - Virtual Meeting, 800 NE Oregon St., Suite 150, Portland, OR 97232

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 343868791

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony virtually during this hearing, sign up on our website at [www.oregon.gov/pharmacy/pages/](http://www.oregon.gov/pharmacy/pages/)

rulemaking-information or email your first and last name, email address and phone number to

pharmacy.rulemaking@bop.oregon.gov to receive a calendar invitation to join the virtual hearing. Please indicate which rule(s) you would like to comment on.

You must submit written comments before 4:30PM on November 21, 2023. Email written comments to pharmacy.rulemaking@bop.oregon.gov.

NEED FOR THE RULE(S)

Proposed new rules and proposed amendments for Division 041 include general requirements for an outlet and requirements for personnel, drug procurement, out of state pharmacies, prescription requirements, prescription validity, operating a laboratory and prescription transfer requirements for Drug Outlet pharmacies.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Institute for Safe Medication Practices. Despite Technology, Verbal Orders Persist, Read Back is Not Widespread, and Errors Continue. May 2017. Accessed September 29, 2023 - <https://www.ismp.org/resources/despite-technology-verbal-orders-persist-read-back-not-widespread-and-errors-continue>

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

The proposed amendments are not expected to affect racial equity in this state.

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## FISCAL AND ECONOMIC IMPACT:

Proposed amendments may financially impact out-of-state pharmacies if the Drug Outlet Pharmacy does not currently require the Oregon licensed PIC to be physically present in the pharmacy on a regular basis to ensure compliance. A Drug Outlet may be faced with ceasing dispensing, delivering or distributing drugs into Oregon immediately if they do not have a PIC. An out-of-state pharmacy may need to employ an additional Oregon licensed Pharmacist in order to ensure the outlet does not have to cease dispensing, delivering or distributing drugs into Oregon. When the board sends the proposed rules to a rulemaking hearing, licensees, registrants and stakeholders will have an opportunity to provide fiscal and economic impact statements during the open comment period.

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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).*

(1) The proposed rule amendments have no additional economic impact on state agencies, units of local government, or the public.

(2)(a) The proposed rule amendments applies to licensees and registrants of the Oregon Board of Pharmacy. Approximately 30% of Drug Outlet Pharmacy (RP &IP) registrants identify as a small business.

(b) The rulemaking imposes no additional mandatory reporting, recordkeeping or other administrative requirements on small businesses.

(c) The rulemaking imposes no additional requirements regarding equipment, supplies, labor or administration.

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

Licensees and registrants who identify as a small business will receive an email notice of proposed rulemaking via GovDelivery and will have an opportunity to provide public comment on the proposed rules for the board's consideration.

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

The resources involved in convening a RAC were not necessary to amend/develop these rules. Board members represent the interests of persons and communities likely to be affected by the proposed rules and were able to provide information necessary to amend the rules. The board believes that it is necessary for all pharmacies that serve Oregon residents to adhere to Oregon pharmacy laws and employ a PIC at all times, whether in-state or out-of-state.

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## RULES PROPOSED:

855-041-1010, 855-041-1018, 855-041-1019, 855-041-1060, 855-041-1105, 855-041-1115, 855-041-1190, 855-041-2115

AMEND: 855-041-1010

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

CHANGES TO RULE:

855-041-1010

Outlet (RP & IP): Personnel ¶¶

Each Drug Outlet Pharmacy must: ¶¶

(1) ~~HA~~t all times have one Pharmacist-in-~~e~~Charge 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 (PIC) who is normally present in the pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet Pharmacy compliance. ¶¶

(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. ¶¶

(24) 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. ¶¶

(45) 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

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 855-019, 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 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 855-025-0035; 41-1040.¶~~

~~(57) Comply with the Pharmacist's determination in OAR 855-019-020115-0120(41)(e)-k;¶~~

~~(68) 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 recurrence.~~

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.151, 2022 HB 4034, ORS 689.508, ORS 689.155

ADOPT: 855-041-1019

RULE SUMMARY: Adds new rule for drug procurement requirements for a Drug Outlet.

CHANGES TO RULE:

855-041-1019

Drug: Procurement

A Drug Outlet Pharmacy may only receive drugs from an Oregon Registered Drug Outlet (i.e. Wholesaler, Manufacturer or Pharmacy).

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-1060

RULE SUMMARY: Amends rule by modifying PIC requirements for out of state pharmacies that dispense, deliver or distribute drugs into Oregon. Changes term "non-resident" to "out-of-state." Removes requirement for outlet to be in "good standing" in state where pharmacy is physically located. Removes four-month window to designate PIC upon initial registration and 90 day window for change in PIC. Requires pharmacies to follow Oregon standards for practice of pharmacy in OAR 855-115.

CHANGES TO RULE:

855-041-1060

~~Non-Resident~~Out-of-State Pharmacies ¶¶

~~(1) For the purpose of these rules, a non-resident~~An "out-of-state pharmacy" is any establishment located outside 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~~out-of-state 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~~out-of-state pharmacy must be registered and in good standing with the Board of Pharmacy in the pharmacy's state of residence~~state where the pharmacy is physically located~~. ¶¶

~~(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 have, at all times when dispensing, delivering or distributing drugs into Oregon, an Oregon licensed PIC, who is physically present in the pharmacy on a regular basis for a sufficient amount of time as needed to ensure Drug Outlet pharmacy compliance and is responsible for ensuring compliance with all applicable Oregon, and to provide supervision and control in the pharmacy laws and rules when dispensing, delivering or distributing drugs into Oregon. To qualify for this designation, the person~~individual 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;~~state where the pharmacy is physically located; ¶¶

~~(c) Annually complete a self-inspection form using the board's Non-Resident Retail Drug Outlet Self-Inspection Form prior to July 1~~Comply with the PIC qualifications and limitations in OAR 855-115-0205; 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 li~~Comply with the PIC requirements in OAR 855-115-0210(1)(a-h) and (2). ¶¶

~~(5) An out-of-state pharmacy must~~cease 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~~drug dispensing, delivery, distribution and provision of pharmacy services into Oregon while there is not an Oregon licensed PIC. ¶¶

~~(6) Each out-of-state pharmacy must ensure each prescription that is dispensed, delivered or distributed into Oregon complies with the standards for the practice of pharmacy in OAR 855-115.~~

Statutory/Other Authority: ORS 689.205

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

AMEND: 855-041-1105

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. Requires Pharmacist to clarify discrepancies or uncertainties regarding a prescription. Requires read back of an oral prescription. Clarifies prescriber authority to request no substitution for the manufacturer of a drug.

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 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 transmitted

(2) The following information is required for all, 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) For 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 of 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, address, and contact phone number 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 forms 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) For:

(e) The date of issuance and, if different from the date of issuance, the date of filling, and

(f) The total number of refills authorized by the prescribing practitioner;

(3g) In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication, a valid signature:

(A) For non-controlled substances:

(i) 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 by electronic transmission that there practitioner's agent manual or electronic signature.

(iii) Received by the pharmacy with no substitution for the specified brand name drug in a prescription electronically, the prescribing practitioner's or practitioner's agent electronic signature.

(B) For controlled substances:

(a) For Received by the pharmacy via hard-copy written prescription issued, the prescription must have an original or a prescription orally communicated over the telephone, instruction may usginal manually-signed signature from the prescribing practitioner.

(ii) Received by the pharmacy via facsimile, the prescription must have any one of the following original manually-signed signature from the prescribing 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. ctitioner.

(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

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent shall provide any other information required for controlled substances pursuant to federal regulations.

(3) If there are any discrepancies or uncertainties regarding the prescription, the Pharmacist promptly seek clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the prescription from the prescribing practitioner or the practitioner's agent.

(4) An oral prescription must:

(a) Be promptly reduced to writing or entered into an electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions shall not be default values on the prescription.

(4) 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 name, initials or electronic identifier of the licensee receiving the prescription;

(B) The name of the person transmitting the prescription; and

(b) After the prescription has been transcribed, the licensee must verify accuracy by:

(i) Reading back the prescription as transcribed to the person transmitting it; or

(ii)

(ii) Listening to the voicemail a second time; and

(c) The confirmation of accuracy in (b) must be documented on the prescription.

(5) The prescription originated from an authorized practitioner or practitioner's agent:

(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 prescription contains all of the information specified in (2) and for controlled substances in OAR 855-080-0085.

(7) In accordance with ORS 689.515(3) and ORS 689.522, the pharmacy dispenses the prescription pursuant to the prescribing practitioner has not designated on the prescription that substitution is prohibited;

(c) The patient for whom the biological product is prescribed is inform's request that there may be no substitution for the specified brand name or manufacturer of a drug.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the substitution prior to dispensing the biosimilar product 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) The pharmacy or pharmacist provide Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words written, electronic or telephonic notification of the substitution similar meaning.

(b) For an electronically transmitted prescription to, the prescribing practitioner or the prescribing practitioner's staff within three (3) business days of dispensing the biosimilar product; and

(c) The pharmacy or pharmacist retains a record of the substitution for a period of not less than three (3) year'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.

(5) Upon The written request 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 or electronic record of each prescription must be retained on file as required by OAR 855-041-1160, and in the case of controlled substances, under rules adopted 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



AMEND: 855-041-1115

RULE SUMMARY: Amends rule by revising and relocating OAR 855-019-0210(2), and adding prescription validity requirements prior to dispensing for a Drug Outlet.

CHANGES TO RULE:

855-041-1115

~~Verification of Prescription Authenticity Validity ¶~~

~~Alteration of a written prescription, other than by a pharmacist's or practitioner's authorization~~ Each Drug Outlet Pharmacy must ensure that:¶

~~(1) Prior to dispensing a prescription, a Pharmacist has verified its validity. In order for a prescription drug to be valid it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing of the prescription drug is upon the prescribing practitioner, in any manner constitutes an invalid order unless verified with the prescriber, and a corresponding responsibility rests with the pharmacist who dispenses the prescription.¶~~

~~(2) A prescription is considered not valid if:¶~~

~~(a) At the time of presentation, the prescription shows evidence of alteration, erasure, or addition by any person other than the person who wrote it;¶~~

~~(b) The prescription does not contain the required information as provided in OAR 855-041-1105;¶~~

~~(c) The prescription is expired per OAR 855-041-1125; or¶~~

~~(d) The prescription is for a controlled substance and does not comply with the requirements of OAR 855-080-0085.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508

ADOPT: 855-041-1190

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

RULE SUMMARY: Amends rule by adding requirements for prescription transfers, relocates and revises existing language from OAR 855-019-0210(8).

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) ~~PA pharmacies using the same electronic prescription database 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 ~~ac~~re 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