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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

02/23/2022 3:00 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Adds definitions for alarm, audiovisual communication, entry and surveillance systems; Procedural rule review.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 03/29/2022 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: 03/29/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy

800 NE Oregon St., Suite 150

Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 414 724 81# for audio only.

You may file written comments before 4:30PM on March 29, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Adds definition for alarm system, audiovisual communication system, entry system, and surveillance system; Amends use of these terms in promulgated rules. Removes references to a security system.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

None.

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

Since the proposed rules provide clarity for currently promulgated rules, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

None anticipated.

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).

None anticipated.

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

Small businesses were not involved with the development of the proposed rule amendment.

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

A RAC was not consulted, board staff proposed rule amendments to ensure clarity.

RULES PROPOSED:

855-020-0110, 855-041-1020, 855-041-3220, 855-041-3230, 855-041-3235, 855-041-3240, 855-041-3245, 855-041-3250, 855-041-5055, 855-041-6410, 855-065-0012, 855-139-0100, 855-139-0210, 855-139-0215, 855-139-0230, 855-139-0550

AMEND: 855-020-0110

RULE SUMMARY: Proposed revision amends (6) real-time continuous audio and visual communication and adds "audiovisual communication system" to ensure clarity to registrants.

CHANGES TO RULE:

855-020-0110

Prescribing Practices

(1) A pharmacist located and licensed in Oregon may prescribe and dispense FDA-approved drugs and devices included on either the Formulary or Protocol Compendia, set forth in this Division. A pharmacist may only prescribe a drug or device consistent with the parameters of the Formulary and Protocol Compendia, and in accordance with federal and state regulations.¶

(2) A pharmacist must create, approve, and maintain policies and procedures for prescribing post-diagnostic drugs and devices or providing patient care services pursuant to statewide drug therapy management protocols. The policies and procedures must describe current and referenced clinical guidelines, and include but not be limited to:¶

- (a) Patient inclusion and exclusion criteria;¶
- (b) Explicit medical referral criteria;¶
- (c) Care plan preparation, implementation, and follow-up;¶
- (d) Patient education; and¶
- (e) Provider notification; and¶
- (f) Maintaining confidentiality.¶

(3) The pharmacist is responsible for recognizing limits of knowledge and experience and for resolving situations beyond their expertise by consulting with or referring patients to another health care provider.¶

(4) For each drug or device the pharmacist prescribes, the pharmacist must:¶¶

(a) Assess patient and collect subjective and objective information, including the diagnosis for Formulary Compendia items, about the patient's health history and clinical status. The pharmacist's physical assessment must be performed in a face-to-face, in-person interaction and not through electronic means; and¶¶

(b) Utilize information obtained in the assessment to evaluate and develop an individualized patient-centered care plan, pursuant to the statewide drug therapy management protocol and policies and procedures; and¶¶

(c) Implement the care plan, to include appropriate treatment goals, monitoring parameters, and follow-up; and¶¶

(d) Provide notification to the patient's identified primary care provider or other care providers when applicable within five business days following the prescribing of a Compendia drug or device.¶¶

(5) The pharmacist must maintain all records associated with prescribing and other related activities performed for a minimum of 10 years, and a copy must be made available to the patient and provider upon request. Pharmacy records must be retained and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and then may be stored in a secure off-site location if retrievable within three business days. Records and documentation may be written, electronic or a combination of the two. ¶¶

(6)-If consultation is provided through an electronic means, the Oregon licensed Pharmacist must use real-time audio-visual communication system to conduct the consultation.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.645, ORS 689.649

AMEND: 855-041-1020

RULE SUMMARY: Proposed amendments include repealing (5) which removes a waiver for pharmacy compliance with (1)-(4) and also removes a reference to board approved "security system" for which there is not a definition to ensure clarity to registrants.

CHANGES TO RULE:

855-041-1020

Security of Prescription Area ¶

(1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to ensure the security of those drugs.¶

(2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.¶

(3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041- 2100.¶

(4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.¶

~~(5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041-6310, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such security system, as approved by the Board, shall be maintained in the pharmacy.~~

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.205

AMEND: 855-041-3220

RULE SUMMARY: Proposed revisions amend the inconsistent use of "real-time audio and visual connection", "continuous audio/visual connection" and "continuous audio and visual connection" and instead utilizes "audiovisual communication system" consistently to ensure clarity to registrants in (1)(3) and (4).

CHANGES TO RULE:

855-041-3220

Telework: Supervision Requirements

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the supervising Oregon licensed Pharmacist from the Drug Outlet must:¶

- (1) Utilize ~~technology that enables real-time~~ an audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;¶
 - (2) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by Certified Oregon Pharmacy Technicians and Interns;¶
 - (3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern and Certified Oregon Pharmacy Technician and that the ~~continuous audio/visual connection~~ audiovisual communication system is fully operational;¶
 - (4) Ensure that an Oregon licensed Pharmacist using professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the ~~real-time audio and visual connection~~ audiovisual communication system with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;¶
 - (5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and¶
 - (6) Ensure the Intern or Certified Oregon Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction and control at all times.¶
 - (7) The Oregon licensed Pharmacist who is supervising an Intern or Certified Oregon Pharmacy Technician at a Telework Site must:¶
 - (a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;¶
 - (b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;¶
 - (c) Document the following within 24 hours of the review in (b):¶
 - (A) Number of each licensee's patient interactions;¶
 - (B) Number of each licensee's patient interactions pharmacist is reviewing; ¶
 - (C) Date and time of licensee patient interaction pharmacist is reviewing; ¶
 - (D) Date and time of pharmacist review of licensee's patient interaction; and¶
 - (E) Pharmacist notes of each interaction reviewed; and¶
 - (d) Report any violation of OAR 855 to the Oregon registered Drug Outlet Pharmacy within 24 hours of discovery and to the board within 10 days. ¶
 - (8) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (7)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.
- Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3230

RULE SUMMARY: Proposed revision amends "continuous audio and visual connection" in (2) and (5) and adds "audiovisual communication system" to ensure clarity to registrants.

CHANGES TO RULE:

855-041-3230

Telework: Technology

The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet and the Pharmacist from the Drug Outlet must: ¶

(1) Use still image capture or store and forward for verification of prescriptions with a camera that is of sufficient quality and resolution so that the Oregon licensed Pharmacist from the Oregon registered Drug Outlet Pharmacy can visually identify each: ¶

(a) Source container including manufacturer, name, strength, lot, and expiration; ¶

(b) Dispensed product including the imprint and physical characteristics; ¶

(c) Completed prescription container including the label; and ¶

(d) Ancillary document provided to patient at the time of dispensing. ¶

(2) Test the ~~continuous audio and visual connection~~ audiovisual communication system and document that it operates properly before engaging in telework. ¶

(3) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising, directing and controlling the Intern and Certified Oregon Pharmacy Technician at the Telework Site. ¶

(4) Ensure access to: ¶

(a) Appropriate and current pharmaceutical references based on the services offered; and ¶

(b) Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters. ¶

(5) Train the Oregon licensed Pharmacists, Interns and Certified Oregon Pharmacy Technicians in the operation of ~~continuous audio and visual connection~~ audiovisual communication system.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3235

RULE SUMMARY: Proposed revision amends (1) by removing "continuous audio and visual connection" and adds "audiovisual communication system" to ensure clarity to registrants.

CHANGES TO RULE:

855-041-3235

Telework: Personnel

(1) The Oregon licensed Pharmacist-in-charge of the Drug Outlet Pharmacy is responsible for all operations at Drug Outlet Pharmacy including responsibility for the ~~continuous audio and visual connection~~ audiovisual communication system and enforcing policies and procedures.¶

(2) A Drug Outlet Pharmacy may not utilize Pharmacy Technicians, or unlicensed personnel at Telework Sites. ¶

(3) An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins teleworking.¶

(4) The Oregon licensed Pharmacist from the Drug Outlet Pharmacy who is supervising a licensee at a Telework Site must determine and document how many licensed individuals the pharmacist is capable of supervising, directing and controlling based on the services being provided. ¶

(5) When supervising an Intern or Certified Oregon Pharmacy Technician working at a Telework Site, the Oregon licensed Pharmacist may supervise no more than four licensees among all locations, including the Drug Outlet Pharmacy.¶

(6) The Drug Outlet Pharmacy is required to comply with the pharmacist's determination in (4) and retain records.¶

(7) Prior to working at a Telework Site, the Intern or Certified Oregon Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3240

RULE SUMMARY: Proposed revision includes amending "real-time audio and visual connection" in (2)(C) and adds "audiovisual communication system" to ensure clarity to registrants.

CHANGES TO RULE:

855-041-3240

Telework: Environment and Security

(1) Telework Sites must be located in a designated area where:¶

(a) All equipment is stored; ¶

(b) All work is performed; and¶

(c) Confidentiality is maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern or Certified Oregon Pharmacy Technician.¶

(2) The Pharmacist-in-charge of the Drug Outlet Pharmacy and each Oregon licensed Pharmacist supervising a Telework Site is responsible for ensuring the Telework Site has a designated work area that is secure and has been approved and documented by an Oregon licensed Pharmacist prior to utilization. ¶

(3) All computer equipment used at the Telework Site must:¶

(a) Establish and maintain a secure connection to the pharmacy and patient information;¶

(b) Utilize equipment that prevents unauthorized access to the pharmacy and patient information; and¶

(c) Be configured so that the pharmacy and patient information is not accessible when:¶

(A) There is no Oregon licensed Pharmacist actively supervising the Intern or Certified Oregon Pharmacy Technician who is assisting in the practice of pharmacy from a Telework Site; or¶

(B) There is no Pharmacist, Intern or Certified Oregon Pharmacy Technician present at the Telework Site; or¶

(C) Any component of the ~~real-time audio and visual connection~~audiovisual communication system is not functioning; and¶

(d) Comply with all security and confidentiality requirements.¶

(4) A record must be maintained with the date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site.¶

(5) Interns and Certified Oregon Pharmacy Technicians may only work from a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.¶

(6) All records must be stored in a secure manner that prevents access by unauthorized persons.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3245

RULE SUMMARY: Proposed revision amends "audio and visual connection" and adds "audiovisual communication system" in (2)(b) and (2)(h) to ensure clarity to registrants.

CHANGES TO RULE:

855-041-3245

Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge is accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working from a Telework Site. The written policies and procedures must be maintained at the Drug Outlet Pharmacy and must be available to the board upon request. ¶

(2) The written policies and procedures must include at a minimum the services, responsibilities and accountabilities of the licensee engaging in telework including;¶

(a) Security;¶

(b) Operation, testing and maintenance of the audio-and-visual ~~connec~~mmunication;¶

(c) Detailed description of work performed;¶

(d) Oregon licensed Pharmacist supervision, direction and control of Interns and Certified Oregon Pharmacy Technicians;¶

(e) Recordkeeping;¶

(f) Patient confidentiality;¶

(g) Continuous quality improvement;¶

(h) Plan for discontinuing and recovering services if the audio-and-visual connection disruption occursmmunication system is disrupted;¶

(i) Confirmation of dedicated, secure Telework Sites;¶

(j) Documenting the identity, function, location, date and time of the licensees engaging in telework;¶

(k) Written agreement with licensees engaging in telework outlining specific functions performed, conditions and policies governing the operation of the Telework Site; and¶

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3250

RULE SUMMARY: Proposed revision includes amending "audio and visual" with "audiovisual communication system" to (3)(f) to ensure clarity to registrants.

CHANGES TO RULE:

855-041-3250

Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees at Telework Sites the recordkeeping requirements OAR 855-041-3205 through OAR 855-041-3250 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 created at Telework Sites must be stored at the Drug Outlet 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) Records must be stored at the Telework site in a manner that prevents unauthorized access.¶

(3) Records must include, but are not limited to:¶

(a) Patient profiles and records;¶

(b) Patient contact and services provided;¶

(c) Date, time and identification of the licensee accessing patient or pharmacy records from a Telework Site;¶

(d) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;¶

(e) List of employees working from Telework Sites that includes:¶

(A) Name;¶

(B) License number;¶

(C) Verification of each license; ¶

(D) Address of Telework Site; and¶

(E) Name of the Oregon licensed Pharmacist who verified each licensure, approved licensee to telework and approved each Telework Site;¶

(f) Audio and visual connection communication system testing and training;¶

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

(h) Data and telephone audio must be retained for 6 months; and¶

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

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-5055

RULE SUMMARY: Proposed revision removes "real-time audio-visual technology" and adds "audiovisual communication system" in the 1st paragraph and in (3) to ensure clarity to registrants.

CHANGES TO RULE:

855-041-5055

Remote Distribution Facility (RDF)

The purpose of these rules is to provide for the use of a Certified Oregon Pharmacy Technician functioning outside of a pharmacy to prepare drugs only for administration to a patient by another healthcare provider, and where requisite pharmacist supervision and verification is provided remotely by an Oregon licensed pharmacist via ~~real-time~~ an audio-visual technology communication system. ¶

(1) A pharmacy physically located in Oregon may make written application to operate a RDF. ¶

(2) The Board may approve an application for registration as a RDF which includes the following: ¶

(a) An operation plan; ¶

(b) Policies and Procedures; ¶

(c) A training plan; ¶

(d) A quality assurance plan for ensuring that there is a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems; and ¶

(e) The fee specified in Division 110. ¶

(3) Notwithstanding the definition of "supervision by a pharmacist" in Division 006, supervision in a RDF may be accomplished by a pharmacist via an audio-visual technology communication system from the applying pharmacy. ¶

(4) Notwithstanding rules in this Division and in Divisions 019 and 025, a Certified Oregon Pharmacy Technician who works in a RDF may have access to the facility without the physical presence of a pharmacist, but may only perform Board approved functions when under the supervision of a pharmacist.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-6410

RULE SUMMARY: Proposed revision includes amending (7)(b) by removing "security system" and adding "access" to ensure clarity to registrants.

CHANGES TO RULE:

855-041-6410

Emergency Department Distribution ¶¶

(1) A practitioner or associate practitioner with prescriptive authority in Oregon who is a member of the hospital's medical staff may dispense an emergency supply of drugs to a patient examined by them or by an associate practitioner subject to the following requirements:¶¶

(a) The prescriber shall offer the patient the option of being provided a prescription that may be filled at the pharmacy of the patient's choice;¶¶

(b) During consultation with the patient or the patient's caregiver, the prescriber shall clearly explain the appropriate use of the drug supplied and the need to have a prescription for any additional supply of the drug filled at a pharmacy of the patient's choice;¶¶

(c) The patient must be given instructions on the use and precautions for taking the drug;¶¶

Labeling¶¶

(d) The drug is in a manufacturer's unit-of-use container, such as an inhaler, or hospital pre-pack that has been labeled by the pharmacy with:¶¶

(A) Name of drug, strength, and number of units. When a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶¶

(B) Accessory cautionary information as required for patient safety;¶¶

(C) Product identification label if the drug is not in unit-of-use packaging;¶¶

(D) An expiration date after which the patient should not use the drug; and¶¶

(E) Name, address and phone number of the hospital pharmacy.¶¶

(e) The following information must be added to the drug container by the practitioner or nurse before dispensing to the patient:¶¶

(A) Name of patient;¶¶

(B) Directions for use by the patient;¶¶

(C) Date of issue;¶¶

(D) Unique identifying number as determined by policy and procedure;¶¶

(E) Name of prescribing practitioner; and¶¶

(F) Initials of the dispensing nurse or practitioner.¶¶

Distribution Record¶¶

(f) A prescription or record of the distribution must be completed by the practitioner or nurse. This record must contain:¶¶

(A) Name of patient;¶¶

(B) Date of issuance;¶¶

(C) Drug name and strength distributed;¶¶

(D) Units issued;¶¶

(E) Name of practitioner;¶¶

(F) Initials of the dispensing nurse or practitioner; and¶¶

(G) Instructions given to the patient as labeled.¶¶

(g) Any additional information required by state and federal laws and regulations for the distribution of a drug to an outpatient;¶¶

(h) The record must be reviewed and documented by a pharmacist for accuracy and completeness. The pharmacist shall review the record of dispensing of drugs within 24 hours. However, if the pharmacy is closed, records shall be reviewed during the first day the pharmacy is open but not to exceed 72 hours following the dispensing; and¶¶

(i) Errors and discrepancies will be included in hospital and pharmacy QA review process and available to the Board.¶¶

(2) A controlled substance may only be distributed or dispensed to an outpatient by the examining practitioner after the patient has been examined by the practitioner and a legitimate medical purpose for a controlled substance has been determined. Distribution of a controlled substance must comply with all applicable state and federal laws and regulations.¶¶

(3) The CPO or PIC and appropriate hospital committee will establish a limited selection and quantity of drugs to be included in the Emergency Department formulary and the amount contained in each prepak that may be distributed to meet only the acute care needs of a patient; for example, an emergency supply of drugs. The amount

dispensed may not exceed a 48 hour supply except for:¶

(a) A drug in the manufacturer's unit-of-use packaging such as an inhalant or a topical drug;¶

(b) A full course of therapy that may be dispensed if in the professional judgment of the pharmacist or practitioner this would be in the patient's best interest such as an antibiotic;¶

(4) Any additional preparation for use of the medication must be completed prior to discharge; for example, reconstituting antibiotics;¶

~~Automated Dispensing Machine~~¶

(5) For the purpose of this rule an Automated Dispensing Machine (ADM) is a machine or contrivance which will prepare a completed and labeled prescription which is ready for dispensing to the patient or patient's representative.¶

(6) An Automated Dispensing Machine; may only be located within the Emergency Department in a secure environment that has no direct public access, and when used, must be part of the discharge procedure;¶

(7) When the patient or patient's representative receives the prescription from an ADM;¶

(a) A registered nurse or practitioner or pharmacist must be present at the time of dispensing; and¶

(b) A registered nurse or practitioner or pharmacist will grant access to the ADM for the release of the drugs to be dispensed using a password protected or biometric ~~security system~~ access; and¶

(c) The patient or patient's representative will obtain the drug using a specific patient access code.¶

(8) Only a pharmacy technician, certified pharmacy technician, intern or pharmacist may access the drug supply in the ADM.¶

(9) The CPO or PIC will establish policies and procedures for use of the ADM including, but not limited to emergency access and down time procedures for the ADM.¶

(10) Upon written request, the ~~B~~board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing and will be time limited.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.505

AMEND: 855-065-0012

RULE SUMMARY: Proposed revisions include amending (3)(a) by removing "access controls" and adding "entry system" and amending (3)(b) by adding "system" to ensure clarity for registrants.

CHANGES TO RULE:

855-065-0012

Storage of Drugs ¶¶

(1) As a condition for receiving and retaining a wholesale distributor registration issued under these rules, an applicant must satisfy the Board that the applicant has and will continuously maintain acceptable storage and handling conditions and facilities standards for each facility at which drugs are received, stored, warehoused, handled, held, offered, marketed, or displayed, or from which drugs are transported, including:¶¶

(a) Suitable construction of the facility and appropriate monitoring equipment to ensure that drugs in the facility are maintained in accordance with labeling or in compliance with official compendium standards.¶¶

(b) Suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations.¶¶

(c) Adequate storage areas to provide appropriate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.¶¶

(d) A quarantine area for the separate storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, suspected counterfeit, otherwise unfit for distribution, or contained in immediate or sealed secondary containers that have been opened.¶¶

(e) Maintenance of the facility in a clean and orderly condition.¶¶

(f) Maintenance of the facility in a commercial, nonresidential building.¶¶

(g) Freedom of the facility from infestation by insects, rodents, birds or vermin of any kind.¶¶

(2) The facility must be equipped with appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of drugs.¶¶

(3) The facility must meet security standards including but not limited to:¶¶

(a) ~~Access controls~~ entry system that restricts access to areas where drugs are held, to authorized personnel.¶¶

(b) An after-hours central alarm system or a comparable entry detection system.¶¶

(c) Adequate outside perimeter lighting.¶¶

(d) Safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-139-0100

RULE SUMMARY: Proposed amendments include removing "security" and adding "alarm", "deter and detect" in (3), and adds "surveillance system" language in (3)(c). Removes "with an audible alarm" and adds "if unauthorized access occurs" in (6)(a) and amends (6)(b) by removing "keypad or other electronic" and adds "is controlled by an Oregon licensed Pharmacist". Removes "audiovisual link and adds "video" in (6)(c) to ensure clarity to registrants.

CHANGES TO RULE:

855-139-0100

Security

- (1) The area in a registered RDSP where legend and/or controlled substances are stored, possessed, prepared, compounded or repackaged must be restricted in access by utilizing physical barriers to include floor to ceiling walls and a locked separate entrance to ensure the security of those drugs.¶
- (2) The RDSP Affiliated Pharmacy, the RDSP, Oregon licensed Pharmacist-in-charge of the RDSP Affiliated Pharmacy and each Oregon licensed Pharmacist supervising the RDSP is responsible for the security of the prescription area including provisions for adequate safeguards against loss, theft or diversion of prescription drugs, and records for such drugs.¶
- (3) The RDSP must be locked and the ~~security~~alarm system armed to prevent, deter and detect entry when:¶
 - (a) There is no Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy actively supervising the RDSP; or¶
 - (b) There is no Certified Oregon Pharmacy Technician present in the RDSP; or¶
 - (c) Any component of the surveillance system is not functioning.¶
- (4) A record must be maintained with the name and license number of each person entering the pharmacy area of the RDSP.¶
- (5) No one may be in the prescription area of a RDSP unless authorized in real-time by an Oregon licensed Pharmacist who is supervising the RDSP and from the RDSP Affiliated Pharmacy.¶
- (6) Minimum security methods must include a properly functioning:¶
 - (a) Alarm system ~~with an audible alarm~~ at the RDSP and real-time notification to a designated licensee of the RDSP Affiliated Pharmacy;¶
 - ~~(b) Electronic keypad or other electron if unauthorized access occurs;¶~~
 - (b) Electronic entry system that is controlled by an Oregon lic-entry system that sed Pharmacist and records the:¶
 - (A) Identification of the Oregon licensed Pharmacist authorizing access and securing the RDSP;¶
 - (B) Identification of the Certified Oregon Pharmacy Technician accessing and securing the RDSP; and¶
 - (C) Date and time of each activity. ¶
 - (c) Surveillance system that utilizes continuously accessible and recorded ~~audiovisual link~~video between the RDSP Affiliated Pharmacy and the RDSP. The system must provide a clear view of:¶
 - (A) Dispensing site entrances;¶
 - (B) Preparation areas;¶
 - (C) Drug storage areas;¶
 - (D) Pick up areas;¶
 - (E) Office areas; and¶
 - (F) Publicly accessible areas.

Statutory/Other Authority: ORS 475.035, ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0210

RULE SUMMARY: Proposed revisions include removing "telepharmacy" and adding "surveillance system in (1) and amending (2) by removing "continuous audio and visual technology" and adding "audiovisual communication system" and adding "All patient interactions" to ensure clarity to registrants.

CHANGES TO RULE:

855-139-0210

Outlet: Supervision

A RDSP and its RDSP Affiliated Pharmacy must:¶¶

- (1) Ensure prescription drugs are only dispensed at the RDSP if an Oregon licensed Pharmacist is supervising the Certified Oregon Pharmacy Technician, and the ~~telepharmacy~~ surveillance system is fully operational;¶¶
 - (2) Ensure an Oregon licensed Pharmacist supervises, directs and controls each Certified Oregon Pharmacy Technician at the RDSP using ~~continuous audio and visual technology~~ which communication system. All patient interactions must be recorded, reviewed and stored;¶¶
 - (3) The Oregon licensed Pharmacist who is supervising Certified Oregon Pharmacy Technician at a RDSP must:¶¶
 - (a) Using professional judgment, determine the percentage of patient interactions for each licensee that must be reviewed to ensure public health and safety with a minimum of 10% of patient interactions observed or reviewed;¶¶
 - (b) Review patient interactions within 48 hours of the patient interaction to ensure that each licensee is acting within the authority permitted under their license and patients are connected with a pharmacist upon request;¶¶
 - (c) Document the following within 24 hours of the review in (3)(b):¶¶
 - (A) Number of each licensee's patient interactions;¶¶
 - (B) Number of each licensee's patient interactions pharmacist is reviewing; ¶¶
 - (C) Date and time of licensee patient interaction pharmacist is reviewing; ¶¶
 - (D) Date and time of pharmacist review of licensee's patient interaction; and¶¶
 - (E) Pharmacist notes of each interaction reviewed; and¶¶
 - (d) Report any violation of OAR 855 to the RDSP Affiliated Pharmacy within 24 hours of discovery and to the board within 10 days. ¶¶
 - (4) The Oregon registered Drug Outlet Pharmacy must comply with the pharmacist's determination in (3)(a), employ adequate staff to allow for completion of the review within 48 hours, and retain records.¶¶
 - (5) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by the Certified Oregon Pharmacy Technician.¶¶
 - (6) Develop, implement and enforce a plan for responding to and recovering from an interruption of service which prevents an Oregon licensed Pharmacist from supervising a Certified Oregon Pharmacy Technician at the RDSP.
- Statutory/Other Authority: ORS 689.205, ORS 689.225
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.305

AMEND: 855-139-0215

RULE SUMMARY: Proposed amendments include removing "real-time" and adding "system" in (2) to ensure clarity to registrants.

CHANGES TO RULE:

855-139-0215

Outlet: Pharmacist Utilization

A RDSP and its RDSP Affiliated Pharmacy must:¶

(1) Utilize an Oregon licensed Pharmacist from the RDSP Affiliated Pharmacy to perform the professional tasks of interpretation, evaluation, DUR, verification and counseling before the prescription is dispensed; and¶

(2) Utilize an Oregon licensed Pharmacist and ~~real-time~~ an audio-visual communication system to provide counseling or accept the refusal of counseling from the patient or the patient's agent for each prescription being dispensed when counseling is required under OAR 855-019-0230 and when requested and document the interaction.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0230

RULE SUMMARY: Proposed amendments include removing "real-time audio-visual communication connection" and adding "audiovisual communication system" to ensure clarity to registrants.

CHANGES TO RULE:

855-139-0230

Outlet: Non-Sterile Compounding

If non-sterile preparations are compounded at the RDSP, the RDSP and its RDSP Affiliated Pharmacy must:

(1) Adhere to the requirements of OAR 855-045;

(2) Ensure an Oregon licensed Pharmacist:

(a) Supervises via a ~~real-time~~ audio-visual communication system all steps of the compounding; and

(b) Documents and visually verifies each item required in OAR 855-139-0041205.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-139-0550

RULE SUMMARY: Proposed amendments include removing "audio and visual connection" and adding "audiovisual communication system" to (2)(f) and adds "system" to (2)(h) to ensure clarity to registrants.

CHANGES TO RULE:

855-139-0550

Records: General Requirements

(1) The recordkeeping requirements OAR 855-139 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) The RDSP must maintain all required records unless these records are maintained in the RDSP Affiliated Pharmacy.¶

(3) Records retained by the Drug Outlet must include, but are not limited to:¶

(a) Patient profiles and records;¶

(b) Date, time and identification of each individual and activity or function performed;¶

(c) If filling prescriptions, date, time and identification of the licensee and the specific activity or function of the person performing each step in the dispensing process;¶

(d) Controlled substance inventory and reconciliation;¶

(e) Oregon licensed Pharmacist physical inspection of RDSP;¶

(f) ~~Audio and visual connection~~ communication system testing and individual training on use of the ~~audio and visual connection~~ communication system; ¶

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

(h) Data, telephone audio and surveillance system data must be retained for 6 months; and¶

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

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.508