OFFICE OF THE SECRETARY OF STATE
SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

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

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/25/2021 5:10 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural rule review proposes telework rules, repeals outdated regulations for remote processing and TCVP

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 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.

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

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/23/2021
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.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

The amendments to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

The telework proposed rules in OAR 855-041-3205 through OAR 855-041-3250 will allow for remote work by Interns and Certified Oregon Pharmacy Technicians under the under the supervision, direction and control with verification by an Oregon-licensed pharmacist outside of a public health emergency on behalf of drug outlet. Proposed telework rules

replace remote processing rules in OAR 855-041-3100 through OAR 855-041-3130 and provide clarity on how technicians may assist in the practice of pharmacy.

OAR 855-041-5100 states that a Technician Checking Validation Program is a program that uses a technician checker to check functions completed by another technician. This program does not include a step for an Oregon licensed Pharmacist to perform final verification of work completed by a Certified Oregon Pharmacy Technician. The board proposes to repeal OAR 855-041-5100 through OAR 855-041-5170.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

21 USC 351 (XX/XX/XXXX) Adulterated drugs and deviceshttps://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=g
section351&num=0&saved=L3ByZWxpbUB0aXRsZTIxL2NoYXB0ZXI5L3N1YmNoYXB0ZXI1%7CZ3JhbnVsZWlkOlVTQy1wcr
21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices https://uscode.house.gov/view.xhtml?hl=false&edition=prelim&req=g
section352&num=0&saved=L3ByZWxpbUB0aXRsZTIxL2NoYXB0ZXI5L3N1YmNoYXB0ZXI1%7CZ3JhbnVsZWlkOlVTQy1wcr

---

FISCAL AND ECONOMIC IMPACT:

OAR 855-006-0005: No anticipated fiscal impact.

OAR 855-041-3205 through OAR 855-041-3250: These costs are estimated for one employee performing telework for one registered drug outlet under the supervision, direction and control of one Oregon licensed Pharmacist.
Estimated costs to purchase a platform that allows for virtual communications, including audio and video technology that can be recorded and stored, varies based on the vendor a company chooses, number of licenses purchased, types of services purchased and costs can vary depending on usage. Example, if a company wanted to use Microsoft Teams, they would typically purchase Microsoft 365 and costs will vary based on paid subscription and number of users. To add the Teams function to Microsoft 365 may cost $0 to $20 per month per user depending on the contract.
The proposed rules require that all telephone audio is recorded, reviewed and stored, which is possible using a virtual platform such as Teams, however if a company chose to use a landline option, would need to invest in a program that is able to store and record data which can vary in costs based on the device and program from $20 per month for a phone line with additional costs for the phone ranging from $10 to $300 per device, a device or program associated with recording calls is estimated to cost anywhere from $160 - $5000 depending on vendor and type of equipment or service procured. There are most likely additional costs associated for storage to retain calls, and costs depend on how much data storage a company chooses to purchase based on volume of calls.
The proposed rules also require a secure connection to the pharmacy such as a virtual private network and possibly multi-factor authorization. VPN services vary based on vendor and available services which are estimated to cost anywhere from $12 to $50 per month per user depending on vendor and what services are purchased. There are additional costs with acquiring a system that can provide multi-factor authorization which can vary in price depending on the vendor and what services are purchased and what device is used to receive authorization codes. Estimated costs associated with multi-factor authorization solution could range from $0 to $500 per user to implement depending on devices, complexity and services available to procure.
Pharmacies are not required to utilize telework. Those that choose to do so will avoid overhead costs associated with the office environment which may help offset the cost of compliance with these proposed rules.

OAR 855-041-5100 through OAR 855-041-5170: TCVP - Currently there are 4 institutional pharmacies utilizing TCVP. When these rules are repealed, there are potential increased personnel expenses to the registrant. OAR 855-041-5130 requires extensive training of Certified Oregon Pharmacy Technicians to participate in TCVP that will no longer be needed, but there will be an increased cost to utilize a pharmacist to perform final verification of medications. It is estimated that a registrant utilizing TCVP would spend 2 hours per day on cart check and ADC fill check. Utilization of a

pharmacist costs approximately $50/hr more than utilization of a technician resulting in approximately $36,500 per year of increased personnel costs to the registrant.

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).

There are no known economic impacts to the Oregon Board of Pharmacy. If independent pharmacies choose to participate they would be subject to the fiscal impact listed above.

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

Small businesses were not involved in the development of proposed amendments to these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

855-006-0005, 855-041-1060, 855-041-3000, 855-041-3100, 855-041-3105, 855-041-3110, 855-041-3115, 855-041-3120, 855-041-3125, 855-041-3130, 855-041-3200, 855-041-3205, 855-041-3210, 855-041-3215, 855-041-3220, 855-041-3225, 855-041-3230, 855-041-3235, 855-041-3240, 855-041-3245, 855-041-3250, 855-041-5100, 855-041-5120, 855-041-5130, 855-041-5140, 855-041-5150, 855-041-5160, 855-041-5170

AMEND: 855-006-0005

RULE SUMMARY: The revisions to the proposed rule are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-006-0005
Definitions ¶

As used in OAR Chapter 855:¶
(1) "Adulterated" has the same meaning as set forth in 21 USC 351 (v. XX/XX/XXXX).¶
(2) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.¶
(~~2~~3) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashiering, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.¶
(~~3~~4) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.¶
(4~~5~~) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an individual patient and:¶
(a) Is agreed to by one pharmacist and one practitioner; or¶
(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.¶
(~~5~~6) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:¶

(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the pharmacist and the patient, in the course of professional practice; or¶
(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or¶
(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.¶
(~~6~~7) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.¶
(~~7~~8) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶
(~~8~~9) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶
(~~9~~10) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶
(10~~1~~) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.¶
(11~~2~~) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.¶
(12~~3~~) "Misbranded" has the same definition as set forth in 21 USC 352 (v. XX/XX/XXXX).¶
(14) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section ~~shall~~must not be construed to prohibit monitoring by practitioners or their agents.¶
(13~~5~~) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.¶
(14~~6~~) "Nationally Certified Exam" means an exam that is approved by the board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.¶
(15~~7~~) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶
(16~~8~~) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:¶
(a) The creation and retention of accurate and complete patient records;¶
(b) Assuming authority and responsibility for product selection of drugs and devices;¶
(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;¶
(d) Maintaining confidentiality of patient information.¶
(17~~9~~) "Official compendium" means the official United States Pharmacopeia <USP>, official National Formulary <NF> (USP 43-NF 38 v. 2021), official Homeopathic Pharmacopoeia of the United States <HPUS> (v.2021), or any supplement to any of these. ¶
(20) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.¶
(21~~8~~) Participation in Drug Selection and Drug Utilization Review:¶
(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.¶
(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review

include, but are not limited to:¶
(A) Over-utilization or under-utilization;¶
(B) Therapeutic duplication;¶
(C) Drug-disease contraindications;¶
(D) Drug-drug interactions;¶
(E) Incorrect drug dosage;¶
(F) Incorrect duration of treatment;¶
(G) Drug-allergy interactions; and¶
(H) Clinical drug abuse or misuse.¶
(~~19~~22) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:¶
(a) Cure of a disease;¶
(b) Elimination or reduction of a patient's symptomatology;¶
(c) Arrest or slowing of a disease process; or¶
(d) Prevention of a disease or symptomatology.¶
(2~~0~~3) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the board but has not completed the specialized education program pursuant to OAR 855-025-0012.¶
(2~~1~~4) "Practice of clinical pharmacy" means:¶
(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;¶
(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and¶
(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.¶
(2~~2~~5) "Practice of pharmacy" is as defined in ORS 689.005.¶
~~(23) "Prescription drug" or "legend drug" is as defined in ORS 689.005 and:¶~~
~~(a) Required by federal law, prior to being dispensed or delivered, to be labeled with "Rx only"; or¶~~
~~(b) Required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by practitioners only.¶~~
(~~24~~6) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.¶
(2~~5~~7) "Prohibited conduct" means conduct by a licensee that:¶
(a) Constitutes a criminal act against a patient or client; or¶
(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶
(2~~6~~8) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶
(a) Assure retention of their purity and potency;¶
(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶
(c) Assure security and minimize the risk of their loss through accident or theft;¶
(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶
(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶
(2~~7~~9) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶
(~~28~~30) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.¶
(~~29~~31) "Specialized Education Program" means;¶
(a) A program providing education for persons desiring licensure as pharmacy technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or¶
(b) A structured program approved by the board and designed to educate pharmacy technicians in one or more specific issues of patient health and safety that is offered by:¶
(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;¶
(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or¶

(C) A trade association recognized by the board as representing pharmacies.¶
(~~30~~) ~~"Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified Oregon pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified Oregon pharmacy technician's action. During the declared public health emergency timeframe related to the 2020 COVID-19 pandemic, "supervision by a pharmacist" means pharmacist monitoring of a pharmacy technician or intern being supervised, coupled with the ability to control and be responsible for the technician or interns actions and for the following remote processing functions only: prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders.~~ ¶
(~~31~~2) "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶
(3~~2~~3) "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified Oregon pharmacy technician.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155

AMEND: 855-041-1060

RULE SUMMARY: The revisions to the proposed rule are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1060
Non-Resident Pharmacies ¶

(1) For the purpose of these rules, a non-resident pharmacy i~~ncludes, but is not limited to: Retail, Institutional, Remote Processing, Central Fill, and D~~s 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/~~C~~consulting ~~Drug Outlets.~~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 ~~shall~~must be registered with the Oregon Board of Pharmacy.¶
(3) To qualify for registration under these rules, every non-resident pharmacy ~~shall~~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 ~~shall~~must designate an Oregon licensed Pharmacist-in-Charge (PIC), who ~~shall~~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) Complete the annual non-resident PIC self-inspection report prior to February 1 each year; and¶
(d) Provide the PIC self-inspection report as requested by the ~~B~~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 ~~B~~board correspondence and inquiries.¶
(7) A new Pharmacist-in-Charge must be appointed, and communication made to the ~~B~~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

REPEAL: 855-041-3000

RULE SUMMARY: OAR 855-041-3000 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3000~~
~~Purpose and Scope~~
~~(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.¶~~
~~(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.¶~~
~~(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.¶~~
~~(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3100

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3100~~
~~Purpose and Scope~~
~~The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription drug processing by a pharmacy. Any facility that processes drug orders on behalf of an Oregon pharmacy shall be licensed in Oregon as a retail or institutional drug outlet. An applicant must submit its policies and procedures to the Board of Pharmacy. An applicant must submit to the Board for approval policies and procedures and a description of how using remote processing will improve patient safety.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3105

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3105~~
~~Definitions~~
~~The following words and terms, when used in OAR 855-041-3100 through 855-041-3130, shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in OAR chapter 855, division 006.¶~~
~~(1) "Remote Processing Pharmacy" means an Oregon licensed pharmacy operated under the direction of a pharmacist-in-charge that processes information related to the practice of pharmacy and engages in remote prescription processing, including central processing.¶~~
~~(2) "Remote Processing Functions" may include, but are not limited to, data entry, prospective drug utilization reviews, refill authorizations and interventions. This does not include the filling process.¶~~
~~(3) "Primary Pharmacy" means an instate Oregon licensed pharmacy that receives a patient's or a prescribing practitioner's request to fill a prescription or drug order and delivers the drug or device directly to the patient or patient's agent, and maintains ownership of the prescription or drug order.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3110

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3110~~
~~General Requirements~~
~~An Oregon licensed pharmacy may outsource prescription drug processing to a remote processing pharmacy provided both pharmacies:¶~~
~~(1) Have the same owner; or¶~~
~~(2) Have a written shared pharmacy services contract or agreement that specifies:¶~~
~~(a) The services to be provided by each pharmacy;¶~~
~~(b) The responsibilities of each pharmacy; and¶~~
~~(c) The accountabilities of each pharmacy.¶~~
~~(3) Maintain a separate Oregon pharmacy license for each location involved in providing services;¶~~
~~(4) Share a common electronic file or have appropriate technology or interface to allow access to information required to process and fill a prescription drug order;¶~~
~~(5) Establish, maintain and enforce a policy and procedures manual as required by OAR 855-041-3115;¶~~
~~(6) Ensure that each prescription has been properly processed, filled and counseling has been provided to the patient;¶~~
~~(7) Designate a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the pharmacy's resident state if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;¶~~
~~(8) Allow prospective drug utilization reviews, refill authorizations, interventions, and patient counseling for an Oregon patient must be performed only by a licensed pharmacist in Oregon or in the state in which the pharmacy is located;¶~~
~~(9) Ensure that each technician processing an order for an Oregon patient is a Certified Oregon Pharmacy Technician and is supervised by a licensed pharmacist or is a licensed technician in the state in which the pharmacy is located and is supervised by a licensed pharmacist in the state in which the pharmacy is located;¶~~
~~(10) Comply with all applicable federal and state laws and rules;¶~~
~~(11) Conduct an annual review of the written policies and procedures and document such review.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3115

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3115~~
~~Policies and Procedures~~
~~(1) In addition to the requirements of OAR 855-041-1040, the primary and the remote processing pharmacy is each accountable for establishing, maintaining, and enforcing its own written policies and procedures manual. The policies and procedures manual must include, but need not be limited to the following:¶~~
~~(a) The responsibilities of each pharmacy;¶~~
~~(b) The policies and procedures that protect confidentiality and ensure the integrity of patient information;¶~~
~~(c) Compliance with all applicable federal and state laws and rules;¶~~
~~(d) Records sufficient to identify by name, initials, or unique identification code, the identity and the specific activities of each pharmacist or technician who performed any processing function, and the location where each activity was performed;¶~~
~~(e) A continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, to pursue opportunities to improve patient care, and to resolve identified problems; and¶~~
~~(f) Documentation of any errors or irregularities identified by the quality improvement program.¶~~
~~(2) The written policies and procedures manual shall be maintained at all pharmacies involved in remote processing and must be available to the Board upon request.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3120

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3120~~
~~Records~~
~~(1) The recordkeeping requirements OAR 855-041-3100 through 855-041-3130 are in addition to the requirements of other recordkeeping rules of the Board.¶~~
~~(2) The remote processing pharmacy must maintain all required records unless these records are maintained in the primary pharmacy.¶~~
~~(3) Both recordkeeping systems must:¶~~
~~(a) List the name, address, telephone number, and all license and registration numbers of each pharmacy involved in remote prescription processing;¶~~
~~(A) Document verification of each license and registration;¶~~
~~(B) Document the name of the individual responsible for verification of licensure and registration status.¶~~
~~(b) Identify by name, initials, or unique identification code the identity and the specific activities of each pharmacist or technician who performed any part of the prescription process;¶~~
~~(c) Include quality improvement program documentation;¶~~
~~(d) Be able to produce an audit trail showing each prescription process.¶~~
~~(4) 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;¶~~
~~(5) The primary pharmacy shall maintain records that:¶~~
~~(a) Indicate the date the request for processing was transmitted to the remote processing pharmacy; and¶~~
~~(b) Indicate the date the prescription information was received by the primary pharmacy.¶~~
~~(6) The remote processing pharmacy shall maintain records that:¶~~
~~(a) Track the prescription drug order during each step in the order entry process;¶~~
~~(b) Identify the name, initials, or unique identification code and the specific activity of each pharmacist or pharmacy technician who performed any activity related to processing the prescription including receipt, transmission or delivery of information.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3125

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3125~~
~~Prescription or Drug Order Processing~~
~~A prescription or drug order for a controlled substance may be processed by a remote processing pharmacy when permitted by law and consistent with federal rules.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3130

RULE SUMMARY: OAR 855-041-3100 through OAR 855-041-3130: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-3130~~
~~Prohibited Practices~~
~~A remote processing pharmacy may not process a prescription on behalf of a primary pharmacy that is not registered with the Board, if required by the laws and rules of Oregon to be registered.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

ADOPT: 855-041-3200

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-3200
Telework: Purpose and Scope
The purpose of OAR 855-041-3200 through OAR 855-041-3250 is to provide minimum requirements for pharmacy services conducted via telework.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3205

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-3205
Telework: Definitions
(1) "Telework" means the practice or assistance in the practice of pharmacy physically outside of a registered drug outlet in a telework site. ¶
(2) "Telework Site" means a location that is not a registered drug outlet where an Oregon licensed Pharmacist may practice pharmacy and an Intern or Certified Oregon Pharmacy Technician may assist in the practice of pharmacy as employees of an Oregon registered drug outlet.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3210

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-3210
Telework: Registration
The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of the Drug Outlet Pharmacy are responsible for all licensees engaging in the practice of pharmacy or assisting in the practice of pharmacy from Telework Sites.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3215

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-3215
Telework: General Requirements
(1) Each Oregon registered Drug Outlet Pharmacy and Pharmacist-in-charge of a Drug Outlet Pharmacy must ensure that Interns and Certified Oregon Pharmacy Technicians working from a Telework Site work under the supervision, direction and control of an Oregon licensed Pharmacist.¶
(2) A Pharmacist that engages in the practice of pharmacy and an Intern or Certified Oregon Pharmacy Technician that assists in the practice of pharmacy from a Telework Site for any person or facility located in Oregon must:¶
(a) Be licensed by the board; and ¶
(b) Comply with all applicable federal and state laws and rules.¶
(3) Drugs and devices may not be at a Telework Site.¶
(4) The Oregon registered Drug Outlet Pharmacy and the Pharmacist-in-charge of a Drug Outlet Pharmacy must:¶
(a) Have a written agreement that includes all conditions, duties and policies governing the licensee engaged in telework activities; ¶
(b) Maintain a continuously updated list of all licensees engaged in telework and the Telework Sites to include:¶
(A) Address, phone number and hours that telework is performed for each Telework Site;¶
(B) Functions being performed by licensees engaged in telework; and ¶
(C) The Oregon licensed Pharmacist providing supervision, direction and control for each non-pharmacist licensee;¶
(c) Develop, implement and enforce a continuous quality improvement program for services provided from a Telework Site 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;¶
(d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern and Certified Oregon Pharmacy Technician responsible for each telework function;¶
(e) Develop, implement and enforce a process for a virtual inspection of the Telework Site by an Oregon licensed Pharmacist at least once every 6 months or more frequently as deemed necessary by the Oregon licensed Pharmacist. The inspection must be documented and records retained; and¶
(f) Utilize an Oregon licensed Pharmacist and real-time audio communication 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 or when requested and document the interaction.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3220

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 audio and visual connection and have appropriate technology or interface to allow access to information required to complete assigned duties;¶
(2) Ensure all telephone audio is recorded, reviewed and stored;¶
(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 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 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 25% of patient interactions 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 24 hours, and retain records.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3225

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-3225
Telework: Confidentiality
The Oregon registered Drug Outlet Pharmacy, Pharmacist-in-charge of the Drug Outlet Pharmacy, and the Pharmacist, Intern and Certified Oregon Pharmacy Technician from the Drug Outlet Pharmacy must:¶
(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR 855-025, OAR 855-031, and OAR 855-041.¶
(2) Ensure the security and confidentiality of patient information and pharmacy records.¶
(3) Document and report any confirmed breach in the security of the system or confidentiality. Report of the breach must be reported in writing to the board within ten days of discovery of the event.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3230

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 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.
Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205
Statutes/Other Implemented: ORS 689.155

ADOPT: 855-041-3235

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 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

ADOPT: 855-041-3240

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 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

ADOPT: 855-041-3245

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 connection;¶
(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 audio and visual connection disruption occurs;¶
(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

ADOPT: 855-041-3250

RULE SUMMARY: OAR 855-041-3200 through OAR 855-041-3250: Rules permit a pharmacist, pharmacy intern or pharmacy technician to work remotely at a secured off-site, non-pharmacy location on behalf of a drug outlet. The revisions to the proposed rules are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

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 testing and training;¶
(g) Data, telephone audio, audio and video, still image capture, store and forward images, security and surveillance data. This must be retained according to (1); and¶
(h) 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

REPEAL: 855-041-5100

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5100~~
~~Definitions~~
~~(1) "Error" in Automated Distribution Cabinet (ADC) is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date in a line item. All errors in a line item counts as one error.¶~~
~~(2) "Error" in a unit of use cart is any occurrence of a wrong drug, dose, quantity, or dosage form or the inclusion of any drug with an expired date. All errors in any single dose count as one error.¶~~
~~(3) "Line Item" is a checking unit for ADC restocking (example: one specific drug and dose, regardless of quantity).¶~~
~~(4) "Technician Checker" is an Oregon certified technician who has completed the TCVP validation process and is currently authorized to check another technician's work.¶~~
~~(5) "Technician Checking Validation Program (TCVP)" is a program that uses a technician checker to check functions completed by another technician.¶~~
~~(6) "Unit Dose" is the physical quantity of a drug product designed to be administered to a patient specifically labeled to identify the drug name, strength, dosage amount and volume, if applicable. The unit dosed drug can be obtained from the manufacturer or repackaged from an external re-packager. A drug may be repackaged on-site through a batch repackaging process that includes a pharmacist as a check. Unit dose examples include oral solids individually packaged by a manufacturer or re-packaged, oral liquids drawn up in a labeled oral syringe, all individually labeled injectable products, and pre-mixed IV products.¶~~
~~NOTE: Technician Checking Validation Program (TCVP) The TCVP is a tool to allow the re-direction of a pharmacist from a distributive task to a cognitive task. It is designed to allow a pharmacist to improve patient safety by focusing on assessing the accuracy and (appropriateness of the medications ordered and on educating staff and patients. The development of individualized training programs is the responsibility of each pharmacy in order to tailor the program to the patient population and medication distribution system of the institution. Assessment questions must be tailored to the site and be changed periodically as appropriate. It is the responsibility of the pharmacist-in-charge to ensure that all training is completed and documented prior to a technician (performing as a technician checker.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5120

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5120~~
~~Hospital and Pharmacist in Charge Requirements~~
~~(1) Only a hospital pharmacy may apply to participate in a TCVP. To participate in the TCVP, the hospital pharmacy must meet the following requirements:¶~~
~~(a) The hospital pharmacy must develop policies and procedures for the TCVP to include a list of high-risk medications that are excluded from the TCVP. The policies and procedures for the TCVP must be available in the pharmacy for board inspectors.¶~~
~~(b) The hospital pharmacy must obtain approval from the appropriate committee before the TCVP can be implemented;¶~~
~~(c) The hospital pharmacy must have a drug distribution system that is structured to allow for one additional check of the distributed medications by a licensed nurse or other licensed health care professional with authority to administer medications after the delivery of checked medications; and¶~~
~~(d) The Pharmacist-in-Charge is responsible for the TCVP and will document any error, or irregularity in the quality assurance documentation records.¶~~
~~(2) A hospital may not operate a TCVP without prior written approval from the Oregon Board of Pharmacy. To apply for approval, the hospital must submit the following to the Board:¶~~
~~(a) Copies of written training material that will be used to train technicians as technician checkers;¶~~
~~(b) Copies of quality assurance documentation records and forms that will be used to evaluate the technician checkers and the proposed TCVP;¶~~
~~(c) Copies of the policy and procedures for the proposed TCVP; and¶~~
~~(d) A description of how the proposed TVCP will improve patient safety by focusing on assessing the accuracy and appropriateness of the medications ordered and on educating staff and patients.¶~~
~~(e) Other items as requested by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5130

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5130~~
~~Technician Eligibility and Training~~
~~(1) Only Oregon certified technicians who undergo specific training may work as technician checkers. The training must include the following:¶~~
~~(a) A minimum of one year of drug distribution experience;¶~~
~~(b) Didactic lecture or equivalent training with a self-learning packet;¶~~
~~(c) Practical sessions that consist of individual training in checking a cart fill or ADC that is provided by a pharmacist; and¶~~
~~(d) Initial Validation Process as described in OAR 855-041-5140(1).¶~~
~~(2) The practical training sessions must include:¶~~
~~(a) The trainee observing a technician checker or pharmacist performing the checking process that the trainee is learning;¶~~
~~(b) The trainee performing the initial check with a pharmacist verifying all doses;¶~~
~~(c) The trainee completing the validation process with a pharmacist verifying all doses;¶~~
~~(d) The introduction of artificial errors into a live or simulated environment, to monitor the ability of the technician to catch errors. Artificial errors introduced into the live environment, which are not corrected by the technician, must be removed.¶~~
~~(e) The pharmacist must document and notify a technician checker of any errors found during training.¶~~
~~(3) If at any time a TCVP technician loses his or her validation the technician must be retrained and revalidated before acting as a technician checker.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5140

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5140~~
~~Initial Validation Process and Quality Assurance Process~~
~~(1) Initial Validation Process: The initial process to validate a trainee's ability to accurately check another technician's work must include:¶~~
~~(a) Unit of Use: For initial validation of a trainee to check a unit of use cart fill, the trainee must obtain a 99.8% accuracy rate in 1500 total doses, divided among five separate training checks. A trainee who makes more than three errors in 1500 doses fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.¶~~
~~(A) In each initial validation check, a pharmacist must check the accuracy of all unit of use medications after the trainee has checked them. The pharmacist must document any errors in the unit of use cart and discuss them with the trainee.¶~~
~~(B) In each initial validation check, the pharmacist will introduce at least three errors. The pharmacist coordinating the training check will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.¶~~
~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.¶~~
~~(b) ADC or non-emergent trays and kits: For initial validation of a trainee to fill ADC or non-emergent trays and kits, the trainee must obtain a 99.8% accuracy rate in 500 total line items, divided among five separate training checks. A trainee who makes more than one error in 500 line items fails the validation and may not work as a technician checker until the checking process is repeated and until successfully completed.¶~~
~~(A) In each initial validation check, a pharmacist must check the accuracy of all ADC or non-emergent tray or kit medications after the trainee has checked them. The pharmacist must document any errors and discuss them with the trainee.¶~~
~~(B) In each initial validation check, the pharmacist will artificially introduce at least three errors. The pharmacist will keep a record of the introduced errors and will ensure that all introduced errors are removed before medications are distributed.¶~~
~~(C) The pharmacist must document the results of each initial validation check and retain the results in the quality assurance file.¶~~
~~(2) Quality Assurance Process: The Quality Assurance Process that ensures on-going competency of technician checkers must include:¶~~
~~(a) Quality checks conducted in the same manner as the applicable initial validation process described in section one of this rule, except that the quality check sample must consist of at least 300 doses for technicians checking unit of use carts and at least 100 line items for technicians checking ADC or non-emergent trays and kits.¶~~
~~(b) The quality checks must occur on random and unannounced dates and times.¶~~
~~(c) A technician checker who makes more than one error fails the quality check and may not work as a technician checker unless the technician first passes a second quality check within 30 days of the failed quality check. If the technician does not pass the second quality check within 30 days, the technician must be retrained and revalidated before working as a technician checker.¶~~
~~(d) The results of each quality check must be documented, including the total number of doses or line items checked, a description of each error, the total number of errors, and the percent error rate. Documentation must be retained in the quality assurance file.¶~~
~~(3) Timing and Frequency of Quality Checks: A technician checker must undergo a quality check at least monthly. A technician checker who has successfully completed three consecutive monthly quality checks must be checked at least quarterly for at least one year. A technician checker who has successfully completed four consecutive quarterly quality checks must be checked at least every six months.¶~~
~~(4) A technician checker who does not perform TCVP duties for more than six months must undergo initial validation as described in section one of this rule.¶~~
~~(5) A description of the quality assurance process must be included in the hospital's and the pharmacy's quality assurance program and error reporting system.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5150

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5150~~
~~Checking Procedure~~
~~(1) A technician checker must use the following procedure when checking another technician's work:¶~~
~~(a) A pharmacy technician fills the medication for the cart fill or ADC restocking batch or non-emergent trays and kits.¶~~
~~(b) A technician checker must check the accuracy of cart fill batches or ADC or non-emergent trays and kits. The technician checker shall review the medications for the correct drug, dose, dosage form, and quantity and must review the expiration dates of medications.¶~~
~~(c) If the technician checker discovers a filling error the technician checker must record the error and return the product to the technician who originally filled it, if available, or to another technician. The filling technician must correct the error and the technician checker must check the correction. A pharmacist or another technician checker must check any cart fill batches, ADC or non-emergent tray or kit, or medication corrections filled by a technician checker¶~~
~~(d) If a technician checker is not available, then all doses must be checked by a pharmacist.¶~~
~~(2) This checking process continues until all doses have been checked and determined to be correct.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5160

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5160~~
~~Eligible Specialized Functions~~
~~(1) The following specialized functions are eligible for participation in the TCVP:¶~~
~~(a) Cart fill;¶~~
~~(b) ADC batch replacement; and¶~~
~~(c) Non-Emergent kits and trays.¶~~
~~(2) Upon written request, the Board may permit additional specialized functions if to do so will further public health or safety. A waiver granted under this section shall be effective only when issued in writing and approved by the Board.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-5170

RULE SUMMARY: OAR 855-041-5100 through OAR 855-041-5170: Repeals outdated regulations in alignment with the board's strategic plan.

CHANGES TO RULE:

~~855-041-5170~~
~~Records~~
~~(1) Unless specified otherwise, 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 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 PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety and welfare. Records must include:¶~~
~~(a) Technician checker training documents;¶~~
~~(b) List of high risk medications;¶~~
~~(c) Documentation of any errors, irregularities and results of each initial validation check.¶~~
~~(d) Documentation of quality assurance and forms used to evaluate the technician checker including:¶~~
~~(A) Total number of doses or line item checks;¶~~
~~(B) Description of errors;¶~~
~~(C) Total number of errors; and¶~~
~~(D) Percent error rate.¶~~
~~(e) Documentation of the initial validation check.~~
~~Statutory/Other Authority: ORS 689.205~~
~~Statutes/Other Implemented: ORS 689.155~~