



PERMANENT ADMINISTRATIVE ORDER

BP 37-2021

CHAPTER 855
BOARD OF PHARMACY

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FILING CAPTION: Proactive procedural rule review proposes telework rules.

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RULES:

855-041-1060, 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

AMEND: 855-041-1060

NOTICE FILED DATE: 10/25/2021

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 ~~includes, but is not limited to: Retail, Institutional, Remote Processing, Central Fill, and~~ is any establishment located out of Oregon that engages in the dispensing, delivery or distribution of drugs to Oregon. A non-resident pharmacy also includes entities that provide pharmacy services to Oregon, such as drugless/consulting 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 Board correspondence and inquiries.¶¶

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

Statutory/Other Authority: ORS 689.205

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

ADOPT: 855-041-3200

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

CHANGES TO RULE:

855-041-3205

Telework: Definitions

(1) "Telework" means the practice or assistance in the practice of pharmacy physically located outside of a registered drug outlet when working as an employee of an Oregon 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

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

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, and phone number where 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

NOTICE FILED DATE: 10/25/2021

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.

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 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 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 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

ADOPT: 855-041-3225

NOTICE FILED DATE: 10/25/2021

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.

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 breach of 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

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

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

NOTICE FILED DATE: 10/25/2021

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.

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) 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