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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/25/2022 2:38 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amends Telework rules pursuant to 2022 HB 4034; Clarifies licensee role at Telework Site

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Portland, OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

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

DATE: 05/24/2022

TIME: 9:30 AM

OFFICER: Rachel Melvin

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

SPECIAL INSTRUCTIONS:

This hearing meeting will be held virtually via Microsoft Teams.

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

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Clarifies licensees who can work from a Telework Site. Incorporates directives of 2022 HB 4034 related to duplication, downloading or removal of records from an electronic database.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2022 HB 4034 <https://olis.oregonlegislature.gov/liz/2022R1/Downloads/MeasureDocument/HB4034/Enrolled>

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

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

FISCAL AND ECONOMIC IMPACT:

Pharmacies are not required to utilize telework, no fiscal impact is anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the Oregon Board of Pharmacy or other local government agencies. Pharmacies are not required to utilize telework.

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

Small businesses were not involved in the development of the rules, proposed amendments are directives of 2022 HB 4034 and based on public comment received during March 2022 rulemaking public comment period.

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

Directives of 2022 HB 4034.

RULES PROPOSED:

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: 855-041-3205

RULE SUMMARY: Adds and/or Pharmacy Technician after Certified Oregon Pharmacy Technician, and 'contractors' pursuant to directives of 2022 HB 4034 in (2). Removes requirement for an Oregon licensed pharmacist to practice pharmacy via telework from a Telework Site.

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 a contractor or 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~~ Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician may assist in the practice of pharmacy as contractors or employees of an Oregon registered drug outlet.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3210

RULE SUMMARY: Proposed amendment removes 'engaging in the practice of pharmacy or' as an Oregon licensed pharmacist is not required to practice pharmacy via telework from a Telework Site.

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~~ at Telework Sites.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3215

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after Certified Oregon Pharmacy Technician pursuant to directives of 2022 HB 4034. Adds (4)(D) 'Implement measures to'.

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, and Pharmacy Technicians working ~~from~~ at 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 or Pharmacy Technician that assists in the practice of pharmacy ~~from~~ at 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~~ via ~~the~~ 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¶
 - (D) Implement measures to prevent their recurrence;¶
 - (d) Develop, implement and enforce a procedure for identifying the Oregon licensed Pharmacist, Intern ~~and~~, Certified Oregon Pharmacy Technician, and Pharmacy Technician responsible for each telework function;¶
 - (e) Develop, implement and enforce a process for a virtual inspection of ~~the~~ each 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3220

RULE SUMMARY: Proposed amendments include adding and/or Pharmacy Technician after Certified Oregon Pharmacy Technician, and adds 'observation' pursuant to directives of 2022 HB 4034.

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 an audiovisual communication system and have appropriate technology or interface to allow access to information required to complete assigned duties;
- (2) Ensure telephone audio is recorded, reviewed and stored for all patient interactions completed by Interns, Certified Oregon Pharmacy Technicians, and InterPharmacy Technicians;
- (3) Ensure an Oregon licensed Pharmacist is supervising, directing and controlling each Intern ~~and~~, Certified Oregon Pharmacy Technician, and Pharmacy Technician and that the audiovisual communication system is fully operational;
- (4) Ensure that an Oregon licensed Pharmacist using reasonable professional judgment, determines the frequency of "check-ins" for each licensee being supervised via the audiovisual communication system with a minimum of at least once per work shift to ensure patient safety, compliance with federal and state laws, and documents the interaction;
- (5) Be readily available to answer questions and fully responsible for the practice and accuracy of the licensee; and
- (6) Ensure the Intern ~~or~~, Certified Oregon Pharmacy Technician, or Pharmacy Technician knows the identity of the Oregon licensed Pharmacist who is providing supervision, direction, and control at all times.
- (7) ~~¶~~ Ensure the Oregon licensed Pharmacist who is supervising an Intern ~~or~~, Certified Oregon Pharmacy Technician, or Pharmacy Technician at a Telework Site ~~must~~:

 - (a) ~~Uses~~ reasonable professional judgment; to determine the percentage of patient interactions for each licensee that must be observed or reviewed to ensure public health and safety with a minimum of 5% of patient interactions observed or reviewed;
 - (b) Reviews 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) Documents the following within 24 hours of the observation or review in (b):
 - (A) Number of each licensee's patient interactions;
 - (B) Number of each licensee's patient interactions ~~¶~~ Pharmacist is has observed or reviewed; ¶
 - (C) Date and time of licensee patient interaction ~~¶~~ Pharmacist is has observed or reviewed; ¶
 - (D) Date and time of ~~¶~~ Pharmacist observation or review of licensee's patient interaction; and ¶
 - (E) Pharmacist notes of each interaction observed or reviewed; and ¶
 - (d) Reports 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); ~~e~~; and ¶
 - (9) Employ adequate staff to allow for ~~comple~~;
 - (a) Observation of the review within 48 hours; ~~i~~; and ~~¶~~
 - (b) Create records; and ¶

- (10) Retain records.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3225

RULE SUMMARY: Proposed amendments add and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician' pursuant to directives of 2022 HB 4034. Adds references to OAR 855-020 and OAR 855-139 to (1) and adds 'each' to (3).

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, and Pharmacy Technician from the Drug Outlet Pharmacy must:¶

(1) Ensure patient and prescription information is managed in compliance with OAR 855-019, OAR 855-020, OAR 855-025, OAR 855-031, OAR 855-041 and OAR ~~855-041~~139.¶

(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~~each 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3230

RULE SUMMARY: Proposed amendments add and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician', adds configuration and records requirements for telework to prevent patient and pharmacy records from being duplicated or downloaded when a pharmacy database is accessed remotely. Revisions are necessary pursuant to directives of 2022 HB 4034.

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) Test the audiovisual communication system with the Telework Site and document that it operates properly before ~~engaging in telework, the Intern, Certified Oregon Pharmacy Technician, or Pharmacy Technician engages in telework at the Telework Site.~~ ¶

(2) 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, and Pharmacy Technician~~ at the Telework Site. ¶

(3) 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. ¶

(4) Train the Oregon licensed Pharmacists, Interns ~~and, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians~~ in the operation of the audiovisual communication system. ¶

(5) For verification of prescriptions, use still image capture or store and forward 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.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3235

RULE SUMMARY: Proposed amendments include adding 'or Pharmacy Technician' to (3) after Certified Oregon Pharmacy Technician pursuant to directives of 2022 HB 4034. Repeals experience requirements for telework, requirement for pharmacist to determine and document number of licensees they are capable of supervising, directing and controlling via telework, technician ratio related to telework, and requirement for outlet to comply with pharmacist determination regarding number of licensees they are capable of supervising, directing and controlling via telework.

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 the Drug Outlet Pharmacy including responsibility for the audiovisual communication system and enforcing policies and procedures.¶

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

(3) ~~An Intern or Certified Oregon Pharmacy Technician working at a Telework Site is required to have at least one year experience performing similar services for an Oregon registered Drug Outlet Pharmacy during the three years preceding the date the Intern or Certified Oregon Pharmacy Technician begins~~unlicensed personnel to engage in 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~~Prior to working at a Telework Site, the 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,~~or Pharmacy Technician and the Oregon licensed Pharmacist supervising the Telework Site must have completed a training program on the use of all equipment necessary for secure operation of the Telework Site.

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

Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-3240

RULE SUMMARY: Adds and/or 'Pharmacy Technician' after 'Certified Oregon Pharmacy Technician', adds configuration and records requirements for telework to prevent patient and pharmacy records from being duplicated or downloaded when a pharmacy database is accessed remotely. Revisions are necessary pursuant to directives of 2022 HB 4034. Removes requirement for Pharmacist to only access computer equipment via telework from a Telework Site.

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¶

(~~2~~) Confidentiality ~~is~~must be maintained such that patient information cannot be viewed or overheard by anyone other than the Pharmacist, Intern-~~or~~, Certified Oregon Pharmacy Technician, or Pharmacy Technician.¶

(~~23~~) 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. ¶

(~~34~~) All computer equipment used ~~at the T~~for 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, or Pharmacy Technician who is assisting in the practice of pharmacy ~~from~~at a Telework Site; or¶

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

(C) Any component of the audiovisual communication system ~~is not functioning~~with the Telework Site is not functioning; ¶

(d) Be configured so information from any patient or pharmacy records are not duplicated, downloaded, or removed from the electronic database when an electronic database is accessed remotely; and¶

(~~e~~) Comply with all security and confidentiality requirements.¶

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

(~~56~~) Interns ~~and~~, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians may only work ~~from~~at a Telework Site when authorized in real-time by an Oregon licensed Pharmacist who is supervising the licensee at the Telework Site.¶

(~~67~~) 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, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3245

RULE SUMMARY: Adds and/or 'Pharmacy Technicians' after 'Certified Oregon Pharmacy Technicians' in (2)(d) pursuant to directives of 2022 HB 4034. Adds 'at a Telework Site to (2)(j), adds 'and requirement to comply with telework' to (2)(k) and removes 'governing the operation of the Telework Site'.

CHANGES TO RULE:

855-041-3245

Telework: Policies and Procedures

(1) If a Drug Outlet Pharmacy utilizes licensees ~~at Tvia telework Sites~~, the Drug Outlet Pharmacy and the Oregon licensed Pharmacist-in-charge ~~is~~are accountable for establishing, maintaining, and enforcing written policies and procedures for the licensees working ~~from via Ttelework 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 audiovisual communication;¶

(c) Detailed description of work performed;¶

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

(e) Recordkeeping;¶

(f) Patient confidentiality;¶

(g) Continuous quality improvement;¶

(h) Plan for discontinuing and recovering services if the audiovisual communication system is disrupted;¶

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

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

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

(l) Equipment.

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-041-3250

RULE SUMMARY: Adds configuration and records requirements for telework to prevent patient and pharmacy records from being duplicated or downloaded when a pharmacy database is accessed remotely. Revisions are necessary pursuant to directives of 2022 HB 4034. Amends requirements for providing records of licensee addresses at Telework Sites for inspection by the board upon request.

CHANGES TO RULE:

855-041-3250

Telework: Records

(1) If a Drug Outlet Pharmacy utilizes licensees ~~at T~~via 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 of Telework Site addresses must be made available within 3 business days. Records created via telework must be stored ~~at~~by 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) ~~R~~Physical records may not be stored at the Telework ~~site~~Site. ¶

(3) Records may not be duplicated, downloaded, or removed when accessed via telework.¶

(4) Records must be stored in a manner that prevents unauthorized access.¶

(35) 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 ~~who perform~~working from T telework Sites that includes:¶

(A) Name;¶

(B) License number;¶

~~(C) Verification of each licens~~ and expiration date;¶

~~(D)~~ Address of Telework Site; and¶

~~(E)~~ Name of the Oregon licensed Pharmacist who ~~v~~;¶

~~(i) Verified each licensure, a~~(A-C);¶

~~(ii) Approved licensee to telework; and a~~¶

~~(iii) Approved each Telework Site~~;¶

(f) Audiovisual communication system testing and training;¶

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

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

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

Statutory/Other Authority: ORS 689.135, ORS 689.151, ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034