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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/25/2022 4:20 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Technician final verification; General responsibilities of Pharmacists, Pharmacy Technicians and Drug Outlets

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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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)

Proposed amendments include adding rules concerning 'final verification' by a Certified Oregon Pharmacy Technician or Pharmacy Technician, adding general requirements for a Pharmacist and drug outlet, to align with proposed revisions to general requirements for Certified Oregon Pharmacy Technicians and Pharmacy Technicians and striking language that is no longer relevant.

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

Proposed amendments provide clarity, transparency for licensees/registrants and promotes patient safety, no effects on racial equity are anticipated.

FISCAL AND ECONOMIC IMPACT:

No fiscal impact 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).

A Drug Outlet may need to amend current policies and procedures to be in compliance with the proposed rules.

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

Small businesses were not involved with the development of the proposed rules, amendments are directives of 2022 HB 4034.

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

Directives of 2022 HB 4034.

RULES PROPOSED:

855-019-0200, 855-025-0023, 855-025-0040, 855-041-0018, 855-041-1040, 855-041-6050

AMEND: 855-019-0200

RULE SUMMARY: Proposed amendments add new language related to general responsibilities of a Pharmacist and pharmacy including being responsible for not only their own actions, but those of an Intern, Certified Oregon Pharmacy Technician, and Pharmacy Technician. Adds additional Pharmacist responsibilities related to compliance, assisting in the practice of pharmacy, supervision of pharmacy personnel, policy enforcement, security, maintaining records and access to the pharmacy. Adds 'reasonable' in front of 'professional judgment'.

CHANGES TO RULE:

855-019-0200

Pharmacist: General Responsibilities of a Pharmacist ¶

ORS 689.025 states that "the practice of pharmacy in the State of Oregon is declared a health care professional practice affecting the public health, safety and welfare". Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes. A pharmacist licensed to practice pharmacy by the Board has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful pharmacist in the same or similar circumstances.¶

(1) A pharmacist while on duty must ensure that the pharmacy complies with all state and federal laws and rules governing the practice of pharmacy is responsible for their own actions; however, this does not absolve the

pharmacy from responsibility for the Pharmacist's actions. ¶

(2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians. ¶

(23) Only a Pharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require the reasonable professional judgment of a Pharmacist include but are not limited to: ¶

(a) Drug Utilization Review; ¶

(b) Counseling; ¶

(c) Drug Regimen Review; ¶

(d) Medication Therapy Management; ¶

(e) Collaborative Drug Therapy Management or other post-diagnostic disease state management, pursuant to a valid agreement; ¶

(f) Practice pursuant to State Drug Therapy Management Protocols; ¶

(g) Prescribing a drug or device, as authorized by statute; ¶

(h) Ordering, interpreting and monitoring of a laboratory test; ¶

(i) Oral receipt or transfer of a prescription; and ¶

(j) Final verification of the work performed by those under their supervision. ¶

(34) A Pharmacist may not delegate any task listed in OAR 855-019-0200(2), except that a pharmacist may permit an intern to perform the duties of a pharmacist under their direction and supervision, after the intern has successfully completed his or her first academic year, and only after successful completion of coursework corresponding to those duties: ¶

(a) Comply with all state and federal laws and rules governing the practice of pharmacy; ¶

(b) Ensure each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician only assists in the practice of pharmacy under the supervision, direction, and control of a Pharmacist; ¶

(c) Ensure non-Pharmacist personnel only perform duties they are licensed and trained to perform. ¶

(4d) An intern cannot prescribe a drug or device and cannot perform final verification. ¶

(5) A pharmacist who is Know the identity of each Intern, Certified Oregon Pharmacy Technician and Pharmacy Technician under their supervision, direction and control at all times; ¶

(e) When supervising an intern is responsible for the actions of that intern; however, this does not absolve the intern from responsibility for their own actions. ¶

(6) A pharmacist on duty is responsible, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Board, directing and controlling based on the services being provided. ¶

(7f) A pharmacist may not permit non-pharmacist personnel to perform any duty they are not licensed and trained to perform. ¶

(8) A pharmacist while on duty is responsible for Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians and Pharmacy Technicians as required by OAR 855-025-0035; ¶

(g) Ensure the security of the pharmacy area including: ¶

(a) Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs; ¶

(b) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules; ¶

(c) Ensuring that only a pharmacist has access to the pharmacy when the pharmacy is closed Pharmacist has access to the pharmacy when the pharmacy is closed. ¶

(5) A Pharmacist may delegate final verification of drug and dosage form, device, or product to a Certified Oregon Pharmacy Technician or Pharmacy Technician per ORS 689.005 when the following conditions are met: ¶

(a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification; ¶

(b) The Certified Oregon Pharmacy Technician or Pharmacy Technician does not use discretion in conducting final verification; ¶

(c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and ¶

(d) Ensure the Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification. ¶

(6) A Pharmacist may permit an Intern under their direction and supervision to perform any task listed in OAR 855-019-0200(3), except that an Intern may not: ¶

(a) Perform the duties of a Pharmacist until after the Intern has successfully completed their first academic year, and only after successful completion of coursework corresponding to those duties; ¶

(b) Prescribe a drug or device; or ¶

(c) Perform final verification or verification as defined in OAR 855-006-0005.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.025, ORS 689.151, ORS 689.155, ORS 689.645, ORS 689.682, ORS 689.689, 2022 HB 4034

ADOPT: 855-025-0023

RULE SUMMARY: Adds general responsibilities for Certified Oregon Pharmacy Technician and Pharmacy Technician related to compliance, assisting in the practice of pharmacy, performing duties they are trained for, accessing the pharmacy and performing final verification. Adds 'reasonable' in front of 'professional judgment'.

CHANGES TO RULE:

855-025-0023

Certified Oregon Pharmacy Technician and Pharmacy Technician: General Responsibilities:

- (1) A Certified Oregon Pharmacy Technician or Pharmacy Technician is responsible for their own actions; however, this does not absolve the Pharmacist and the pharmacy from responsibility for the Certified Oregon Pharmacy Technician or Pharmacy Technician's actions.¶
 - (2) A Certified Oregon Pharmacy Technician or Pharmacy Technician must:¶
 - (a) Comply with all state and federal laws and rules governing the practice of pharmacy;¶
 - (b) Only assist in the practice of pharmacy under the supervision, direction, and control of a Pharmacist;¶
 - (c) Know the identity of the Pharmacist who is providing supervision, direction and control at all times;¶
 - (d) Only work within the scope of duties permitted by their license;¶
 - (e) Only perform duties they are trained to perform; and¶
 - (f) Only access the pharmacy area when a Pharmacist is on duty. ¶
 - (3) A Certified Oregon Pharmacy Technician or Pharmacy Technician may not engage in the practice of pharmacy as defined in ORS 689.005.¶
 - (4) A Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification of the drug and dosage, device or product when:¶
 - (a) The Pharmacist utilizes reasonable professional judgment to determine that a Certified Oregon Pharmacy Technician or Pharmacy Technician may perform final verification; ¶
 - (b) No discretion is needed;¶
 - (c) The Pharmacist delegating final verification is supervising the Certified Oregon Pharmacy Technician or Pharmacy Technician; and¶
 - (d) The Certified Oregon Pharmacy Technician or Pharmacy Technician is performing a physical final verification.
- Statutory/Other Authority: ORS 689.205, 2022 HB 4034
Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

AMEND: 855-025-0040

RULE SUMMARY: Adds 'unless requirements of OAR 855-025-0023(4) are met' in (2)(g). Replaces 'medication' with 'prescription in (3)(c). Adds 'reasonable' in front of 'professional judgment'.

CHANGES TO RULE:

855-025-0040

Certified Oregon Pharmacy Technician and Pharmacy Technician; Tasks and Guidelines ¶¶

- (1) Non-licensed pharmacy personnel may enter non-prescription information into a computer record system and may perform clerical duties such as filing prescriptions, delivery, housekeeping, and general record keeping, but the responsibility for the accuracy of the non-licensed pharmacy personnel's work lies with the Pharmacist.¶¶
- (2) Only persons licensed with the Board as a Certified Oregon Pharmacy Technician or ~~Certified Oregon Pharmacy Technician~~, acting in compliance with all applicable statutes and rules and under the supervision of a Pharmacist, may assist in the practice of pharmacy by the following:¶¶
- (a) Packing, pouring or placing in a container for dispensing, sale, distribution, transfer possession of, any drug, medicine, poison, or chemical which, under the laws of the United States or the State of Oregon, may be sold or dispensed only on the prescription of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.¶¶
- (b) Reconstituting prescription medications. The supervising Pharmacist must verify the accuracy in all instances.¶¶
- (c) Affixing required labels upon any container of drugs, medicines, poisons, or chemicals sold or dispensed upon prescription of a practitioner authorized by law to prescribe those drugs, medicines, poisons, or chemicals.¶¶
- (d) Entering information into the pharmacy computer. The Certified Oregon Pharmacy Technician or ~~Certified Oregon Pharmacy Technician~~ shall not make any decisions that require the exercise of judgment and that could affect patient care. The supervising Pharmacist must verify prescription information entered into the computer and is responsible for all aspects of the data and data entry.¶¶
- (e) Initiating or accepting oral or electronic refill authorization from a practitioner or practitioner's agent, provided that nothing about the prescription is changed, and record the medical practitioner's name and medical practitioner's agent's name, if any;¶¶
- (f) Prepackaging and labeling of multi-dose and unit-dose packages of medication. The Pharmacist must establish the procedures, including selection of containers, labels and lot numbers, and must verify the accuracy of the finished task.¶¶
- (g) Picking doses for unit dose cart fill for a hospital or for a nursing home patient. The Pharmacist must verify the accuracy of the finished task unless the requirements of OAR 855-025-0023(4) are met.¶¶
- (h) Checking nursing units in a hospital or nursing home for nonjudgmental tasks such as sanitation and out of date medication. Any problems or concerns shall be documented and initialed by a Pharmacist.¶¶
- (i) Recording patient or medication information in computer systems for later verification by the Pharmacist.¶¶
- (j) Bulk Compounding; Solutions for small-volume injectables, sterile irrigating solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for the pharmacy or other departments of a hospital. The supervising Pharmacist must verify the accuracy in all instances.¶¶
- (k) Preparation of parenteral products as follows:¶¶
- (A) Performing functions involving reconstitution of single or multiple dosage units that are to be administered to a given patient as a unit. The supervising Pharmacist must verify the accuracy in all instances.¶¶
- (B) Performing functions involving the addition of one manufacturer's single dose or multiple unit doses of the same product to another manufacturer's prepared unit to be administered to a patient. The supervising Pharmacist must verify the accuracy in all instances.¶¶
- (l) Performing related activities approved in writing by the Board.¶¶
- (3) In order to protect the public, safety, health and welfare, Certified Oregon Pharmacy Technicians or ~~Certified Oregon Pharmacy Technicians~~ shall not:¶¶
- (a) Communicate or accept by oral communication a new or transferred prescription of any nature;¶¶
- (b) Receive or transfer a prescription to another pharmacy without the prior verification of a Pharmacist.¶¶
- (c) Provide a prescription or medication to a patient without a Pharmacist's verification of the accuracy of the dispensed ~~medic~~prescription;¶¶
- (d) Counsel a patient on medications or perform a drug utilization review;¶¶
- (e) Perform any task that requires the reasonable professional judgment of a Pharmacist; or¶¶
- (f) Engage in the practice of pharmacy as defined in ORS 689.045.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034

ADOPT: 855-041-0018

RULE SUMMARY: Adds procedural requirements for the Drug Outlet related to complying with state and federal laws and rules, training of personnel, ensure and enforce policies and procedures, complying with pharmacist determination, and implementing a quality improvement program.

CHANGES TO RULE:

855-041-0018

Outlet: General Requirements

A drug outlet pharmacy must:

(1) Ensure each prescription is dispensed in compliance with OAR 855-019, OAR 855-025, OAR 855-031 and OAR 855-041;

(2) Comply with all applicable federal and state laws and rules;

(3) Ensure all licensees are trained to appropriately perform their duties prior to engaging or assisting in the practice of pharmacy;

(4) Ensure and enforce the drug outlet written procedures for use of Certified Oregon Pharmacy Technicians or Pharmacy Technicians as required by OAR 855-025-0035;

(5) Comply with the Pharmacist's determination in OAR 855-019-0200(4)(e);

(6) Develop, implement and enforce a continuous quality improvement program for dispensing services from a drug outlet pharmacy designed to objectively and systematically;

(a) Monitor, evaluate, document the quality and appropriateness of patient care;

(b) Improve patient care; and

(c) Identify, resolve and establish the root cause of dispensing and DUR errors and prevent their reoccurrence.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

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

AMEND: 855-041-1040

RULE SUMMARY: Reorganizes rule to ensure clarity to licensees and registrants. Adds, , requirements that policies and procedures include maintaining and testing pharmacy system equipment, sanitation, pharmacist supervision of personnel, drug and device procurement related to receiving and delivery, utilization of Certified Oregon Pharmacy Technicians, Pharmacy Technicians and Oregon licensed Pharmacist, recordkeeping, patient confidentiality, pharmacy closures, and interpretation, translation and prescription reader services. Proposed amendments include necessary amendments to align with the directives of 2022 HB 4034.

CHANGES TO RULE:

855-041-1040

Drug-Outlet: Policies and Procedures ¶

~~Each~~(1) The drug outlet pharmacy and its Pharmacist in Charge is accountable for establishing, maintaining, and enforcing their written procedures for:¶

~~(1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;¶
(2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled~~olicies and procedures for the drug outlet pharmacy. 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 responsibilities of the drug outlet pharmacy including;~~¶

~~(3a) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area~~Security;¶

~~(b) Operation, testing and maintenance of pharmacy systems and equipment;~~¶

~~(c) Sanitation;~~¶

~~(d) Storage of drugs;~~¶

~~(e) Dispensing;~~¶

~~(f) Pharmacist supervision, direction and control of non-Pharmacists;~~¶

~~(4g) Documenting the date, time and identification of the pharmacist responsible for~~licensee and the verification of each dispensed medication;¶

~~(5) Ensuring the delivery of each completed prescription to the correct party~~specific activity or function of the person performing each step in the dispensing process;¶

~~(h) Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians;~~¶

~~(6i) Providing appropriate confidential professional advice concerning medications to patients or their ag~~Certified Oregon Pharmacy Technician or Pharmacy Technician final verification, if utilized;¶

~~(j) Drug and/or device procurements;~~¶

~~(7k) Prescribing services and maintenance of records for prescribing pharmacist;~~Receiving of drugs and/or devices;¶

~~(l) Delivery of drugs and/or devices;~~¶

~~(8m) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties~~Utilization of Oregon licensed Pharmacist (i.e. DUR, Counseling);¶

~~(n) Recordkeeping;~~¶

~~(9o) Establishing and maintaining a~~Patient confidentiality;¶

~~(p) Continuous Q~~quality Assurance Program; and¶

~~(10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132~~improvement;¶

~~(q) Plan for discontinuing and recovering services in the event of a pharmacy closure;~~¶

~~(r) Training: initial and ongoing; and~~¶

~~(11) Ensuring drugs are stored as required by OAR 855-041-1036s) Interpretation, translation and prescription reader services.~~

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

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

AMEND: 855-041-6050

RULE SUMMARY: Removes outdated language pertaining to verification and final verification that does not align with the directives of 2022 HB 4034.

CHANGES TO RULE:

855-041-6050

Definitions- Automated Distribution Cabinet (ADC) ¶

~~(1)~~ In these rules, OAR 855-041-6000 through 855-041-6999, the terms below have these meanings:¶

~~(a)~~ "Automated Distribution Cabinet" (ADC) means a computerized drug storage device or cabinet that allows a drug to be stored and dispensed near the point-of-care, while controlling and tracking drug distribution;¶

~~(b)~~ "Drug" means a drug, a prescription device, a biological medication, a chemical or any combination of these terms;¶

~~(c)~~ "Central pharmacy" means a pharmacy within a licensed hospital with a single location and inventory, which prepares and distributes drugs to secondary storage areas in the facility, and remote locations;¶

~~(d)~~ "Chief Pharmacy Officer" (CPO) means an Oregon licensed pharmacist who supervises the pharmacy operations in a hospital. The CPO may hold the title of Pharmacy Manager, Pharmacy Director, Director of Pharmacy, Pharmacy Administrator or other pharmacy supervisory management title within the organization. The PIC may also be the CPO if there is only one pharmacy in the hospital;¶

~~(e)~~ "Drug profile" means a complete and comprehensive summary of a patient's current drugs and details of each drug including information such as active ingredient, strength and form, dose and directions for use, and other supplementary information;¶

~~(f)~~ "Licensed Independent Practitioner" (LIP) means an individual permitted by law and by the organization to provide care and services, without direction or supervision, within the scope of the individual's license;¶

~~(g)~~ "Out-patient" means a person who is not residing in the facility but who is registered with the facility and is using the facility for treatment or diagnostic services;¶

~~(h)~~ "Remote storage area" means a patient care area which is part of the hospital that is under the supervision and control of the hospital's central pharmacy but is not located in the same building as the central pharmacy;¶

~~(i)~~ "Secondary drug storage area" means an area in a hospital or licensed residential facility, which is supplied by a central pharmacy and may include facilities such as a drug room, a distribution cabinet or a hospital department;¶

~~(j)~~ "Unit-dose" means a quantity of a drug designed to be administered to a patient, such as:¶

~~(A)~~ An oral solid individually packaged or re-packaged;¶

~~(B)~~ An oral liquid drawn up in a labeled oral syringe;¶

~~(C)~~ An injectable product; or¶

~~(D)~~ A pre-mixed IV product.¶

~~(2) Notwithstanding 855-006-0005 and 855-019-0200(2) and (3), for the purpose of these rules, OAR 855-041-6000 through 855-041-6999, verification or final verification means the confirmation by a pharmacist of the correctness, exactness and accuracy of the act, tasks, or function as specified elsewhere in this Division of rules.~~

Statutory/Other Authority: ORS 689.205, 2022 HB 4034

Statutes/Other Implemented: ORS 689.155, 2022 HB 4034