#### OFFICE OF THE SECRETARY OF STATE

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### ARCHIVES DIVISION

STEPHANIE CLARK DIRECTOR

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

# PERMANENT ADMINISTRATIVE ORDER

BP 28-2022

CHAPTER 855

**BOARD OF PHARMACY** 

**FILED** 

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

**Drug Outlets** 

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CONTACT: Rachel Melvin 800 NE Oregon St., Suite 150 Filed By:

971-673-0001 Portland,OR 97232 Rachel Melvin

pharmacy.rulemaking@bop.oregon.gov Rules Coordinator

**RULES**:

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

AMEND: 855-019-0200

REPEAL: Temporary 855-019-0200 from BP 25-2022

NOTICE FILED DATE: 04/25/2022

RULE SUMMARY: 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, 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 pPharmacist licensed to practice pharmacy by the Bboard has the duty to use that degree of care, skill, diligence and reasonable professional judgment that is exercised by an ordinarily careful pPharmacist in the same or similar circumstances.¶

- (1) A <u>pP</u>harmacist <u>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.¶</u>
- (2) A Pharmacist and pharmacy are responsible for the actions of Interns, Certified Oregon Pharmacy Technicians, and Pharmacy Technicians.¶
- (23) Only a pPharmacist may practice pharmacy as defined in ORS 689.005, to include the provision of patient care services. Activities that require threasonable professional judgment of a pPharmacist 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 vVerification of the work performed by those under their supervision.¶
- $(3\underline{4})$  A pPharmacist 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 ust: ¶
- (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 ilntern 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 responsi, Certified Oregon Pharmacy Technician or Pharmacy Technician, determine how many licensed individuals the Pharmacist is capable of or supervising all pharmacy personnel, and ensuring that pharmacy personnel only work within the scope of duties allowed by the Boar, directing and controlling based on the services being provided.¶
- (7<u>f</u>) 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:¶
- $(\underline{a}\underline{A})$  Providing adequate safeguards against theft or diversion of prescription drugs, and records for such drugs;  $\P$  ( $\underline{b}\underline{B}$ ) Ensuring that all records and inventories are maintained in accordance with state and federal laws and rules;  $\P$
- (e<u>C</u>) 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.  $\P$
- (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 and 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

NOTICE FILED DATE: 04/25/2022

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

<u>Certified Oregon Pharmacy Technician and Pharmacy Technician: General Responsibilities</u>

(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

REPEAL: Temporary 855-025-0040 from BP 25-2022

NOTICE FILED DATE: 04/25/2022

RULE SUMMARY: Adds 'unless requirements of OAR 855-025-0023(4) are met' in (2)(g). Replaces 'medication' with

'prescription in (3)(c).

**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 <u>Bb</u>oard as a <u>Certified Oregon</u> Pharmacy Technician or <u>Certified Oregon</u> 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 <u>Certified Oregon</u> Pharmacy Technician or <del>Certified Oregon</del> 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 <u>unless the requirements of OAR 855-025-0023(4) are met</u>.¶
- (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.  $\P$
- (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.¶
- (I) Performing related activities approved in writing by the <u>Bb</u>oard.¶
- (3) In order to protect the public, safety, health and welfare, <u>Certified Oregon</u> Pharmacy Technicians or <del>Certified Oregon</del> 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 medicaprescription;¶
- (d) Counsel a patient on medications or perform a drug utilization review;¶

(e) Perform any task that requires the professional judgment of a Pharmacist; or  $\P$  (f) Engage in the practice of pharmacy as defined in ORS 689.015.

Statutory/Other Authority: ORS 689.205, 2022 HB 4034 Statutes/Other Implemented: ORS 689.155, 2022 HB 4034 ADOPT: 855-041-0018

NOTICE FILED DATE: 04/25/2022

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

NOTICE FILED DATE: 04/25/2022

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 <u>olicies</u> 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;¶
- $(3\underline{a})$  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 <u>date</u>, <u>time and</u> identification of the <u>pharmacist responsible for licensee and</u> the <u>verification</u> of each <u>dispensed medication</u>;
- (5) Ensuring the delivery of each completed prescription to the correct partyspecific activity or function of the person performing each step in the dispensing process;¶
- (h) Utilization of Certified Oregon Pharmacy Technicians or Pharmacy Technicians;¶
- (6<u>i</u>) Providing appropriate confidential professional advice concerning medications to patients or their agCertified Oregon Pharmacy Technician or Pharmacy Technician final verification, if utilized;¶
- (j) Drug and/or device procurements;¶
- (7<u>k</u>) Prescribing services and maintenance of records for prescribing pharmacist Receiving of drugs and/or devices;¶
- (I) 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;¶
- (90) Establishing and maintaining a Patient confidentiality;¶
- (p) Continuous Qquality 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

REPEAL: Temporary 855-041-6050 from BP 25-2022

NOTICE FILED DATE: 04/25/2022

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:  $\P$  (a1) "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;  $\P$  (b2) "Drug" means a drug, a prescription device, a biological medication, a chemical or any combination of these terms:  $\P$
- (<u>e3</u>) "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;¶ (<u>e4</u>) "Chief Pharmacy Officer" (CPO) means an Oregon licensed <u>pP</u>harmacist 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 $\underline{5}$ ) "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; $\P$
- ( $\underline{f6}$ ) "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; ¶ ( $\underline{g7}$ ) "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; ¶
- ( $\frac{48}{9}$ ) "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;  $\P$  ( $\frac{19}{9}$ ) "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;  $\P$  ( $\frac{10}{9}$ ) "Unit-dose" means a quantity of a drug designed to be administered to a patient, such as:  $\P$
- (Aa) An oral solid individually packaged or re-packaged;¶
- (Bb) An oral liquid drawn up in a labeled oral syringe;¶
- $(\underline{\mathsf{C}}\underline{\mathsf{c}})$  An injectable product; or  $\P$
- (Đd) A pre-mixed IV product.¶
- (2) Not withstanding 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