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CHAPTER 855
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RULES:

855-041-3000, 855-041-3300, 855-041-3305, 855-041-3310, 855-041-3315, 855-041-3320, 855-041-3325, 855-041-3330, 855-041-3335, 855-041-3340, 855-110-0007

AMEND: 855-041-3000

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Strikes "Consulting/Drugless Pharmacy Outlets Purpose and Scope" from the rule title and strikes (4) as the rules referenced are being repealed.

CHANGES TO RULE:

855-041-3000

~~Purpose and Scope~~ Central Fill and Remote Processing Outlet Designations

(1) The purpose of OAR 855-041-3005 through 855-041-3045 is to provide minimum requirements of operation for centralized prescription drug filling by a pharmacy.¶

(2) The purpose of OAR 855-041-3100 through 855-041-3130 is to provide minimum requirements of operation for remote prescription processing by a pharmacy.¶

(3) Prior to initiating one of the above drug outlet models, a description of how the model will be utilized must be submitted to the Board.¶

~~(4) The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a consulting or drugless pharmacy. Prior to initiating this model, a description of how the model will be utilized to improve patient safety must be submitted to the Board.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

REPEAL: 855-041-3300

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3300 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3300~~

~~Purpose and Scope~~

~~The purpose of OAR 855-041-3300 through 855-041-3340 is to establish a secure environment where a consulting pharmacist can provide pharmaceutical care and store health protected information in a single physical location. This location may be an office located in a home or other secure location. Registration is not required if records used or generated by a consulting pharmacist are stored in a location registered by the Board as a retail or institutional drug outlet or if the location is under the control of a practitioner who uses the services of the consulting pharmacist. The consulting pharmacist must be able to provide the Board with documentation of their pharmaceutical care activities. These rules are intended to ensure that a location where a pharmacist is engaged in Independent Pharmacy Practice may safely store records and protected health information. An applicant must submit to the Board for approval policies and procedures and a description of how their consulting or drugless pharmacy will be utilized to improve patient safety.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3305

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3305 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3305~~

~~Definitions~~

~~The following words and terms, when used OAR 855-041-3300 through 855-041-3340 shall have the following meanings, unless the context clearly indicates otherwise. Any term not defined in this section shall have the definition set out in the OAR chapter 855, division 6.~~

~~(1) "Consulting or Drugless Pharmacy" means any single physical location where pharmaceutical care services are performed or protected health information may be stored without the storage, possession, or ownership of any drug.~~

~~(2) "Consulting Pharmacist" means any pharmacist as defined by OAR chapter 855, division 6 and is described by chapter 855, division 19.~~

~~(3) "Independent Pharmacy Practice" means the provision of pharmaceutical services not related to physically handling or dispensing pharmaceuticals drugs or devices. This practice is characterized by the practice of an Oregon licensed pharmacist acting as an independent contractor whether or not directly employed or affiliated with an entity that is licensed by the Board. This service also does not include the provision of pharmaceutical care that is conducted within the physical confines or location of a licensed pharmacy registered with the Board.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3310

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3310 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3310~~

~~Registration~~

~~(1) The Consulting Pharmacy shall be registered as a retail or institutional drug outlet and comply with all the requirements of licensure as defined in OAR 855-041-1080 through 855-041-1100.~~

~~(2) The location must be available for inspection by the Board.~~

~~(3) A consulting pharmacist for an Oregon licensed healthcare facility must perform all duties and functions required by the healthcare facility's licensure, as well as any applicable federal and state laws and rules.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3315

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3315 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3315~~

~~Personnel~~

~~(1) Each pharmacy must have a pharmacist-in-charge. To qualify for this designation, the person must hold a license to practice pharmacy in the state of Oregon and in the state in which the pharmacy is located if the pharmacy is out-of-state. The pharmacist-in-charge must be in good standing with both licensing Boards;~~

~~(2) The pharmacy must comply with all applicable state and federal laws and rules governing the practice of pharmacy and maintain records in compliance with requirements of federal law and Board rules;~~

~~(3) A consulting pharmacist who provides services to any person or facility located in Oregon, must be an Oregon licensed pharmacist except that a pharmacist working in an out-of-state pharmacy, who only performs the professional tasks of interpretation, evaluation, DUR, counseling and verification associated with their dispensing of a drug to a patient in Oregon; and~~

~~(4) Prospective drug utilization reviews, refill authorizations, interventions and patient counseling not associated with the dispensing of a drug for an Oregon patient must be performed by an Oregon licensed pharmacist.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3320

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3320 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3320~~

~~Confidentiality~~

~~(1) Each consulting pharmacy must comply with all applicable federal and state laws and rules regarding confidentiality, integrity and privacy of patient information.~~

~~(2) Each consulting pharmacy must ensure that electronic data systems are secure and comply with applicable federal and state laws and rules.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3325

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3325 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3325~~

~~General Provisions and Minimum Standards-~~

~~(1) A consulting pharmacy shall:~~

~~(a) Maintain appropriate reference materials for drug information according to the scope of consulting services.~~

~~(b) Be located in a secure room with a door and suitable lock, and accessible only to persons authorized by the pharmacist in charge.~~

~~(c) Provide storage sufficient to secure confidential documents and any hardware necessary to access information.~~

~~(d) Be constructed in a manner of materials that make the space separate and distinct from the rest of the home or office building, and that protects the records from unauthorized access.~~

~~(2) A consulting pharmacy located in a residence must be approved by the Board.~~

~~(3) The consulting pharmacist must be able to provide the Board, upon request, with documentation of their pharmaceutical care activities.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3330

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3330 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3330~~

~~Security Requirements-~~

~~(1) All consulting services must occur in a secure environment that includes but is not limited to:~~

~~(a) A closed system or other electronic storage device that is password protected;~~

~~(b) A secure room or safe that is locked to store records when the pharmacist is not directly monitoring them;~~

~~(c) Sufficient encryption for securing confidential documents and any hardware used in accessing authorized patient health information by electronic connection; and~~

~~(d) A data processing system that complies with all federal and state laws and rules to ensure compliant security software.~~

~~(2) Records stored at a practitioner's office must be kept secure either with other records at the facility or independently in a locked room where only the pharmacist, and physician and their agents have access;~~

~~(3) All records must be stored at the approved consulting or drugless pharmacy; and~~

~~(4) Any breach in the security of the system or breach of confidentiality must be documented and reported to the Board within seven days.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3335

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3335 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3335~~

~~Policies and Procedures~~

~~The consulting pharmacy must maintain a current policy and procedures manual that includes at a minimum:~~

~~(1) A policy on protecting confidentiality and integrity of patient information;~~

~~(2) An outline of responsibilities and scope of services;~~

~~(3) A policy on compliance with federal and state laws and rules;~~

~~(4) An operational Quality Assurance Program;~~

~~(5) A policy that describes use of computer systems.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-041-3340

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Repeals OAR 855-041-3340 in its entirety effective at 11:59PM on 2/29/2024 as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

~~855-041-3340~~

~~Records~~

~~(1) The recordkeeping and storage requirements in OAR 855-041-3300 through 855-041-3340 are in addition to the requirements of other recordkeeping and storage rules of the Board. Records and documentation may be written, electronic or a combination of the two.~~

~~(2) Each recordkeeping system must include quality improvement program documentation.~~

~~(3) The PIC must ensure maintenance of written or electronic records and reports as necessary to ensure patient health, safety, and welfare. Records must include but need not be limited to:~~

~~(a) Patient profiles and records;~~

~~(b) A list of current employees and their license numbers;~~

~~(A) Verification of each license and registration;~~

~~(B) The name of the individual responsible for verification of licensure and registration status.~~

~~(c) Copies of all contracts for consulting services and collaborative therapy agreements;~~

~~(d) Copies of all consultation reports submitted to practitioners and facilities.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

AMEND: 855-110-0007

NOTICE FILED DATE: 12/22/2023

RULE SUMMARY: Amends the rule by striking 7(a)(A) "Consulting/Drugless Pharmacy" as new rules in OAR 855-104 and OAR 855-115, effective at 12:00AM on 3/1/2024, regulate pharmacists when lawfully practicing pharmacy outside of a drug outlet and clarify when a drug outlet license is required.

CHANGES TO RULE:

855-110-0007

Fees for Registration, Renewal, and Reinspection of Drug Outlets ¶

- (1) Drug Distribution Agent. Expires September 30 annually - \$400. Late renewal fee (received after September 30) - \$100.¶
 - (2) Drug Room (including Correctional Facility). Expires March 31 annually - \$100. Late renewal fee (received after March 31) - \$75.¶
 - (3) Manufacturer (including Manufacturer Class I, Manufacturer Class II and Manufacturer Class III). Expires September 30 annually - \$525. Late renewal fee (received after September 30) - \$100.¶
 - (4) Nonprescription Drug Outlet. Expires January 31 annually - \$75. Late renewal fee (received after January 31) - \$25.¶
 - (a) This includes the following categories of registration:¶
 - (A) Nonprescription Class A.¶
 - (B) Nonprescription Class B.¶
 - (C) Medical Device, Equipment & Gas Class C.¶
 - (b) Other nonprescription Drug Outlet registration category fees are as follows:¶
 - (A) Nonprescription Class D. Expires January 31 annually - \$100. Late renewal fee (received after January 31) - \$25.¶
 - (B) Nonprescription Class E. Expires January 31 annually - \$0. Late renewal fee (received after January 31) - \$0.¶
 - (5) Prophylactic and/or Contraceptive Wholesaler and/or Manufacturer - \$50. Expires December 31 annually.¶
 - (6) Re-inspection fee - \$100. Applies to any re-inspection of a drug outlet occasioned to verify corrections of violations found in an initial inspection.¶
 - (7) Retail or Institutional Drug Outlet Pharmacy. Expires March 31 annually - \$225. Late renewal fee (received after March 31) - \$75.¶
 - (a) This includes the following categories of registration:¶
 - (A) ~~Consulting "Drugless" Drug Outlet Pharmacy~~¶
 - (~~B~~) Home Dialysis Retail Drug Outlet Pharmacy¶
 - (~~C~~) Institutional Drug Outlet Pharmacy¶
 - (~~D~~) Remote Dispensing Site Retail Drug Outlet Pharmacy¶
 - (~~E~~) Retail Drug Outlet Pharmacy¶
 - (b) Other Retail/Institutional Drug Outlet registration category fees are as follows:¶
 - (A) Charitable Retail Drug Outlet Pharmacy. Expires March 31 annually - \$75. Late renewal fee (received after March 31) - \$25.¶
 - (B) Community Health Clinic (CHC) Retail Drug Outlet Pharmacy. Expires March 31 annually - \$100. Late renewal fee (received after March 31) - \$25.¶
 - (C) Dispensing Practitioner Drug Outlet (DPDO) Retail Drug Outlet Pharmacy. Expires March 31 annually - \$100. Late renewal fee (received after March 31) - \$25.¶
 - (D) Prescription Kiosk Retail Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually.¶
 - (E) Prescription Locker Retail Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually.¶
 - (F) Remote Dispensing Machine Institutional Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually.¶
 - (G) Remote Distribution Facility Institutional Drug Outlet Pharmacy. Expires March 31 annually - \$120. Due by March 31 annually.¶
 - (8) Wholesaler (including Wholesaler Class I, Wholesaler Class II and Wholesaler Class III). Expires September 30 annually - \$525. Late renewal fee (received after September 30) - \$100.
- Statutory/Other Authority: ORS 689.205, ORS 291.055
Statutes/Other Implemented: ORS 689.135, ORS 689.774, ORS 689.305

