

DRAFT RULES

Consulting or Drugless Pharmacies

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 currently required to be registered by the Board as a retail 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

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 006.

(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 006 and is described by OAR Chapter 855, Division 019.

(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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

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 Chapter 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

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 pharmacy's resident state 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, patient counseling, claims submission, claims resolution and adjudication for an Oregon patient must be performed by an Oregon licensed pharmacist.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3320

Confidentiality

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

(2) Each consulting pharmacy must ensure that electronic data systems are secure and meet the applicable federal and state regulations.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

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 protect 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

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 utilizes all federal and state regulation 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3335

Policies and Procedures

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

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

(b) An outline of responsibilities and scope of services;

(c) A policy on compliance with federal and state laws, rules, and regulations;

(d) An operational Quality Assurance Program;

(e) A policy that describes use of computer systems.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-041-3340

Records

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

(2) Each record keeping 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 practitioner and facilities.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155