

DIVISION 41

OPERATION OF PHARMACIES (RETAIL AND INSTITUTIONAL DRUG OUTLETS) CONSULTING PHARMACISTS AND OPERATION OF DRUG ROOMS

855-041-0005 [Renumbered to **855-041-1080** and Amended]

855-041-0007

~~Applicability of Rules~~

~~(1) In conjunction with the rules in division 19 of this chapter, these rules, OAR 855-041-0015 through 855-041-0620 apply to all retail and institutional drug outlets doing business in Oregon, and to the pharmacists working in these outlets.~~

~~(2) The provisions of OAR 855-041-0015 through 855-041-0100 are applicable to all retail drug outlets, including the practice of pharmacy in such outlets, and are applicable to all institutional drug outlets except where OAR 855-041-0105 through 855-041-0160 provide specific exemption or exceptions or where 855-041-0105 through 855-041-0160 are in direct conflict in which case 855-041-0105 through 855-041-0160 shall apply.~~

~~Stat. Auth.: ORS 689.205~~

~~Stats. Implemented: ORS 689.151, 689.155, 689.305~~

~~Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1989, f. & cert. ef. 1-3-89; Renumbered from 855-041-0050, BP 2-2008, f. & cert. ef. 2-20-08~~

855-041-0010 [Renumbered to **855-041-1085**]

855-041-0015 [Renumbered to **855-041-1090** and Amended]

855-041-0016 [Renumbered to **855-041-1170**]

855-041-0017 [Renumbered to **855-041-1095**]

855-041-0020 [Renumbered to **855-041-1010**]

855-041-0025 [Renumbered to **855-041-1015**]

855-041-0026 [Renumbered to **855-041-1020** and Amended]

855-041-0030

~~Loss of Pharmacy Certificate of Registration (Both Retail and Institutional)~~

~~In case of loss of certificate of registration, the Board may require a sworn statement before a notary public to be filed in the Board office before duplicate certificates of registration can be issued.~~

~~Stat. Auth.: ORS 689~~

~~Stats. Implemented:~~

~~Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80~~

855-041-0035 [Renumbered to **855-041-2100** and Amended]

855-041-0036 [Renumbered to **855-041-1025**]

855-041-0037 [Renumbered to **855-041-1030**]

855-041-0040 [Renumbered to **855-041-1035**]

855-041-0055 [Renumbered to **855-041-1145**]

855-041-0056 [Renumbered to **855-041-1135**]

855-041-0057 [Renumbered to **855-041-1140**]

855-041-0060 [Renumbered to **855-041-1040**, **855-041-1160**, **855-041-1165** and Amended]

855-041-0061 [Renumbered to **855-041-1110**]

855-041-0065 [Renumbered to **855-041-1105**, **855-041-1120**, **855-041-1125**, **855-041-1130** and Amended]

855-041-0075 [Renumbered to **855-041-2115**]

855-041-0080 [Renumbered to **855-041-1045**]

855-041-0086 [Renumbered to **855-041-1115**]

855-041-0095 [Renumbered to **855-041-1050**]

855-041-0103 [Renumbered to **855-041-1055**]

855-041-0135 [Renumbered to **855-041-6800** and Amended]

855-041-0140 [Renumbered to **855-041-6840**]

855-041-0145 [Renumbered to **855-041-7050** and Amended]

855-041-0160 [Renumbered to **855-041-7060** and Amended]

855-041-0162 [Renumbered to **855-041-7070** and Amended]

855-041-0164 [Renumbered to **855-041-7080**]

855-041-0165 [Renumbered to **855-041-8050** and Amended]

855-041-0170 [Renumbered to **855-043-0600**]

855-041-0173 [Renumbered to **855-043-0610**]

855-041-0175 [Renumbered to **855-043-0620**]

855-041-0177 [Renumbered to **855-043-0630**]

855-041-0300 [Renumbered to **855-041-1060**]

855-041-0350 [Renumbered to **855-041-4025**]

855-041-0355 [Renumbered to **855-041-4035**]

855-041-0360 [Renumbered to **855-041-4045** and Amended]

855-041-0365 [Renumbered to **855-041-4055**]

855-041-0600 [Renumbered to **855-041-4100**]

855-041-0610 [Renumbered to **855-041-4110**]

855-041-0620 [Renumbered to **855-041-4120** and Amended]

855-041-0645 [Renumbered to **855-041-4200**]

[The following encompasses a title change for Division 041, renumbering and amendments. The yellow highlighted text reflects all changes. The renumbered rules that do not have any revisions are reflected in italics with the section title for your reference. Note the complete text will appear upon filing. The renumbered and amended rules are listed in full text and the changes are identified with highlights, underline and bold.]

DIVISION 41

OPERATION OF PHARMACIES (~~RETAIL AND INSTITUTIONAL~~ AMBULATORY AND RESIDENTIAL DRUG OUTLETS) **~~CONSULTING PHARMACISTS AND OPERATION OF DRUG ROOMS~~**

General

855-041-1010 *from 855-041-0020*
Personnel

855-041-1015 *from 855-041-0025*
Operations of Pharmacy

855-041-1020 *from 855-041-0026*

Security of Prescription Area

- (1) The area in a registered pharmacy where legend and/or controlled substances are stored, possessed, prepared, manufactured, compounded, or repackaged shall be restricted in access, in such a manner as to insure the security of those drugs.
- (2) The pharmacist-in-charge and each pharmacist while on duty shall be responsible for the security of the prescription area including provisions for adequate safeguards against theft or diversion of prescription drugs, and records for such drugs.
- (3) When there is no pharmacist present, the pharmacy shall be secured to prevent entry. All entrances to the pharmacy shall be securely locked and any keys to the pharmacy shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge. When there is no pharmacist present, and it is necessary for non-pharmacist employees or owners to have access to the pharmacy, the prescription area shall be secured from entry as described in OAR 855-041- ~~0035~~ **2100**.
- (4) Prescription drugs and devices and non-prescription Schedule V controlled substances shall be stored within the prescription area or a secured storage area.
- (5) Any security system deviating from the requirements of this section, except as provided in OAR 855-041-~~0120~~ **6310**, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A

written description of such security system, as approved by the Board, shall be maintained in the pharmacy.

Stat. Auth.: ORS 475.035 & 689.205

Stats. Implemented: **ORS 689.205**

855-041-1025 from 855-041-0036

Disposal of Drugs

855-041-1030 from 855-041-0037

Reporting Drug Loss

855-041-1035 from 855-041-0040

Minimum Equipment Requirements

855-041-1040 from 855-041-0060(7)

~~(7) **Drug Outlet Procedures:**~~

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:

~~(a)~~ **(1)** Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;

~~(b)~~ **(2)** Performing mandatory prospective drug utilization reviews; **on all prescriptions both new and refilled;**

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

~~(d)~~ **(4)** Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;

~~(e)~~ **(5)** Ensuring the delivery of each completed prescription to the correct party;

~~(f)~~ **(6)** Providing appropriate confidential professional advice concerning medications to patients or their agents;

~~(g)~~ **(7)** Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties; **and;**

(8) Establishing and maintaining a Continuous Quality Assurance Program.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.508

855-041-1045 from 855-041-0080
Returned Drugs and Devices

855-041-1050 from 855-041-0095
Pharmacy Depots

855-041-1055 from 855-041-0103
Confidentiality

855-041-1060 from 855-041-0300
Out-of-State Pharmacies

Licensure

855-041-1080 from 855-041-0005

Pharmacy Registration (Both Retail and Institutional Drug Outlets)

- (1) Pharmacies shall be registered as either retail drug outlets or institutional drug outlets or both.
- (2) An application for registration of a new pharmacy shall be accompanied by a floor plan drawn to scale and shall be approved by the Board prior to opening.
- (3) The application shall specify the location of the pharmacy and shall indicate the owner, trustee, receiver, or other person applying for the registration. When an applicant is not the owner of the pharmacy, the application shall indicate the owner and the applicant's affiliation with the owner:
 - (a) If the owner is a partnership or other multiple owner, the names of the partners or persons holding the five largest interests shall be indicated on the application;
 - (b) If the owner is a corporation, the name filed shall be the same as filed with the Corporation Commissioner. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests shall be indicated on the application.
- (4) Upon request by the Board, the applicant shall furnish such information as required by the Board regarding the partners, stockholders, or other persons not named in the application.
- (5) The application shall also identify any person who has incidents of ownership in the pharmacy who also has financial interest in any long-term care facility as defined in ORS 442.015.
- (6) A certificate of registration will be issued upon Board approval of the application.

(7) All registration renewal applications shall be accompanied by the annual fee and shall contain the same information required in sections (3) and (4) of this rule.

(8) The initial and annual registration fee for pharmacies is set out in division 110 of this chapter.

(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to in ~~section (7) of this rule~~ **Division 110 of this Chapter** is not paid by March 31 of the current year, a delinquent fee as set out in ~~Division 110 of this e~~**Chapter** shall be included with the application for registration renewal.

(10) The registration is not transferable and the registration fee cannot be prorated.

(11) A change of ownership requires the approval of the Board and new certificate of registration. Application shall be on a form supplied by the Board.

(12) A change of ownership includes any change in the legal form of the business including additions or deletions of partners.

(13) Applicants for change in ownership shall provide the Board with the information required in sections (3), (4), and (5) of this rule.

(14) ~~Following Board approval a~~ **A** change of ownership shall be reported to the Board within 15 days of the occurrence.

(15) No pharmacy shall be operated until a certificate of registration has been issued to the pharmacy by the Board.

Stat. Auth.: ORS 475.035 & 689.205

Stats. Implemented: **ORS 689.155**

855-041-1085 from 855-041-0010

Change of Location of a Pharmacy

855-041-1090 from 855-041-0015

Change of Business Name, Closure (Both Retail and Institutional Drug Outlets)

(1) Any change of business name of a pharmacy must be reported to the Board within 15 days by filing a new application for which no fee is required. ~~New certificates of registration will be issued at the next regular renewal period.~~

(2) Any closure of a pharmacy shall be reported to the Board within 15 days and include notification of the disposition of controlled substances, dangerous, legend, and restricted drugs.

Stat. Auth.: ORS 475.035 & 689.205

Stats. Implemented: **ORS 689.205**

Hist.: 1PB 2-1979(Temp), f. & ef. 10-3-79; 1PB 2-1980, f. & ef. 4-3-80; PB 1-1994, f. & cert. ef. 2-2-94

855-041-1095 from 855-041-0017

Pharmacy Advertising

Prescriptions

855-041-1105 from 855-041-0065(1)-(2)(c)

Requirements for Prescriptions - ~~Prescription Refills~~

(1) Prescriptions, prescription refills, and drug orders must be correctly dispensed in accordance with the prescribing practitioner's authorization. When a prescription is transmitted orally, both the receiving pharmacist's name or initials and the name of the person transmitting must be noted on the prescription.

~~(1)~~ **(2)** Each pharmacy must document the following information:

(a) The name of the patient for whom or the owner of the animal **and the species of the animal** for which the drug is dispensed;

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner or other number as authorized under rules adopted by reference under rule OAR 855-080-0085;

~~(c) If the prescription is for an animal, the species of the animal for which the drug is dispensed.~~

~~(d)~~ **(c)** The name, strength, dosage forms of the substance, quantity prescribed and, if different from the quantity prescribed, the quantity dispensed;

~~(e)~~ **(d)** The directions for use, if given by the practitioner; **and**

~~(f)~~ **(e)** The date of filling, and the total number of refills authorized by the prescribing practitioner; **and**.

~~(2)~~ **(3)** In accordance with ORS 689.515(3), a practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

(a) For a hard copy prescription issued in writing or a prescription orally communicated over the telephone, this instruction may use any one of the following phrases or notations:

(A) No substitution;

(B) N.S.;

(C) Brand medically necessary;

(D) Brand necessary;

(E) Medically necessary;

(F) D.A.W. (Dispense As Written); or

(G) Words with similar meaning.

(b) For an electronically transmitted prescription, the prescriber or prescriber's agent shall clearly indicate substitution instructions by way of the text (without quotes) "brand medically necessary" or words with similar meaning, in the electronic prescription drug order, as well as all relevant electronic indicators sent as part of the electronic prescription transmission.

(c) Such instructions shall not be default values on the prescription.

(4) Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.505 & 689.515

855-041-1110 from 855-041-0061

Tamper-Resistant Prescription

855-041-1115 from 855-041-0086

Verification of Prescription Authenticity

855-041-1120 from 855-041-0065(3)-(5)(e)

Prescription Refills

(3)(1) Where refill authority is given other than by the original prescription, documentation that such refill authorization was given, the date of authorization, and name of the authorizing prescriber or the prescriber's agent must be recorded. This documentation must be readily retrievable. Prescriptions for controlled substances in Schedules III and IV are limited to five refills or six months from date of issue, whichever comes first.

(4)(2) If the practitioner is not available and in the professional judgment of the pharmacist an emergency need for the refill of a prescription drug has been demonstrated, the pharmacist may dispense a sufficient quantity of the drug consistent with the dosage regimen, provided it is not a controlled substance, to last until a practitioner can be contacted for authorization, but not to exceed a 72-hour supply. The practitioner shall be promptly notified of the emergency refill.

(5)(3) Each refilling of a prescription must be accurately documented, readily retrievable, and uniformly maintained for three years. This record must include:

- (a) The identity of the responsible pharmacist;
- (b) Name of the patient;
- (c) Name of the medication;
- (d) Date of refill; and
- (e) Quantity dispensed.

(4) Refill quantities may be combined into a single filling if the prescription is not for a controlled substance or psychotherapeutic drug and the prescriber is notified of the change.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.505 & 689.515

855-041-1125 from 855-041-0065(6)

Prescription Expiration

This section of rule addresses the expiration date of the prescription and not the expiration date of the drug.

(6)(1) After ~~two~~ **one**-years from date of issue, a prescription for a non-controlled substance becomes invalid and must be re-authorized by the prescriber.

(2) When used alone as a prescription refill designation the abbreviation, "PRN" for a non-controlled substance means that the medication can be refilled in proper context for a period of one year.

(a) When this abbreviation is used alone as a means to authorize refills for a controlled substance, the medication can be refilled in proper context for a period of six months or five refills, whichever comes first.

(b) When this abbreviation is used in conjunction with a definite time period, or a specific number of refills, the non-controlled medication can be refilled in proper context for a period not to exceed ~~two~~ **one**-years

(3) The prescription shall not be refilled out of context with the approximate dosage schedule unless specifically authorized by the prescriber.

(4) A "non-controlled substance" means those drugs defined as "legend" pursuant to ORS 689.005(29) but does not include those drugs or substances controlled under the jurisdiction of the United States Department of Justice Drug Enforcement Administration.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.505 & 689.515

Labeling

855-041-1130 from 855-041-0065(7)-(8)

Prescription Labeling

~~(7)~~ **(1)** Prescriptions must be labeled with the following information:

- (a) Name, address and telephone number of the pharmacy;
- (b) Date;
- (c) Identifying number;
- (d) Name of patient;
- (e) Name of drug, strength, and quantity dispensed; when a generic name is used, the label ~~shall~~ **must** also contain the ~~name~~ **identifier** of the manufacturer or distributor;
- (f) Directions for use by the patient;
- (g) Name of practitioner;
- (h) Required precautionary information regarding controlled substances;
- (i) Such other and further accessory cautionary information as required for patient safety;
- (j) An expiration date after which the patient should not use the drug or medicine. Expiration dates on prescriptions must be the same as that on the original container unless, in the pharmacist's professional judgment, a shorter expiration date is warranted. Any drug bearing an expiration date shall not be dispensed beyond the said expiration date of the drug; and
- (k) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, shall be labeled with its physical description, including any identification code that may appear on tablets and capsules.

~~(8)~~ **(1)** Upon written request and for good cause, the Board may waive any of the requirements of this rule. A waiver granted under this section shall only be effective when it is issued by the Board in writing.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.505 & 689.515

855-041-1135 from 855-041-0056

Defines Labeling and Container Requirements for Repackage Drugs

855-041-1140 from 855-041-0057

Customized Patient Medication Packages

Dispensing

855-041-1145 from 855-041-0055

New Containers

Records

855-041-1160 from 855-041-0060(1)-(4)(c)

Prescription Records and Retention

(1) Definitions. The following definitions apply to this rule:

(a) An "original prescription" is a prescription maintained in the same physical manner in which a pharmacy first receives the prescription. For example, for a prescription received by the pharmacy in writing on a prescription form, the original prescription consists of the original writing on the prescription form. For a prescription received by the pharmacy orally over the telephone, the original consists of the writing or electronic record that reflects receipt of the oral prescription.

(b) "Filing" and "file" mean the storage of the original prescription in such a manner that the original prescription is safeguarded and readily retrievable.

(2) Every pharmacy and pharmacist-in-charge of a pharmacy must ensure that original prescriptions are properly filed in compliance with this rule.

(3) All original prescriptions shall be filed for a minimum of three years from the date of first dispensing and shall at all times be open for inspection by the prescriber, and the Board of Pharmacy or its duly authorized agent.

(4) After 120 days, the paper prescription may be destroyed and filed in an electronic form if:

(a) The electronic form shows the exact and legible image of the original prescription;

(b) Notes of clarifications of and changes to the prescription are directly associated with the electronic form of the prescriptions; and

(c) The prescription is not for a controlled substance.

~~(8)~~**(5)** This rule is not intended to alter or supersede the recordkeeping requirements of any other federal or Oregon statute or rule, including but not limited to ORS 689.508, OAR 855-041-~~0065~~**1120**, and rules related to records for prescriptions for controlled substances.

(6) Unless specified otherwise, all records and documentation required by OAR 855 Division 041 must be retained for three years and made available to the Board for inspection upon request. Records must be stored onsite for at least one year and may be stored 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.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.508

855-041-1165 from 855-041-0060(5)-(6)

Patient Medical Record

~~(5)~~**(1)** A patient record system shall be maintained by pharmacies for all patients for whom prescription drug orders are dispensed, except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs. The patient record system shall provide for readily retrievable information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

- (a) Full name of the patient for whom the drug is intended;
- (b) Address and telephone number of the patient;
- (c) Patient's age or date of birth;
- (d) Patient's gender;
- (e) Chronic medical conditions;
- (f) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;
- (g) Known allergies, drug reactions, and drug idiosyncrasies; and
- (h) If deemed relevant in the pharmacist's professional judgment:

(A) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and

(B) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

~~(6) Patient records shall be maintained for a period of not less than three years.~~

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.151, 689.155, 689.508

855-041-1170 from 855-041-0016

Grounds for Discipline

General Community Pharmacy

855-041-2100 from 855-041-0035

Operation of a Double Set-Up Pharmacy in a Retail Drug Outlet

A double set-up is an establishment having both a retail drug outlet registration and a nonprescription drug outlet registration. In a double set-up:

(1) The retail drug outlet (pharmacy) must be a separate operation, completely contained by an enclosure which assures safe storage. This enclosure must be from floor to ceiling or be at least ten feet from the floor. This area is to be easily distinguished by the public. When the retail drug outlet (pharmacy department) is closed, then as a nonprescription drug outlet the establishment is subject to the provisions of OAR 855-035-0005 and 855-035-0020.

(2) When a pharmacist is not in attendance, a closed sign shall be posted at the entrances stating the hours of the pharmacy's operation. All entrances to the retail drug outlet shall be closed off and securely locked. Any keys to the retail drug outlet (pharmacy) shall remain in the possession of the pharmacist-in-charge and other employee pharmacists as authorized by the pharmacist-in-charge if the retail drug outlet (pharmacy) is closed while the nonprescription outlet (shopkeeper) remains open.

(3) Any system deviating from the requirement of this section, except as provided in OAR 855-041-0120 **6310**, shall be approved by the Board prior to implementation. Requests for such approval shall be in writing and provide a detailed description of the proposed system. A written description of such system, as approved by the Board, shall be maintained in the pharmacy.

Stat. Auth.: ORS 689.**205**

Stats. Implemented: **ORS 689.205**

855-041-2115 from 855-041-0075

Transfer of Prescription Info Between Pharmacies

Retail Drug Outlet for Home Dialysis Supplies

855-041-4025 from 855-041-0350

Purpose and Scope

855-041-4035 from 855-041-0355

Definitions

855-041-4045 from 855-041-0360

Drug Delivery and Control

- (1) An Oregon licensed pharmacist must be designated as the pharmacist-in-charge who will provide direction and supervision of the operation and staff.
- (2) Deliveries of supplies must be made only pursuant to a current prescription order from an authorized prescriber. The prescription order must be maintained on file at the outlet. Supplies will be limited to dialysis solutions as defined in OAR 855-041-0355 **4035**. No other legend medication ordered for the patient may be provided by the outlet.
- (3) All patient records must be maintained in a secure area with a locking door. Access to the patient records area is allowed only when a pharmacist is present except in the event of an emergency. In the event of an emergency, any entry by individuals other than the pharmacist must be documented. In the absence of a pharmacist, the door to the patient records area must remain locked at all times.
- (4) Copies of all prescriptions must be reviewed by the pharmacist and a complete set of prescription records for all patients serviced by the outlet must be maintained in the patient records area for a minimum of three years.
- (5) A minimum of two current reference books that are specific and relevant to dialysis therapy must be maintained in the outlet to assist in the appropriate delivery of care to patients. Other reference material and equipment must be maintained to be consistent with the scope of services provided by the outlet.
- (6) A current copy of Oregon Revised Statutes, Chapter 689, a current copy of Oregon Administrative Rules, chapter 855, and a minimum of three years of the Oregon Board of Pharmacy quarterly newsletters must be maintained in a loose leaf binder or other readily retrievable means.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-041-4055 from 855-041-0365

Duties of the Pharmacist

Remote Dispensing

855-041-4100 from 855-041-0600

Definitions

855-041-4110 from 855-041-0610

Duties and Responsibilities of the Pharmacist-in-Charge

855-041-4120 from 855-041-0620

Drug Delivery and Control

(1) Each RDM must be registered with the Board, under the control of and connected via computer with a Responsible Pharmacy, but not located in a pharmacy. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The Responsible Pharmacy must establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws and regulations.

(2) The following must be conspicuously displayed at the site of the RDM:

- (a) RDM license;
- (b) DEA registration if required;
- (c) A certified copy of the Responsible Pharmacy license; and
- (d) A certified copy of the Pharmacist-In-Charge license.

(3) Documentation as to type of equipment, serial numbers, content, policies and procedures, and location shall be maintained in the pharmacy for review by the board. Such documentation must include, but is not limited to:

- (a) Location of RDM(s);
- (b) Manufacturer's name and model for each RDM;
- (c) Description of how the RDM is used;
- (d) Quality assurance procedures to determine continued appropriate use of the automated device; and

(e) Policies and procedures for training of appropriate personnel, system operation, safety, security, accuracy, patient confidentiality, oral counseling by a pharmacist or pharmacist-intern, access, and malfunction.

(4) Policies and procedures addressing the operation of the RDM must be maintained in the pharmacy responsible for the APS and at the location at which the RDM has been installed.

(5) All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the pharmacy for a minimum of three years and must be readily available to the Board. Such records shall include:

(a) Identity of RDM accessed;

(b) Identification of the individual accessing the RDM;

(c) Type of transaction;

(d) Date and time of transaction;

(e) Name, strength, dosage form, and quantity of the drug accessed;

(f) Name of the patient for whom the drug was ordered;

(g) Name of the prescribing practitioner

(h) Such additional information as the pharmacist-in-charge may deem necessary; and

(6) Only an Oregon registered technician or an Oregon licensed pharmacist may have access to the RDM.

(7) Only an Oregon registered technician or an Oregon licensed pharmacist may stock medications in the RDM.

(8) All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws and regulations, including OAR 855-041-0065(6)(a)(k) **1130**.

(9) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(10) Oral counseling, as required by OAR 855-041-0100 **019-0230**, shall be provided by the pharmacist at the time of dispensing by a two-way audio and video hookup with the Responsible Pharmacy.

(11) The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded or unused medications in accordance with existing state and federal laws and regulations.

(12) The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist-In-Charge.

(13) A Responsible Pharmacy located outside of Oregon that operates a RDM in Oregon must be currently licensed and in good standing in Oregon. The Pharmacist-In-Charge must also be currently licensed and in good-standing both in Oregon and in the state in which the Responsible Pharmacy is located.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.205

Remote Dispensing Facilities

855-041-4200 from 855-041-0645

Remote Dispensing Facility (RDF)

Hospitals with Drug Rooms

855-041-6800 from 855-041-0135

Supervision of Consulting Pharmacist

(1) In a hospital having a drug room and no pharmacy, the drug room must be supervised by a licensed pharmacist who provides his or her services with sufficient professionalism, quality and availability to adequately protect the safety of the patients and to properly serve the needs of the facility. The arrangements for a consulting pharmacist shall be in writing, and shall, at a minimum, provide that:

(a) The pharmacist is to act in the capacity of a part-time director;

(b) The pharmacist shall provide on-call service at all times;

(c) Adequate storage facilities for drugs will be provided; and

(d) All drugs supplies shall be labeled so as to insure that recalls can be effected and that proper control and supervision of such drugs may be exercised.

(2) One registered nurse supervisor and only one in any given shift may have access to the drug room and may remove drugs therefrom, except in an emergency situation. In that case, such nurse may designate another licensed nurse to obtain the required drug(s). Any access to the drug room deviating from the requirements of this section must be approved by the Board prior to implementation. The registered nurse supervisor shall be designated in writing by the appropriate committee of the hospital and shall, prior to being permitted to obtain access to the drug room, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required. Such education and training shall be given by the director of pharmacy, who shall require, at a minimum, the following records and procedures:

(a) Drugs can only be removed from the drug room on a practitioner's written order, or verbal order which has been reduced to writing;

(b) A log of drugs withdrawn from a drug room shall be maintained and initialed by the registered nurse;

(c) Drugs shall be removed for outpatients only in compliance with section (3) of this rule.

(3) The consultant pharmacist who is the part-time director of pharmaceutical services shall in concert with the appropriate committee of the hospital medical staff, develop policies and procedures which shall be implemented to provide emergency pharmaceuticals to outpatients during the hours when normal community or hospital pharmacy services are not available. Such policies shall allow the designated registered nurse supervisor to issue medications pursuant to the pharmacist's standing orders, which shall provide:

(a) A written order of a practitioner authorized to prescribe a drug is presented;

(b) The medication is prepackaged by a pharmacist and contains:

(A) Name, address and telephone number of the hospital;

(B) Name of drug, strength, and number of units; when a generic name is used, the label shall also contain the name of the manufacturer or distributor;

(C) Required precautionary information regarding controlled substances;

(D) Such other and further accessory cautionary information as required for patient safety;

(E) An expiration date after which the patient should not use the medication.

(c) No more than a 24-hour supply is provided to the patient, except when the pharmacist has informed the nurse supervisor that normal services will not be available within 24 hours;

(d) The container is labeled by the nurse supervisor before presenting to the patient, and shows the following:

(A) Name of patient;

(B) Directions for use to the patient;

(C) Date;

(D) Identifying number;

(E) Name of prescribing practitioner;

(F) Initials of the supervisor.

(e) The original written order by the prescriber is retained for verification by the pharmacist after completion by the nurse supervisor and shall bear:

(A) Name and address of patient;

(B) Date of issuance;

(C) Units issued;

(D) Initials of supervisor issuing medication.

(f) The original written order is verified by the pharmacist, initialed, dated, and filed in a separate location for a period of three years for Board inspection;

(g) The withdrawal of a single dose for immediate administration to the patient need not follow the requirements of subsection (d) of this section.

(4) Emergency Kits:

(a) Emergency Kit Drugs Defined. Emergency kit drugs are those drugs which may be required to meet the immediate therapeutic needs of in-patients, and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from such other source;

(b) Supplying Pharmacist. All emergency kit drugs shall be prepared by a licensed pharmacist;

(c) Drugs Included. The director of pharmacy and the medical staff of the hospital shall jointly determine and prepare a list of drugs, by identity and quantity, in amounts sufficient for immediate therapeutic requirements, to be included in emergency kits. Such list of drugs shall be reviewed annually by the appropriate medical staff committee;

(d) Storage. Emergency kits shall be stored in areas to prevent unauthorized access and to insure a proper environment for preservation of the drugs within them, as required in official compendia;

(e) Labeling -- Interior. All drugs contained in emergency kits shall be labeled in accordance with OAR 855-041-0130(7) **6420**;

(f) Labeling -- Exterior. The exterior of emergency kits shall be labeled to clearly and unmistakably indicate that it is an emergency drug kit and it is for use in emergencies only; such label shall also contain a listing of the name, strength and quantity of the drugs contained therein and an expiration date;

(g) Expiration Date. The expiration date of an emergency kit shall be the earliest expiration date on any drug supplied in the kit. Upon the occurrence of the expiration date, the supplying pharmacist shall open the kit and replace expired drugs;

(h) Removal of Drugs. Drugs shall be removed from emergency kits by authorized personnel only pursuant to a valid order or by the supplying pharmacist;

(i) Notifications. Whenever an emergency kit is opened or has expired, the supplying pharmacist shall be notified and the pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients.

Stat. Auth.: ORS 689.**205**

Stats. Implemented: **ORS 689.205**

855-041-6840 from 855-041-0140

Drug Distribution and Control from a Drug Room Hospital

Pharmacists Serving Long Term Care Facilities and Community Based Care Facilities

855-041-7050 from 855-041-0145

Definitions

As used in OAR 855-041-0145 **7000** through 855-041-0164 **7080**:

(1)(a) "Long term care facility" means a facility with permanent facilities that include inpatient beds, providing medical services, including nursing services but excluding surgical procedures except as may be permitted by the rules of the director, to provide treatment for two or more unrelated patients. "Long Term Care facility" includes skilled nursing facilities and intermediate care facilities but may not be construed to include facilities licensed and operated pursuant to ORS 443.400 to 443.455.

(b) For the purposes of Schedule II prescriptions in 21 CFR 1306.11-1306.13, the DEA definition of "long term care facility" as defined in 21 CFR 1300.01(25) includes "community based care facilities."

(2) "Community Based Care Facility" means a home, facility or supervised living environment licensed or certified or otherwise recognized by an agency of the state of Oregon which provides 24-hour care, supervision, and assistance with medication administration. These include but are not limited to Adult Foster Homes, Residential Care Facilities (RCF), Assisted Living Facilities (ALF), Group Homes for the Developmentally Disabled and Mentally Retarded and Inpatient Hospice.

(3) "Pharmaceutical Care" means the responsible provision of any or all of the following services by the pharmacist:

- (a) Develop and maintain policies and procedures for pharmaceutical services;
- (b) Provide direction and oversight regarding all aspects of the acquisition, disposition, handling, storage, and administration of drugs including but not limited to the following:
 - (A) Receipt and interpretation of physician's orders;
 - (B) Ordering and receiving of medications;
 - (C) Handling of emergency drugs and supplies;
 - (D) Labeling of all drugs;
 - (E) Selection of drug delivery systems;
 - (F) Development of systems to provide timely delivery of drugs and supplies;
 - (G) Monitoring of drug storage conditions and expiration dates;
 - (H) Monitoring accuracy and efficiency of medication administration and compliance with physician's orders;
 - (I) Establishing and monitoring of appropriate record keeping;
 - (J) Accountability of controlled substances;
 - (K) Return, release, and/or destruction of discontinued or outdated drugs; and
 - (L) Compliance with state and federal laws and regulations related to pharmaceutical services and medication management.
- (c) Provide training and in-service education to facility staff;
- (d) Perform drug regimen review for each resident on a regularly scheduled basis for the purpose of promoting therapeutic appropriateness and achieving the desired drug therapy outcomes by identifying issues such as:
 - (A) Over-utilization or underutilization;
 - (B) Therapeutic duplication;
 - (C) Drug-disease contraindications;
 - (D) Drug-drug interactions;
 - (E) Incorrect drug, drug dosage or duration of drug treatment;

- (F) Drug-allergy interaction;
- (G) Clinical abuse/misuse;
- (H) Untreated indication;
- (I) Monitoring and assessing of drug therapy outcomes;
- (e) Communicate effectively with residents' physicians and facility staff; and
- (f) Participate in resident care planning.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.0305

855-041-7060 from 855-041-0160

Drug Distribution and Control

(1) Pharmacies or pharmacists that supply emergency drug kits to and/or accept returned medications from long term care facilities or community based care facilities must:

(a) Assist in the establishment and supervision of:

(A) The policies and procedures for the safe storage, distribution, administration, and disposition of drugs;

(B) The maintenance of controlled drug accountability records; and

(C) The policies and procedures for professional advice/medication counseling of patients and/or their care givers.

(b) Have some pharmacists visit and provide consultant services on a regular basis; **and**

~~(c) Have some pharmacists perform the quality assurance activities defined in OAR 855-041-0132; and~~

~~(d)~~ **(c)** Supervise the implementation of the policies and procedures involving the security, storage, stocking, labeling, and notification of use of emergency drugs kits and supplemental drug supplies.

(2) Arrangements can be made in advance by a provider pharmacy with a long term care facility or a community based care facility to:

(a) Provide emergency drug kits to those facilities permitted by their license to have them; and

(b) Allow only a designated licensed nurse present in the facility access to the emergency drug kit or the on-site pharmacy pursuant to OAR 855-041-0120(3) **6310**.

(3) An emergency drug kit consists of those drugs that may be required and are authorized by a practitioner to meet the immediate therapeutic needs of patients, when medication is not readily available directly from a pharmacy.

(4) The emergency drug kit inventory is the property of the provider pharmacy, and the provider pharmacy consultant is responsible for developing the policy and procedures for storing and stocking the emergency drug kit.

(5) Medication(s) can only be removed from the emergency drug kit or the on-site pharmacy by a designated licensed nurse pursuant to a practitioner's order.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-041-7070 from 855-041-0162

Labeling and Distribution

(1) Except as provided in subsection (2) of this section, all drugs dispensed for individual patients must be labeled as required by OAR 855-041-0065(6) **1120**, or administered by health care professionals from a unit dose system as defined in OAR 855-041-0130(8) **6050(j)**.

(2) Pharmacies that provide long term care facilities or community based care facilities with pharmaceuticals can supply, on the order of a practitioner, and consistent with the policy and procedures of the pharmacy or pharmacist providing consultant services:

(a) Injectables for immunization and screening;

(b) Irrigation solutions; and

(c) Bulk manufacturer's container(s) of topical scabicides and pediculicides.

(3) Institutional pharmacies that dispense medications to patients in long term care facilities and community based care facilities must maintain for three years the records required by

OAR 855-041-0065(4) **1120**, and comply with the patient counseling requirements of OAR 855-041-0100(1) **19-0230**.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.305

855-041-7080 from 855-041-0164

Pharmaceutical Care in Community Based Care Facilities

Home Health Care Agencies

855-041-8050 from 855-041-0165

Emergency Drug Supply in Home Health Care Agencies

Pharmacists serving home health care agencies may provide for an emergency supply of drugs to be made available to registered nurses to treat immediate therapeutic needs of their patients or clients during such time as the pharmacy services are not available. Arrangements shall be made in advance by the provider pharmacist for provision of the emergency drug supply:

- (1) Emergency drugs defined. Emergency drugs are those non-controlled substances which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in a timely manner;
- (2) Portable Container. Subject to all provisions of this section, a licensed pharmacy may furnish to a home health agency licensed by the State an emergency drug supply in a portable container for emergency in home treatment or adjustment of drug therapy by the home health agency nurse;
- (3) Drugs included. The pharmacist(s) and the practitioner(s) who represent the agency shall jointly determine and review annually a list of items and quantities to be included in the emergency supply. Drugs shall only be available therein, in amounts sufficient for immediate therapeutic requirements. The selected list shall include only drugs to treat the following specific conditions:
 - (a) Allergic reactions;
 - (b) Diabetic emergencies;
 - (c) Severe nausea and vomiting;
 - (d) Pulmonary congestion or congestive heart failure;
 - (e) Local or topical anesthetics for catheter and needle placement;
 - (f) Hydration due to hypovolemia or shock;
 - (g) Routine catheter maintenance; and
 - (h) Narcotic analgesic overdose.

(4) Security. The emergency drug supply shall be stored in a manner to prevent loss of drugs, and available only to authorized licensed personnel. It may be kept in a room adjacent to the locked pharmacy, or in a secure area in the Home Health/Home I.V. nursing office;

(5) Storage. The emergency drug supply shall be stored in areas suitable to prevent unauthorized access and to insure a proper environment for preservation of the drugs as required in official compendia;

(6) Labeling-Exterior. The exterior of the emergency drug supply shall be labeled to clearly indicate it as an emergency supply. Labeling shall also include the expiration date of the drug supply. A complete listing of the contents of the supply shall be readily available;

(7) Labeling-Interior. All drugs contained in the emergency medication supply shall in the manufacturer's container or be labeled in accordance with OAR 855-041-~~0056~~ **1135**;

(8) Drugs added to parenteral solutions. Whenever any drug is added to a parenteral solution, whether within or outside the direct personal supervision of a pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, expiration date, administration time and infusion rate when applicable, and name or initials of person so adding. This excludes any single dose medication prepared and totally administered immediately;

(9) Removal of drugs. Emergency drugs shall be removed for administration only by authorized licensed personnel pursuant to a prescriber's order. A copy of this order shall be forwarded to the provider pharmacist within 72 hours to be reviewed and filed in the pharmacy. Verification of this review shall be a hand written initial of the reviewing pharmacist on that copy of the order;

(10) Expiration Date. The expiration date of the emergency drug supply shall indicate the month and year, and shall be the earliest expiration date of any drug in the supply. The provider pharmacist shall examine the supply and replace drugs prior to their expiration.

Stat. Auth.: ORS 475.035 & 689.205

Stats. Implemented: ORS 689.225