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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
10/25/2021 5:13 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Proactive procedural rule review

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/23/2021 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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

HEARING(S)

Auxilary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/23/2021
TIME: 9:30 AM
OFFICER: Rachel Melvin
ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232
SPECIAL INSTRUCTIONS:
This hearing meeting will be held virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 472 815 435# for audio only.

You may file written comments before 4:30PM on November 23, 2021 by emailing your comments to pharmacy.rulemaking@bop.oregon.

NEED FOR THE RULE(S)

The proposed revisions are to clarify the date of incorporated standards of reference, as discussed in with the current Oregon Attorney General's Administrative Law Manual and Uniform and Model Rules of Procedure under the Administrative Procedures Act (07/2019).

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

United States Pharmacopeia -National Formulary <NF> (USP 43-NF38 v. 2021) https://www.uspnf.com/

Homeopathic Pharmacopoeia of the United States (HPUS) (v. 2021): https://www.hpus.com/Related Federal Statutes/Rules:

Poison Prevention Packaging Act: 16 CFR 1700 (XX/XX/XXXX) Poison Prevention Packaging, 16 CFR 1701 (XX/XX/XXXX) Statements of Policy and Interpretation, and 16 CFR 1702 (XX/XX/XXXX) Petitions for Exemptions from Poison Preventing Packaging Act Requirements; Petition Procedures and Requirements

21 USC 351 (XX/XX/XXXX) Adulterated drugs and devices, 21 USC 352 (XX/XX/XXXX) Misbranded drugs and devices

42 USC 262 (XX/XX/XXXX) Regulation of biological products

FISCAL AND ECONOMIC IMPACT:

Related to 855-041-1080 New Containers- None anticipated.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

There are no known economic impacts to the Oregon Board of Pharmacy, small businesses or members of the public.

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

Small businesses were not involved in the development of proposed revisions to these rules.

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

There is no fiscal impact as a result of the proposed rule changes.

RULES PROPOSED:

855-007-0120, 855-041-1001, 855-041-1035, 855-041-1040, 855-041-1080, 855-041-1130, 855-041-1135, 855-041-1145, 855-041-6270, 855-045-0200, 855-045-0220, 855-045-0240, 855-065-0005

AMEND: 855-007-0120

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-007-0120
Damage to a Pharmacy and Drug Integrity ¶

(1) If a pharmacy prescription department sustains damage, whether by flood or otherwise, the entire drug inventory, including any prescriptions that are awaiting pickup, is unfit for dispensing, ~~shall~~must be classified as adulterated and must be destroyed unless, ~~in~~ the ~~pharmacist's professional judgment, any item~~drugs are deemed safe for dispensing pursuant to OAR 855-041-1036. Any incident of this nature must be reported to the ~~B~~board within three working days.¶
(2) If a pharmacy loses power that affects temperature or humidity controls such that ~~USP standards for~~the proper storage of drugs ~~have~~pursuant to OAR 855-041-1036 has been violated, such drugs ~~shall~~must be classified as adulterated and may not be dispensed.¶
~~NOTE: for those drugs labeled for storage at "controlled room temperature," the acceptable range of temperature is 68 to 77F with allowances for brief deviations between 59 to 86F.¶~~

(3) Controlled substances damaged, lost or stolen ~~shall~~must be documented and reported to the DEA and the ~~B~~board on DEA Form 41, DEA Form 106 or DEA Form 10~~6~~7 as appropriate.¶
(4) A pharmacy that is required to temporarily close or relocate due to an emergency must report this event to the ~~B~~board within three working days.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-1001

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1001
Definitions ¶

(1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.¶
(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U~~.S.C.~~SC 262(k)(3)(A)(i)(XX/XX/XXXX).¶
(3)-"Drug room" is a drug storage area registered with the ~~B~~board which is secure and lockable.¶
(4) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U~~.S.C.~~SC 262(k)(4)(XX/XX/XXXX).¶
(5) "Reference biological product" means the biological product licensed pursuant to 42 U~~.S.C.~~SC 262(a) (XX/XX/XXXX) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.¶
(6) "Repackage" means the act of taking a drug from the container in which it was distributed by the manufacturer and placing it into a different container without further manipulation of the drug.
Statutory/Other Authority: ORS 689.205, ORS 689.522
Statutes/Other Implemented: ORS 689.155~~ & 342.~~, ORS 689.522

AMEND: 855-041-1035

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1035
Minimum Equipment Requirements ~~(Both Retail and Institutional Drug Outlets)~~ ¶

~~The minimum equipment requirement to open and operate a retail drug outlet and institutional drug outlet in the state of Oregon shall consist of not less than~~(1) Each retail drug outlet and institutional drug outlet must have the following:¶
(~~1~~a) ~~The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.~~Appropriate and current pharmaceutical references (e.g. pharmacology, injectables, and veterinary drugs) based on services offered by the outlet;¶
(~~2~~b) ~~Current and properly filed Oregon Revised Statutes, Chapters 689, and 475; current and properly filed Oregon Administrative Rules, chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintain~~Appropriate and current Oregon Revised Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, standards adopted by reference (e.g. USP) based on services offered by the outlet and a minimum of three years of the Board of Pharmacy quarterly newsletters;¶
(c) Access to appropriate electronic reporting databases (e.g. PDMP, NPLEx, OHA ALERT-IIS) based ~~i~~on ~~house or other readily retrievable means.~~the services offered by the outlet;¶
(d) Appropriate equipment to maintain the proper storage of drugs;¶
(~~3~~e) ~~Official Poison and Exempt Narcotic~~Appropriate equipment and supplies as required by Oregon Re~~g~~vi~~ster if poisons and exempt narcotics are sold or distributed.¶~~
~~(4) Suitable refrigeration.~~ed Statutes, Oregon Administrative Rules, United States Code, Code of Federal Regulations, and standards adopted by reference (e.g. USP) based on services offered by the outlet;¶
(~~5~~f) A sink with running hot and cold water.~~:~~;¶
(~~6~~g) ~~Equipment and supplies appropriate to and based on the standards of practice for the setting as determined by the Pharmacy and Pharmacist-in-Charge.¶~~
~~(7) Failure to have and use~~Signage in a location easily seen by the public where prescriptions are dispensed or administered: ¶
(A) Stating "This pharmacy may be able to substitute a less expensive drug which is therapeutically equi~~pm~~valent ~~necessary to your practice set~~to the one prescribed by your doctor unless you do not approve." The printing ~~constitu~~ this sign must be in block letters ~~unprofessional conduct for purposes of ORS 689.405(1)(a).¶~~
~~(8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions. ¶~~
~~(9) A~~not less than one inch in height. ¶
(B) Providing notification in each of the languages required in OAR 855-041-1132 of the right to free, competent oral interpretation and translation services, including translated prescription labels, for patients who are of limited English proficiency, in compliance with federal and state regulations if the pharmacy ~~that~~ dispenses prescriptions for a patient's self-administration ~~must post signage to provide notification of the right to free, competent oral interpretation and translati;~~¶
(C) Providing notification by posting a closed sign at the entrances stating the hours of the pharmacy's operation when a pharmacist is not in attendance if the pharmacy operates as a double set-up pharmacy per OAR 855-041-2100; and¶
(D) Providing written notice in a conspicuous manner that naloxone and the necessary medical supplies to administer naloxone are available at the pharmacy if naloxone services ~~for patients who are of limited English proficiency, in compliance with federal and state regulations~~are provided by the pharmacy per OAR 855-041-2340.¶
(h) Additional equipment and supplies that are determined as necessary by the Pharmacy or Pharmacist-in-Charge.¶
(2) Failure to have, use and maintain required equipment constitutes unprofessional conduct under ORS 689.405(1)(a).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.508, ORS 689.155, ORS 689.515, ORS 689.564, ORS 689.686

AMEND: 855-041-1040

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1040
Drug Outlet Procedures ¶

Each drug outlet 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;¶
(3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;¶
(4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;¶
(5) Ensuring the delivery of each completed prescription to the correct party;¶
(6) Providing appropriate confidential professional advice concerning medications to patients or their agents;¶
(7) Prescribing services and maintenance of records for prescribing pharmacist;¶
(8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties;¶
(9) Establishing and maintaining a Continuous Quality Assurance Program; ~~and~~¶
(10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132; and¶
(11) Ensuring drugs are stored as required by OAR 855-041-1036.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508

AMEND: 855-041-1080

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1080
Pharmacy Registration (Both Retail and Institutional Drug Outlets) ¶

(1) Pharmacies ~~shall~~must be registered as either retail drug outlets or institutional drug outlets or both.¶
(2) An application for registration of a new pharmacy ~~shall~~must be accompanied by a floor plan drawn to scale and ~~shall~~must be approved by the ~~B~~board prior to opening.¶
(3) The application ~~shall~~must specify the location of the pharmacy and ~~shall~~must 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~~must 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~~must be indicated on the application;¶
(b) If the owner is a corporation, the name filed ~~shall~~must be the same as filed with the ~~Corporation Commissioner~~Secretary of State. The name of the corporation, the names of the corporation officers and the names of the stockholders who own the five largest interests ~~shall~~must be indicated on the application.¶
(4) Upon request by the ~~B~~board, the applicant ~~shall~~must furnish such information as required by the ~~B~~board regarding the partners, stockholders, or other persons not named in the application.¶
(5) The application ~~shall~~must 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 ~~B~~board approval of the application.¶
(7) All registration renewal applications ~~shall~~must be accompanied by the annual fee and ~~shall~~must 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~~OAR 855-110.¶
(9) Pharmacy registration expires March 31, annually. If the annual registration fee referred to ~~in Division 110 of this Chapter~~OAR 855-110 is not paid by March 31 of the current year, a ~~delinquent~~late fee as set out in ~~Division 110 of this Chapter shall~~OAR 855-110 must 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 ~~B~~board and new certificate of registration. Application ~~shall~~must be on a form supplied by the ~~B~~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~~must provide the ~~B~~board with the information required in sections (3), (4), and (5) of this rule.¶
(14) A change of ownership ~~shall~~must be reported to the ~~B~~board ~~within~~ 15 days prior to~~f~~ the occurrence.¶
(15) No pharmacy ~~shall~~may be operated until a certificate of registration has been issued to the pharmacy by the ~~B~~board.
Statutory/Other Authority: ORS 475.035, ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-1130

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1130
Retail Drug Outlet Pharmacy Prescription Labeling ¶

~~(1)~~ Prescriptions must be labeled with the following information:¶
(~~a~~1) Name, address and telephone number of the pharmacy;¶
(~~b~~2) Date of fill;¶
(~~c~~3) Identifying number;¶
(~~d~~4) Name of patient;¶
(e5) Name of drug, strength, and quantity dispensed; when a generic name is used, the label must also contain the identifier of the manufacturer or distributor;¶
(~~f~~6) Directions for use by the patient;¶
(~~g~~7) Name of practitioner;¶
(~~h~~8) Required precautionary information regarding controlled substances;¶
(~~i~~9) Such other and further accessory cautionary information as required for patient safety;¶
(j10) 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~~or one year from the date the drug was originally dispensed and placed in the new container, whichever date is ~~w~~ear~~rantedl~~ier. Any drug ~~bea~~expiring ~~an expiration date shall not be dispensed beyond the said expiration date of the drug; and~~¶
~~(k~~before the expected length of time for course of therapy must not be dispensed;¶
(11) Any dispensed prescription medication, other than those in unit dose or unit of use packaging, ~~shall~~must be labeled with its physical description, including any identification code that may appear on tablets and capsules.¶
~~(l) 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.~~
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.505, ORS 689.515

AMEND: 855-041-1135

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1135
~~Defines~~ Labeling and Container Requirements for Repackaged Drugs ¶

(1) ~~Drugs prepackaged b~~Each pharmacy record keeping system must identify all pharmacy ~~for later own use dispensing on prescription shall be in a container meeting USP standards and~~personnel involved in repackaging including the pharmacist who verified the repackaged drug.¶
(2) A single oral solid drug product repackaged by a pharmacy into unit-dose packaging must:¶
(a) Utilize a unit-dose container-closure system that meets the testing requirements under USP <671> Containers-Performance Testing (12/01/2020) for either Class A or Class B containers and meets or exceeds the original container's specification for light resistance; ¶
(b) Be labeled to identify at a minimum:¶
(~~a~~A) Brand name~~,~~ or generic name ~~and manufacturer;~~;¶
(B) Strength;¶
(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and¶
(~~b~~D) ~~Strength;~~Expiration date. The expiration date used for the repackaged product must not exceed: ¶
(~~c~~i) ~~Lot number;¶~~
~~(d) Manufacturer's expiration date, or any earlier date which, in the pharmacist's professional judgment, is prefer~~6 months from the date of repackaging; or ¶
(ii) The manufacturer's expiration date; or ¶
(iii) 25% of the time between the date of repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.¶
(3) A single oral solid drug product repackaged by a pharmacy into multiple-unit packaging must:¶
(a) Utilize an equivalent container-closure system that is at least as protective as, or more protective than, the original system, complies with criteria established for equivalency and meets or exceeds the original container's specification for light resistance; ¶
(b) Be labele~~.~~d to identify at a minimum:¶
(~~2~~A) ~~An internal control number which references manufacturer and lot number may be utilized~~Brand name or generic name;¶
(B) Strength;¶
(C) Manufacturer and lot number or an internal pharmacy code that references manufacturer and lot number; and¶
(D) Expiration date. The expiration date used for the repackaged product must not exceed the manufacturer's expiration date or one year from the date the drug was placed in the new container, whichever date is earlier.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-1145

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-1145
New Containers ¶

~~In filling the original prescriptions, nothing but new containers~~ Each pharmacy ~~be used. A patient's original container may be refilled if clean and the label is legible and up-to-date. The~~must dispense a drug in a new container s~~t~~ha~~ll~~t compl~~y~~ies with the current provisions of the ~~Federal Consumer Packaging Act (Public Law 91-601, 91st Congress, S. 2162) and rules or regulations adopted thereunder. It must also conform with the current United States Pharmacopoeia/National Formulary monographs for preservation, packaging, storage and labeling~~Poison Prevention Packaging Act in 16 CFR 1700 (XX/XX/XXXX), 16 CFR 1701 (XX/XX/XXXX), and 16 CFR 1702 (XX/XX/XXXX).¶
[Publications: Publications referenced are available from the agency.]
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-041-6270

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-041-6270
Institutional Drug Outlet Pharmacy Prescription Labeling ¶

(1) Each pharmacy record keeping system must identify ~~and document~~ll pharmacy personnel involved in the repackaging including the pharmacist who verifies~~d~~ the repackaged drug.¶
(2) Each ~~pre-packed drug, including a unit-dosa~~ged drug, prepared by the pharmacy and intended for use within the facility ~~shall~~must be in an appropriate container with a label that ~~contain~~meets the requirements of OAR 855-041-1135 and includes:¶
(a) The brand or generic name and expiration date;¶
(b) The manufacturer and lot number, or an internal pharmacy code that references manufacturer and lot number;¶
(c) The strength of the drug.¶
(3) In-patient: Each drug dispensed to an in-patient other than in a unit-dose or manufacturer's unit-of-use packaging must be labeled with the following information:¶
(a) Name and location of patient;¶
(b) Name and strength of drug;¶
(c) Route of administration, when necessary for clarification;¶
(d) Manufacturer and lot number, or internal pharmacy code;¶
(e) Auxiliary labels as needed, and¶
(f) Expiration date.¶
(4) A drug that is ~~to be sent with the patient upon discharge must be labeled in accordance with ORS 689.505(5) and other rules in this Division. Drug counseling information must be provided to the patient or patient's agent.¶~~
~~(5) A label for an outpatient prescription must comply with ORS 689.505(5) and other rules in this Division.¶~~
~~(6) New bar coding or electronic label:~~provided for outpatient use must be dispensed by a retail drug outlet.¶
(5) When a new barcode or electronic label is used to identify a drug the pharmacist must verify and document the accuracy of the identification with all electronic verification systems prior to distribution.¶
(~~7~~6) When~~ever~~ a drug is added to a parenteral solution under the direct supervision of a pharmacist, the admixture must be labeled with a distinctive supplementary label that ~~contains~~¶
~~(a) The n~~includes the:¶
(a) Name, quantity and concentration of the drug added and the primary solution;¶
(b) ~~The d~~Date and time of addition;¶
(c) ~~The e~~Expiration date;¶
(d) ~~The s~~Scheduled time for administration;¶
(e) ~~The i~~Infusion rate, when applicable;¶
(f) ~~The n~~Name or initials of person performing admixture;¶
(g) ~~The i~~Identification of the pharmacy where the admixture was performed; and¶
(h) ~~The n~~Name or initials of the verifying pharmacist.¶
(~~8~~7) The label applied at a secondary storage or remote storage area by a nurse or physician must include: the patient name or patient identifier, quantity and concentration of the drug added and the primary IV solution; the date and time of addition and the initials of the nurse or physician adding the drug.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155, ORS 689.505

AMEND: 855-045-0200

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-045-0200
Application ¶

(1) Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding a drug for use or distribution in Oregon ~~shall~~must register with the ~~B~~board as a drug outlet and comply with ~~B~~board regulations.¶
(2) These rules apply to sterile and non-sterile compounding of a drug.¶
(3) All drug compounding must adhere to standards of the current edition of the United States Pharmacopeia ~~Chapters 795 (USP <795>), 797 (USP <797>) and 800 (USP <800>), as well as all Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7, 71, 85, 151, 659, 731, 823, 825, 1072, 1116, 1160, 1163, 1211 and 1229.5~~(USP) and the National Formulary (NF) including:¶
(a) USP <795> Pharmaceutical Compounding - Non-Sterile Preparations (05/01/2020 v. 2014);¶
(b) USP <797> Pharmaceutical Compounding - Sterile Preparations (05/01/2020 v.2008);¶
(c) USP <800> Hazardous Drugs - Handling in Healthcare Settings (07/01/2020 v. 2020);¶
(d) USP <825> Radiopharmaceuticals - Preparation, Compounding, Dispensing, and Repackaging (12/01/2020 v. 2020); and¶
(e) All Chapters of USP and USP-NF related to the compounding practices at any location. This includes, but is not limited to Chapters 7 (05/01/2020), 51 (05/01/2018), 71 (2013), 85 (05/01/2018), 151 (05/01/2017), 659 (04/01/2021), 660 (05/01/2015), 671 (12/01/2020), 695 (2013), 731 (11/01/2020), 821 (05/01/2017), 823 (2013), 1066 (08/01/2015), 1072 (2013), 1116 (2013), 1151 (05/01/2021), 1160 (12/01/2020), 1163 (12/01/2020), 1176 (05/01/2019), 1191 (05/01/2018), 1211 (03/01/2019), 1229.5 (08/01/2016), 1231 (08/01/2018), and 1821 (05/01/2017).
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-045-0220

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-045-0220
Personnel and Responsibilities ¶

(1) All personnel who prepare and supervise the preparation of a compound must complete appropriate training and be capable and qualified to perform assigned duties.¶
(2) The Pharmacist-in-Charge (PIC) and the drug outlet ~~shall~~must establish, maintain and enforce policies and procedures in accordance with the standards ~~in USP Chapters~~required in OAR 855-045-0200(3) for all aspects of the compounding operation according to the type of compounding performed and ~~shall~~must include written procedures for:¶
(a) Personnel qualifications, to include training, evaluation and requalification;¶
(b) Hand hygiene;¶
(c) Garbing;¶
(d) Engineering and environmental controls, to include equipment certification and calibration, air and surface sampling, and viable particles;¶
(e) Cleaning activities, to include sanitizing and disinfecting, including those compounding personnel and other staff responsible for cleaning;¶
(f) Components, to include selection, handling, and storage;¶
(g) Creating master formulation records, with documented pharmacist approval;¶
(h) Creating compounding records;¶
(i) Establishing beyond-use dates (BUDs);¶
(j) Continuous quality assurance program and quality controls, to include release testing, end-product evaluation, and quantitative/qualitative testing;¶
(k) Completed compounded preparations, to include handling, packaging, storage and transport;¶
(l) Adverse event reporting process and recall procedure. The recall procedure must include notification to the ~~B~~board within 10 working days in the event of a patient-level recall of a compounded drug.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-045-0240

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-045-0240
Labeling of Compounded Drugs ¶

In addition to the labeling requirements specified in ~~Division~~ OAR 855-041, the label of a compounded drug dispensed or distributed must contain the following, at a minimum:¶
(1) The generic or official name of each active ingredient;¶
(2) The strength or concentration of each active ingredient, to include primary solution for a sterile parenteral preparation;¶
(3) The dosage form and route of administration;¶
(4) Rate of infusion, for a sterile parenteral preparation;¶
(5) The total quantity of the drug product;¶
(6) A beyond-use date (BUD), compliant with ~~current USP standards~~standards required in OAR 855-045-0200(3); and¶
(7) Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155

AMEND: 855-065-0005

RULE SUMMARY: Procedural rules revisions to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-065-0005
Definitions ¶

(1) "Affiliate" means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:¶
(a) One business entity controls, or has the power to control, the other business entity; or¶
(b) A third party controls, or has the power to control, both of the business entities.¶
(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:¶
(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or¶
(b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.¶
(3) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the brokered substance.¶
(4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.¶
(5) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.¶
(6) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.¶
(7) "Designated Representative" means an individual designated by each wholesale distributor registered by the ~~B~~board who will serve as the primary contact person for the wholesale distributor with the ~~B~~board and who is responsible for managing the company's operations at that registered location.¶
(8) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.¶
(9) "Illegitimate Product" means a product for which credible evidence shows that the product is:¶
(a) Counterfeit, diverted, or stolen;¶
(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;¶
(c) The subject of a fraudulent transaction; or¶
(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.¶
(10) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.¶
(11) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.¶
(12) "Pedigree" for the purpose of this Division consists of:¶
(a) "Transaction History," which means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.¶
(b) "Transaction Information," which must include, but is not limited to:¶
(A) The proprietary or established name or names of the product;¶
(B) The strength and dosage form of the product;¶
(C) The National Drug Code number of the product;¶
(D) The container size;¶
(E) The number of containers;¶
(F) The lot number of the product;¶

(G) The date of the transaction;¶
(H) The date of the shipment, if more than 24 hours after the date of the transaction;¶
(I) The business name and address of the person from whom ownership is being transferred; and¶
(J) The business name and address of the person to whom ownership is being transferred.¶
(c) "Transaction Statement," which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (FDA) regulations set forth by the Drug Quality and Security Act and includes but is not limited to:¶
(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;¶
(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;¶
(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;¶
(D) Verification that a suspect or illegitimate product was not knowingly shipped;¶
(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;¶
(F) Confirmation that false transaction information was not knowingly provided; and¶
(G) Confirmation that transaction history was not knowingly altered.¶
(13) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.¶
(14) "Quarantine" means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.¶
(15) ~~"Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.¶~~
~~(16) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package for:¶~~
~~(a) Further sale; or¶~~
~~(b) Distribution without a further transaction.¶~~
~~(17)~~ "Suspect Product" means a product for which there is reason to believe that such product is:¶
(a) Potentially counterfeit, diverted, or stolen;¶
(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;¶
(c) Potentially the subject of a fraudulent transaction; or¶
(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death.¶
(1~~8~~6) "Trading Partner" means:¶
(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or¶
(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.¶
(1~~9~~7) "Validate" means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.¶
(~~20~~18) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:¶
(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.¶
(b) The sale of minimal quantities of a prescription drug by retail or institutional pharmacies to licensed practitioners for office use.¶
(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:¶
(A) Emergency medical reasons;¶
(B) Drug or devices used during a federal or state declared emergency; or¶
(C) The transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.¶
(d) Intra company transfer of drugs as defined in these rules.¶
(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.¶
(f) The distribution of a drug or an offer to distribute a drug by a charitable organization to a non-profit affiliate of the organization to the extent permitted by law.¶
(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group

purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.¶
(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.¶
(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.¶
(j) The sale, purchase, or trade of blood and blood components intended for transfusion.¶
(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a dispenser, retail pharmacy, or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.¶
(l) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.¶
(m) The distribution of drugs by a manufacturer registered under ~~division 60~~OAR 855-065 of this chapter of rules of its own products to a person other than a patient.¶
(~~21~~9) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs. The term "Wholesale Distributor" includes but is not limited to, own-label distributors; private-label distributors; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.¶
(2~~2~~0) "Wholesaler" means any wholesale distributor:¶
(a) "Class I Wholesaler" for the purpose of these rules means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, including controlled drugs, devices containing prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons and is required to comply with all pedigree requirements;¶
(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any non-prescription drugs are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.¶
(c) "Class III Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:¶
(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;¶
(B) Prescription devices that do not contain a prescription drug;¶
(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the ~~B~~board;¶
(D) Oxygen USP and medical gases;¶
(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;¶
(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.
Statutory/Other Authority: ORS 689.205
Statutes/Other Implemented: ORS 689.155