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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
08/16/2019 11:14 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Revises Drug Compounding rules in Division 045 and repeals one definition in Division 006.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 09/24/2019 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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Filed By:
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HEARING(S)

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

DATE: 09/24/2019

TIME: 1:30 PM

OFFICER: Portland State Office
Building - Conf. Rm 1D

ADDRESS: Portland State Office
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800 NE Oregon St.
Portland, OR 97232

NEED FOR THE RULE(S):

Revised language related to drug compounding is proposed to address patient safety and incorporates FDA enforced national standards that become effective 12/1/2019. All drug compounding must adhere to the standards of United States Pharmacopoeia (USP) and USP-NF Chapters related to compounding practices at a location where drug compounding occurs. Existing rules no longer meet the acceptable standards for patient safety.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

United States Pharmacopoeia (USP) Chapters, all applicable chapters (on USP website/subscription). FDA Compounding Guidance Documents (available on FDA website). Pew Charitable Trusts - State Oversight of Drug Compounding report. May 2019 Rules Advisory Committee (RAC) minutes, May and June 2018 rulemaking hearing draft rules, hearing report and Board direction. September 2018 Compounding Policy survey results.

FISCAL AND ECONOMIC IMPACT:

The fiscal impact for stakeholders associated with these rules is significant. Compliance costs can be placed into two major categories: initial costs, such as facility remodels and ongoing costs, such as gowning/garbing items and product testing needed for daily compounding activities. It is anticipated that the initial costs to comply are high, ranging

anywhere from an estimated \$50,000 to more than \$3,000,000 per location, depending on the current facility specifications and the type of compounding being performed. The Board is seeking stakeholder input specific to the Board's proposed requirement for accreditation/certification. See OAR 855-045-0210 (1).

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).

Hospital pharmacies and Community Retail Pharmacies (Chain and Independent) that perform non-sterile or sterile compounding will be affected by these rules differently, depending on the services they offer. The number of small businesses in Oregon is less than 200 and may include small hospitals and independent community pharmacies. Older buildings may be more expensive to remodel to satisfy these requirements. Both sterile compounding and non-sterile each have their own reporting records and administrative record keeping activities. Additionally, the cost of professional services, equipment supplies, labor and increased administration will vary depending on current readiness. See the Fiscal and Economic Impact information above.

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

Participants on the RAC included small business owners.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

855-006-0005, 855-045-0200, 855-045-0210, 855-045-0220, 855-045-0230, 855-045-0240, 855-045-0250, 855-045-0260, 855-045-0270

AMEND: 855-006-0005

RULE SUMMARY: Removes "Shared Pharmacy Services" definition, which is no longer valid and renumbers definitions that followed.

CHANGES TO RULE:

855-006-0005

Definitions ¶¶

As used in OAR Chapter 855:¶¶

- (1) "Board" means the Oregon Board of Pharmacy unless otherwise specified or required by the context.¶¶
- (2) "Certified Oregon Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board and has completed the specialized education program pursuant to OAR 855-025-0005. Persons used solely for clerical duties, such as recordkeeping, cashing, bookkeeping and delivery of medications released by the pharmacist are not considered pharmacy technicians.¶¶
- (3) "Clinical Pharmacy Agreement" means an agreement between a pharmacist or pharmacy and a health care organization or a physician that permits the pharmacist to engage in the practice of clinical pharmacy for the benefit of the patients of the health care organization or physician.¶¶
- (4) "Collaborative Drug Therapy Management" means the participation by a pharmacist in the management of drug therapy pursuant to a written protocol that includes information specific to the dosage, frequency, duration and route of administration of the drug, authorized by a practitioner and initiated upon a prescription order for an

individual patient and:¶¶

(a) Is agreed to by one pharmacist and one practitioner; or¶¶

(b) Is agreed to by one or more pharmacists at a single pharmacy registered by the board and one or more practitioners in a single organized medical group, such as a hospital medical staff, clinic or group practice, including but not limited to organized medical groups using a pharmacy and therapeutics committee.¶¶

(5) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:¶¶

(a) As the result of a practitioner's prescription drug order, or initiative based on the relationship between the practitioner, the pharmacist and the patient, in the course of professional practice; or¶¶

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or¶¶

(c) The preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns; or¶¶

~~(d) As a component of a Shared Pharmacy Service agreement as defined in section (21) of this rule.¶¶~~

(6) "Confidential Information" means any patient information obtained by a pharmacist or pharmacy.¶¶

(7) "Consulting Pharmacist" means a pharmacist that provides a consulting service regarding a patient medication, therapy management, drug storage and management, security, education, or any other pharmaceutical service.¶¶

(8) The "Container" is the device that holds the drug and that is or may be in direct contact with the drug.¶¶

(9) "Dispensing or Dispense" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶¶

(10) "Interpretation and evaluation of prescription orders" means the review of the order for therapeutic and legal correctness. Therapeutic review includes identification of the prescription drug ordered, its applicability and its relationship to the other known medications used by the patient and determination of whether or not the dose and time interval of administration are within accepted limits of safety. The legal review for correctness of the prescription order includes a determination that the order is valid and has not been altered, is not a forgery, is prescribed for a legitimate medical purpose, contains all information required by federal and state law, and is within the practitioner's scope of practice.¶¶

(11) "Labeling" means the process of preparing and affixing of a label to any drug container exclusive, however, of the labeling by a manufacturer, packer or distributor of a non-prescription drug or commercially packaged legend drug or device.¶¶

(12) "Monitoring of therapeutic response or adverse effect of drug therapy" means the follow up of the therapeutic or adverse effect of medication upon a patient, including direct consultation with the patient or his agent and review of patient records, as to result and side effect, and the analysis of possible interactions with other medications that may be in the medication regimen of the patient. This section shall not be construed to prohibit monitoring by practitioners or their agents.¶¶

(13) "Medication Therapy Management (MTM)" means a distinct service or group of services that is intended to optimize therapeutic outcomes for individual patients. Medication Therapy Management services are independent of, but can occur in conjunction with, the provision of a medication product.¶¶

(14) "Nationally Certified Exam" means an exam that is approved by the Board which demonstrates successful completion of a Specialized Education Program. The exam must be reliable, psychometrically sound, legally defensible and valid.¶¶

(15) "Non-legend drug" means a drug which does not require dispensing by prescription and which is not restricted to use by practitioners only.¶¶

(16) "Offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of pharmacy" means, among other things:¶¶

(a) The creation and retention of accurate and complete patient records;¶¶

(b) Assuming authority and responsibility for product selection of drugs and devices;¶¶

(c) Developing and maintaining a safe practice setting for the pharmacist, for pharmacy staff and for the general public;¶¶

(d) Maintaining confidentiality of patient information.¶

(17) "Oral Counseling" means an oral communication process between a pharmacist and a patient or a patient's agent in which the pharmacist obtains information from the patient (or agent) and the patient's pharmacy records, assesses that information and provides the patient (or agent) with professional advice regarding the safe and effective use of the prescription drug for the purpose of assuring therapeutic appropriateness.¶

(18) Participation in Drug Selection and Drug Utilization Review:¶

(a) "Participation in drug selection" means the consultation with the practitioner in the selection of the best possible drug for a particular patient.¶

(b) "Drug utilization review" means evaluating prescription drug order in light of the information currently provided to the pharmacist by the patient or the patient's agent and in light of the information contained in the patient's record for the purpose of promoting therapeutic appropriateness by identifying potential problems and consulting with the prescriber, when appropriate. Problems subject to identification during drug utilization review include, but are not limited to:¶

(A) Over-utilization or under-utilization;¶

(B) Therapeutic duplication;¶

(C) Drug-disease contraindications;¶

(D) Drug-drug interactions;¶

(E) Incorrect drug dosage;¶

(F) Incorrect duration of treatment;¶

(G) Drug-allergy interactions; and¶

(H) Clinical drug abuse or misuse.¶

(19) "Pharmaceutical Care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes include:¶

(a) Cure of a disease;¶

(b) Elimination or reduction of a patient's symptomatology;¶

(c) Arrest or slowing of a disease process; or¶

(d) Prevention of a disease or symptomatology.¶

(20) "Pharmacy Technician" means a person licensed by the State Board of Pharmacy who assists the pharmacist in the practice of pharmacy pursuant to rules of the Board but has not completed the specialized education program pursuant to OAR 855-025-0012.¶

(21) "Practice of clinical pharmacy" means:¶

(a) The health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;¶

(b) The provision of patient care services, including but not limited to post-diagnostic disease state management services; and¶

(c) The practice of pharmacy by a pharmacist pursuant to a clinical pharmacy agreement.¶

(22) "Practice of pharmacy" is as defined in ORS 689.005.¶

(23) "Prescription released by the pharmacist" means, a prescription which has been reviewed by the pharmacist that does not require further pharmacist intervention such as reconstitution or counseling.¶

(24) "Prohibited conduct" means conduct by a licensee that:¶

(a) Constitutes a criminal act against a patient or client; or¶

(b) Constitutes a criminal act that creates a risk of harm to a patient or client.¶

(25) "Proper and safe storage of drugs and devices and maintenance of proper records therefore" means housing drugs and devices under conditions and circumstances that:¶

(a) Assure retention of their purity and potency;¶

(b) Avoid confusion due to similarity of appearance, packaging, labeling or for any other reason;¶

(c) Assure security and minimize the risk of their loss through accident or theft;¶

(d) Accurately account for and record their receipt, retention, dispensing, distribution or destruction;¶

(e) Protect the health, safety and welfare of the pharmacist, pharmacy staff and the general public from harmful exposure to hazardous substances.¶¶

(26) "Quality Assurance Plan" is a written set of procedures to ensure that a pharmacy has a planned and systematic process for the monitoring and evaluation of the quality and appropriateness of pharmacy services and for identifying and resolving problems.¶¶

(27) "Responsibility for advising, when necessary or when regulated, of therapeutic values, content, hazards and use of drugs and devices" means advice directly to the patient, either verbally or in writing as required by these rules or federal regulation, of the possible therapeutic response to the medication, the names of the chemicals in the medication, the possible side effects of major importance, and the methods of use or administration of a medication.¶¶

(28) "~~Shared Pharmacy Service~~" means a written agreement, that has been approved in writing by the board, that exists for the processing by a pharmacy of a request from another pharmacy or a practitioner licensed to prescribe the drug, to fill or refill a prescription or a drug order, or to perform processing functions including but not limited to:¶¶

(a) Dispensing;¶¶

(b) Drug utilization review;¶¶

(c) Claims adjudication;¶¶

(d) Refill authorizations;¶¶

(e) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon for Oregon outlets and practitioners located in Oregon only; and¶¶

(f) Therapeutic interventions.¶¶

~~(29)~~ "Specialized Education Program" means;¶¶

(a) A program providing education for persons desiring licensure as pharmacy technicians that is approved by the board and offered by an accredited college or university that grants a two-year degree upon successful completion of the program; or¶¶

(b) A structured program approved by the board and designed to educate pharmacy technicians in one or more specific issues of patient health and safety that is offered by;¶¶

(A) An organization recognized by the board as representing pharmacists or pharmacy technicians;¶¶

(B) An employer recognized by the board as representing pharmacists or pharmacy technicians; or¶¶

(C) A trade association recognized by the board as representing pharmacies.¶¶

~~(30)~~29 "Supervision by a pharmacist" means being stationed within the same work area as the pharmacy technician or certified pharmacy technician being supervised, coupled with the ability to control and be responsible for the pharmacy technician or certified pharmacy technician's action.¶¶

~~(31)~~0 "Therapeutic substitution" means the act of dispensing a drug product with a different chemical structure for the drug product prescribed under circumstances where the prescriber has not given clear and conscious direction for substitution of the particular drug for the one which may later be ordered.¶¶

~~(32)~~1 "Verification" means the confirmation by the pharmacist of the correctness, exactness, accuracy and completeness of the acts, tasks, or functions performed by an intern or a pharmacy technician or a certified pharmacy technician.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.005, 689.151, 689.155, 689.305, 689.405 & 689.455, 689.645

AMEND: 855-045-0200

RULE SUMMARY: Revisions require adherence to USP standards for drug compounding.

CHANGES TO RULE:

855-045-0200

Application ¶¶

~~(1) These rules (OAR 855-045-0200 to 855-045-0270) apply to a~~Any person, including any business entity, located in or outside Oregon that engages in the practice of compounding drugs, ~~or any person, including any business entity, located in any other state that compounds~~a drugs for the use of patients located in Oregon. Compounding of radiopharmaceuticals is specifically exempted from these rules where these rules are in conflict with the rules or guidelines established by the Nuclear Regulatory Commission, the Radiation Protection Services of the Oregon Department of Human Services or any other applicable agency. Any person located outside Oregon that compounds drugs for the use of patients located in Oregon is expected to follow the compounding rules of their home state or these rules, whichever are more stringent.¶¶

~~(2) These rules apply to sterile and non-sterile compounding of medications that are prepared for a specific patient and that are prescribed or ordered subject to a valid practitioner – patient relationship.¶¶~~

~~(3) Whilst the Board does not insist on rigid application of, orr distribution in Oregon shall register with the Board as a drug outlet and comply with these rules (OAR 855-045-0200 to 855-045-0270).¶¶~~

~~(2) These rules apply to sterile and non-sterile compounding of a drug.¶¶~~

~~(3) All drug compounding must adherence to, all the guideline to standards of the current edition of the United States Pharmacopeia Chapters 795 (USP <795> and >), 797 (USP <797>), it expects pharmacists engaging in compounding to adhere to those guidelines that apply to their practice setting and in all situations to comply with the spirit>) and 800 (USP <800>), as well as all Chapters of USP 795 and USP 797.¶¶~~

~~(4) Any compounding activity that is not pursuant to a valid prescription or an order to prepare for administration and for a specific patient is considered to be manufacturing, and any person engaged in manufacturing must be registered in accordance with OAR 855-060-0001, with the following exceptions:¶¶~~

~~(a) Compounding by a pharmacy located in Oregon for a practitioner or dispenser located in Oregon that is covered by a Shared Pharmacy Services agreement as defined in OAR 855-006-0005;¶¶~~

~~(b) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on a routine, regularly observed pattern;¶¶~~

~~(c) Notwithstanding any other provisions of this rule, the preparation of a patient specific product utilizing all non-sterile commercial components, as defined in these rules as Category 1 compounding, is not considered compounding under these rules provided that:¶¶~~

~~(A) Preparation of these products is an infrequent occurrence;¶¶~~

~~(B) Quantity of product prepared does not exceed the requirements of a single prescription except that small quantities can be prepared upon request for in-office use by licensed practitioners-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.~~

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

AMEND: 855-045-0210

RULE SUMMARY: Rules are revised to update registration requirements.

CHANGES TO RULE:

855-045-0210

DefiniRegistrations ¶

As used in this division of administrative rules:¶

(1) "Airborne Particulate Cleanliness Classification" means the level of cleanliness defined by the maximum allowable number of particles per cubic meter of air as specified in the International Organization of Standardization (ISO) Classification Air Cleanliness (ISO 14644-1). The levels used in these rules are:¶

(a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.¶

(b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.¶

(c) ISO Class 8 is an atmospheric environment that contains le(1) In addition to obtaining an Oregon drug outlet registration, all compounding pharmacies must either pass than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.¶

(2) "Beyond Use Date" (BUD) means the date after which the preparation may not be dispensed or admini inspection by a Board approved entity or muste red to a patient. BUD has the same meaning as "Expiration Date".¶

(3) "Biological Safety Cabinet" (BSC) means a ventilated cabinet with an inward airflow for personnel protection, a downward, High Efficiency Particulate Arresting (HEPA) filtered, laminar airflow for product protection, and a HEPA filtered exhaust system for environmental protection.¶

(4) Categories of compounding: In these rules, compounding is defined as:¶

(a) Category 1: Nonsterile – Simple: Generally, the mixing of two or more commercial products. In these rules, this is not considered to be compoundingceive accreditation by a Board approved entity, every 3 years at a minimum, in order to distribute or dispense compounded preparations into and within Oregon.¶

(b2) Category 2: Nonsterile – Complex: Generally, compounding with bulk drug substances or when calculations are required.¶

(c) Category 3: Sterile – Risk Level I: Low Risk, as defined in OAR 855-045-0250.¶

(d) Category 4: Sterile – Risk Level II: Medium Risk, as defined in OAR 855-045-0250.¶

(e) Category 5: Sterile – Risk Level III: High Risk, as defined in OAR 855-045-0250.¶

(5) "CA non-resident drug outlet that distributes a non-patient specific drug compounding Aseptic Isolator" (CAI) means a glove box isolator with a microbially retentive HEPA air filter that maintains an aseptic compounding environmentto Oregon must be registered within the isolator throughout the compounding and material transfer process.¶

(6) "Compounded Sterile Preparation" (CSP) means:¶

(a) A preparation prepared according to the manufacturer's labeled instructions and other manipulations when preparing sterile products that expose the original contents to potential contamination, and includes all preparations compounded in IV rooms; or¶

(b) A preparation containing nonsterile ingredients, or employing nonsterile components and devices, that must be sterilized before administration; orFDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet. ¶

(c3) Biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that possess either of the above two characteristics, and which include, but are not limited to, baths and soaks for live organs and tissues, implants, inhalations, injections, powders for injections, irrigations, metered sprays, and ophthalmic and otic preparations.¶

(7) "Compounding pharmacy" means any pharmacy where sterile or non-sterile compounding occurs on a regular basis.¶

(8) "Parenteral Admixture" means a sterile preparation that is the combination of one or more sterile products with an appropriate admixture vehicle.¶

(9) "Laminar Airflow Hood" (LAF) means a workspace where the work surface is subjected to a constant, HEPA filtered airflow that is directed towards the user. A resident drug outlet that distributes a non-patient specific human drug compound within or outside of Oregon must register with the FDA as a 503B Outsourcing Facility and must register with the Board as a manufacturer drug outlet.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.305

AMEND: 855-045-0220

RULE SUMMARY: Rules are revised to describe personnel and outlet responsibilities when establishing USP-compliant policies and procedures.

CHANGES TO RULE:

855-045-0220

Personnel and Responsibilities ¶

~~(1) Personnel who prepare compounded pharmaceuticals, both sterile and non-sterile, shall be provided with appropriate training before they begin to prepare such products including for CSPs, training in the theoretical principles of aseptic compounding, and training in the practical skills of aseptic manipulation. 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, 1072, 1116, 1160, 1163, 1211 and 1229.5.¶~~

(1) All personnel who prepare and supervise the preparation of compounded pharmaceuticals must complete appropriate training and be capable and practical skills of aseptic manipulation qualified to perform assigned duties.¶

(2) The pharmacist-in-charge (PIC) shall establish pharmacy and the drug outlet shall establish, maintain and enforce policies and procedures that contain protocols in accordance with the guidelines in USP 797, for the initial training and testing of all personnel and for annual retesting in aseptic manipulative skills for those personnel involved in low and medium risk compounding, standards in USP Chapters for all aspects and categories of the compounding operation of non-sterile and sterile preparations that include written procedures for:¶

(3a) Personnel involved in high-risk compounding must be retested in aseptic manipulative skills at least semi-annually, qualifications, to include training, evaluation and requalification;¶

(4b) The PIC shall ensure that training protocols are followed and records are kept for the training of all new personnel and for all continuing education and periodic testing that is completed.¶

(5) The PIC is responsible for the procedures and the overall operation of all activities within the pharmacy and must:¶

(a) Ensure all pharmacy personnel involved in preparing:¶

(c) Garbing;¶

(d) Engineering and environmental controls, addressing but not limited to equipment certification and calibration, air and surface sampling, and viable particles;¶

(e) Cleaning activities, addressing but not limited to sanitizing and disinfecting, to include compounded products are being prepared, and have demonstrated skills commensurate with the complexity of the procedures they are performing;¶

(b) Establish a procedure for verification by a pharmacist of the preparation of each completed compounded product. This verification shall be accompanied by a pharmacist or other staff responsible for cleaning;¶

(f) Components, addressing but not limited to selection, handling, and storage;¶

(g) Creating Master Formulation Records;¶

(h) Creating Compounding Records;¶

(i) Established by a review of each compounded product that includes beyond-use dates (BUDs);¶

(j) Continuous quality assurance program and quality controls, addressing but is not limited to:¶

(A) Ensuring that the drug, dose and dosage form ordered are appropriate for the patient;¶

(B) Verifying that the correct drugs and components were used; release testing, end-product evaluation, quantitative/qualitative testing;¶

(k) Completed;¶

(C) Confirming that the calculation and quantity of each drug and component is correct; compounded preparations, to include handling, packaging, storage and transport;¶

(D) Verifying the label is correct and with appropriate event reporting process and recall procedure. The re-appropriate

contains all the information specified in OAR 855-041-0065 and these rules.¶

(c) Document verification by the pharmacist responsible for the review call procedure must include notification to the 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

REPEAL: 855-045-0230

RULE SUMMARY: Division 45 is revised in its entirety.

CHANGES TO RULE:

~~855-045-0230~~

~~General Requirements~~

~~A person licensed to practice pharmacy by the Oregon Board of Pharmacy who is working in a compounding pharmacy, including a pharmacy that only prepares sterile parenteral products, has the duty to exercise that degree of care, skill, diligence and professional judgment that is used by ordinarily competent, careful pharmacists in the same or similar circumstances in the community of the pharmacist or a similar community.~~

~~(1) A pharmacist engaged in compounding shall:~~

~~(a) Conform to all relevant federal laws and rules;~~

~~(b) Dispense a compounded product only subject to a valid prescription except as provided in OAR 855-045-0200(4), and only when, in their professional judgment, it results from a valid prescriber-patient relationship;~~

~~(c) Compound only products that are not commercially available except as allowed in OAR 855-045-0240(2), and, except that with the prior approval of the Board, a commercial product that is temporarily in short supply or otherwise unavailable, may be compounded subject to OAR 855-045-0200(4)(c);~~

~~(d) Maintain all records in accordance with OAR 855-045-0270;~~

~~(e) Perform final product verification.~~

~~(2) The pharmacist in charge of a compounding pharmacy including a pharmacy that only prepares sterile parenteral products shall ensure that policies and procedures for that pharmacy are reviewed not less than annually, are available for all staff to refer to, and are complied with by all staff. The policies and procedures for a compounding pharmacy shall include but are not limited to, the following:~~

~~(a) An organized index;~~

~~(b) Product formula information;~~

~~(c) Specifications for a compounding log book in compliance with OAR 855-045-0270;~~

~~(d) Conditions and surveillance of the compounding environment;~~

~~(e) Compounding procedures including requirements for use of gowns, shoe covers or dedicated shoes, hair covers, gloves and masks;~~

~~(f) Cleaning and equipment maintenance procedures;~~

~~(g) QA plan and documentation;~~

~~(h) Shipping and delivery procedures;~~

~~(i) Product labeling;~~

~~(j) Procedures for final product verification by the pharmacist;~~

~~(k) Compounded product quality procedures including procedures for establishing BUD;~~

~~(l) Training requirements for all staff;~~

~~(m) Safety procedures and training for personnel handling hazardous materials including:~~

~~(A) Use of personal protective equipment;~~

~~(B) Availability of Manufacturers' Safety Data Sheets;~~

~~(C) Emergency procedures related to spills, fire, or exposure to hazardous materials.~~

~~(n) Requirements for availability of reference materials.~~

~~(3) Pharmacies that compound sterile products including parenteral products shall, when appropriate, also include in their policies and procedures:~~

~~(a) Establishment of BUD;~~

~~(b) End Product Testing;~~

~~(c) Random sampling of both the environment and CSPs.~~

~~(4) The pharmacist in charge of a compounding pharmacy shall ensure that a quality assurance plan is written for that pharmacy and that:~~

~~(a) It includes record keeping requirements for cleaning, testing and calibration of all equipment and devices;~~

~~(b) Pharmacies that compound sterile products shall additionally include:¶¶~~

~~(A) Schedules and protocols for End Product Testing. Pharmacies mixing High Risk Level CSPs or extending Beyond Use Dating (BUD), must establish an End Product Testing schedule that includes random sampling. End Product Testing of a mixing process must show an acceptable sampling of the total preparations prepared annually;¶¶~~

~~(B) Protocols for establishing BUDs. BUDs may not exceed those in USP 797 guidelines unless a quality assurance program is established that verifies End Product Testing beyond the dating established by USP 797. Records to verify sterility and pyrogenicity must be maintained and available for review for three years.¶¶~~

~~(5) Bulk chemicals require a certificate of analysis.¶¶~~

~~(6) The labeling of bulk chemical containers shall contain:¶¶~~

~~(a) The date obtained;¶¶~~

~~(b) The BUD, which shall be established as specified in the pharmacy policies and procedures but not more than five years after opening unless additional testing is conducted to extend that BUD by not more than one year.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

AMEND: 855-045-0240

RULE SUMMARY: Rules revised to clearly articulate the Board's expectations for compliant labeling.

CHANGES TO RULE:

855-045-0240

Sterile Parenteral Products Labeling

(1) In addition to complying with all the other rules in this chapter of rules that are appropriate to their practice setting, pharmacists compounding sterile parenteral products must comply with the following specific rules.

(a) Establish, the labeling requirements specified in Division 041, the label of a compounded drug dispensed or distributed must contain the following, at a maintain and enforce written policies and procedures associated with the pharmacy's preparation and dispensing of parenteral products. Policies and procedures shall be available for inspection at the pharmacy. These policies and procedures shall include all requirements of OAR 855-045-0230 as appropriate to the primum.

(1) The generic or official name of each active ingredient;

(2) The strength or concentration of each active setting and;

(A) Requirements for compounding, labeling and storage of the products;

(B) Requirements ingredient, to include primary solution for administration of sterile parenteral therapy preparation;

(C) Requirements for storage and maintenance of equipment and supplies. The name of the base, diluent, or primary excipient;

(b4) Labeling: In addition to regular labeling requirements, the label shall include: The dosage form and route of administration;

(A5) Rate of infusion, as appropriate;

(B) Beyond Use Date;

(C) Storage requirements or special conditions, if applicable;

(D) Name, quantity and concentration of all ingredients contained in the products, including primary solu for a sterile parenteral preparation;

(E6) Initials of the pharmacist who verified the accuracy of the completed The total quantity of the drug product;

(e7) Patient Care Services: Counseling shall be available to the patient or patient's agent concerning proper use of parenterals and related supplies furnished by the pharmacy.

(2) In addition to A beyond-use date (BUD), complying with all the requirements in section (1) of this rule, licensed pharmacy personnel preparing parenteral admixtures as defined in OAR 855-045-0210 may: current USP standards;

(a8) Prepare multiple source commercially available premixed parenteral admixtures;

(b) Prepare single source premix parenteral admixtures if the individual components of the premixed parenteral sol Handling, storage or drug specific instructions, caution are commercially available;

(c) Reassign a parenteral admixture to another patient if the admixture does not exceed the documented BUD for that admixture y information, and the parenteral admixture that was prepared and dispensed for a patient specific order, and has been stored at all times under the control of a person trained and knowledgeable in the storage and administration of drugs; warnings as necessary or appropriate for proper use and patient safety;

(d9) In the case of a patient specific parenteral admixture, the pharmacist does not need to comply with the worksheet and log requirements in these rules provided that a quality assurance process is in place to address drug recalls, and appropriate safeguards are in placed entity of the pharmacist who verified the accuracy of the completed product.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155

REPEAL: 855-045-0250

RULE SUMMARY: Division 45 is revised in its entirety.

CHANGES TO RULE:

855-045-0250

Definitions of Risk Levels for Sterile Preparations

The three risk levels of CSPs recognized by USP 797 are based on the probability of contamination by microbial, chemical or physical agents. Low-Risk and Medium-Risk Level CSPs are determined by the potential for microbial contamination during preparation, and High-Risk Level CSPs by the potential for not being properly sterilized before administration to patients. These risk levels are defined, and products must be prepared and managed as follows:

(1) Low-Risk Conditions:

(a) CSPs prepared using aseptic manipulation within an air quality environment that is equal to or better than ISO Class 5, using only sterile ingredients, products, components and devices;

(b) No more than three commercially manufactured sterile products and entries into one container of sterile product during preparation;

(c) Manipulations limited to:

(A) Aseptically opening ampoules;

(B) Penetrating sterile stoppers on vials with sterile needles and syringes;

(C) Transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and sterile containers for storage and dispensing.

(d) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 48 hours at controlled room temperature;

(B) BUD up to 14 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20°C .

(2) Medium-Risk Conditions:

(a) CSPs compounded aseptically under Low-Risk Conditions but with the addition of one or more of the following conditions:

(A) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions;

(B) The compounding process includes complex aseptic manipulations other than single-volume transfer;

(C) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.

(b) In the absence of sterility testing, preparations must be properly stored prior to administration as follows:

(A) BUD less than or equal to 30 hours: at controlled room temperature;

(B) BUD up to 9 days: under refrigeration;

(C) BUD up to 45 days: in solid frozen state at -20°C .

(3) High Risk Conditions:

(a) CSPs compounded from non-sterile ingredients, including products manufactured for other routes of administration, or a non-sterile device is employed before terminal sterilization;

(b) Exposure to an air quality environment that does not meet ISO 5 or better conditions for more than one hour for any of the following:

(A) Sterile contents of commercially manufactured products;

(B) CSPs that lack effective antimicrobial preservatives;

(C) Sterile surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs.

(c) Prior to terminal sterilization:

(A) Nonsterile procedures including weighing and mixing occur in an air quality environment that does not meet ISO 7 or better conditions;

(B) Compounding personnel are improperly gloved or garbed;

- (C) Water-containing preparations are stored for more than 6 hours.¶¶
- (d) In the absence of sterility testing:¶¶
 - (A) A preparation must be properly stored prior to administration as follows:¶¶
 - (i) For a BUD not to exceed 24 hours, at controlled room temperature;¶¶
 - (ii) For a BUD up to three days, under refrigeration;¶¶
 - (iii) For a BUD up to 45 days, in solid frozen state at -20°C.¶¶
 - (B) All nonsterile devices must be rinsed thoroughly with sterile, pyrogen-free water then thoroughly drained or dried immediately before use;¶¶
 - (C) Terminal sterilization is required as follows:¶¶
 - (i) CSP solutions passed through a filter with a nominal porosity not larger than 1.2 micron preceding or during filling into their final containers to remove particulate matter;¶¶
 - (ii) Sterilization of high-risk level CSPs by filtration must be performed with a sterile 0.22 micron porosity filter entirely within an air quality environment better than or equal to ISO 5.¶¶
- (4) Immediate use:¶¶
 - (a) A compounded preparation intended for immediate use may be prepared in an air quality environment that does not meet ISO 5 or better conditions and a preparer is not required to wear gloves or gown, provided that it is prepared using aseptic manipulation, only sterile ingredients, products, components and devices are used, and it meets all of the following conditions:¶¶
 - (A) No more than three sterile ingredients, products, components and devices are used;¶¶
 - (B) Only simple manipulation techniques employed;¶¶
 - (C) The preparer completes the preparation without interruption and with no direct contact contamination;¶¶
 - (D) Administration must begin within one hour of preparation;¶¶
 - (E) If prepared by someone other than the person who will administer the drug, labeling must include patient name, name and quantity of ingredients, name of person who prepared it, and exact one hour BUD.¶¶
 - (b) Provided that such preparations do not involve the use of hazardous materials, they are classified as "Low Risk".¶¶
 - (5) "Same-day-use": In this rule, the term "Same-day-use" means that the administration of the preparation shall commence within 24 hours from the time of preparation. A same-day-use product that is prepared using aseptic manipulation in a controlled environment with ISO 5 or better class air quality conditions, using only sterile, ingredients, products, components and devices, may be classified as Low or Medium risk provided that it meets all the following conditions:¶¶
 - (A) Only simple manipulation techniques employed;¶¶
 - (B) The environment meets or exceeds the following conditions:¶¶
 - (i) The mixing cabinet is located in an area that restricts airflow to prevent drafts and reduce particle counts;¶¶
 - (ii) There is a partitioned area around the mixing cabinet to create a buffer zone, which must be at least the width of the hood in front of the mixing cabinet;¶¶
 - (iii) The buffer zone must be clearly identified to prevent cardboard or outer packing material intruding into the buffer zone and to prevent any intrusion during the compounding process;¶¶
 - (iv) The environment is cleaned daily.¶¶
 - (C) The preparer completes the preparation without interruption and with no direct contact contamination;¶¶
 - (D) Batch preparation will not exceed eight CSPs;¶¶
 - (E) Administration of the preparation must begin within twenty-four hours of preparation;¶¶
 - (F) The preparer must use gloves, shoe covers or dedicated shoes, hair covers, gown and mask.¶¶
 - (6) Single-dose vial.¶¶
 - (a) The BUD shall be no greater than one hour from time of initial entry if accessed in an environment worse than ISO 5;¶¶
 - (b) The BUD may be up to 24 hours from time of initial entry if appropriately stored and accessed only in an environment better than or equal to ISO 5;¶¶
 - (c) Medications in a single-dose ampoule may not be reused.¶¶

~~(7) Multi-dose vial. The BUD may be up to one month or the manufacturer's assigned BUD whichever is shorter, from time of initial entry, in accordance with the pharmacy policies and procedures.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

REPEAL: 855-045-0260

RULE SUMMARY: Division 45 is revised in its entirety.

CHANGES TO RULE:

~~855-045-0260~~

~~Pharmacies and Equipment~~

~~Minimum standards for pharmacies and equipment are dependent on the risk level of the products being prepared.¶¶~~

~~(1) Pharmacies and equipment for the preparation of immediate-use CSPs shall be in accordance with OAR 855-045-0250(4).¶¶~~

~~(2) Effective January 1, 2009, for preparation of low-risk level CSPs, an ISO 5 certified or better Biological Safety Cabinet (BSC), or a Compounding Aseptic Isolator (CAI), or a Laminar Airflow Hood (LAF) shall be used.¶¶~~

~~(3) Effective January 1, 2009, for preparation of medium-risk level CSPs, an ISO 5 certified or better BSC, CAI or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. These areas must have positive airflow unless used to prepare hazardous drugs. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.¶¶~~

~~(4) Effective January 1, 2009, for preparation of high-risk level CSPs, an ISO 5 certified or better BSC, CAI, or LAF shall be used. BSCs and LAFs shall be placed in an ISO 7 certified or better buffer room or area. This buffer room or area shall be connected to an ISO 8 certified or better anteroom or area. Unless used to prepare hazardous drugs, the buffer room or zone shall have a positive air pressure of 0.02 to 0.05-inch water column and may not contain a sink or drain. Surfaces and essential furniture in buffer rooms and zones and anterooms shall be nonporous, smooth, nonshedding, impermeable, cleanable and resistant to disinfectants. CAIs may be placed in an area away from traffic and in a room with ISO 8 certified or better environment, or in accordance with the manufacturer's specifications.¶¶~~

~~(5) Hazardous drugs must be prepared in compliance with state and federal regulations.¶¶~~

~~(6) Radiopharmaceuticals must be prepared in accordance with OAR 855-042-0005 through 0025.¶¶~~

~~(7) Pharmacy policies and procedures must include protocols for cleaning and monitoring that include:¶¶~~

~~(a) A cleaning policy that requires the cleaning of all work surfaces in ISO 7 and 8 areas to be performed at least daily. Floors in ISO 7 and 8 areas cleaned at least daily. Surfaces that are used to prepare CSPs must be cleaned either with a high-level disinfectant or with a medium-level disinfectant that is alternated regularly with another medium-level disinfectant. Empty shelving, walls and ceilings in anterooms and buffer rooms will be cleaned at least monthly with appropriate disinfectant solution;¶¶~~

~~(b) All ISO classified areas will be checked and certified by a qualified individual no less than every 6 months and whenever the LAF, BSC, or CAI is relocated or the physical structure of the buffer room or anteroom has been altered;¶¶~~

~~(c) Maintenance, and documentation of maintenance, of all equipment in accordance with manufacturer's specifications.¶¶~~

~~(8) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.~~

~~Statutory/Other Authority: ORS 689.205~~

~~Statutes/Other Implemented: ORS 689.155~~

AMEND: 855-045-0270

RULE SUMMARY: Revision to record keeping requirements to validate compliance with the rules and USP standards.

CHANGES TO RULE:

855-045-0270

Records ¶

~~(1) Except for products prepared subject to OAR 855-045-0200(4)(c), all appropriate compounding logs, formula worksheets and documentation of the preparation.~~ All compounding records, including training documents, master formulation records, compounded preparation records, individual prescription records, and records of dispensing or transfer of all compounded preparations must be maintained in written or electronic format, stored in an organized manner, retained for a minimum of three years and be made readily available for inspection by the Board. Records must be stored on-site for at least one year and then may be stored in a secure off-site location if then retrievable within three business days. Required records include, but are not limited to:¶

(a) Standard operating procedures, including documented annual review;¶

(b) Personnel training, competency assessment, and qualification records, including corrective actions for any failures, including gloved fingertip and thumb sampling test and aseptic manipulation validation. The pharmacy must maintain a training record for each person, including temporary personnel, who compound preparations. At a minimum, the record must contain:¶

(A) Name and signature of the person receiving the training;¶

(B) Documentation of initial and continuing competency evaluation, to include dates and results of required elements outlined in the outlet's policies and procedures; and¶

(C) Name and signature of the pharmacist who is designated as responsible for validation of the completion of all training.¶

~~(c) Engineering and environmental control records, including equipment, calibration, and certification, dispensing or transfer of all compounded products must be stored in an organized manner, retained for a minimum of three years and be available for inspection.~~ environmental air and surface monitoring procedures and results, as well as documentation of any corrective actions taken; and¶

(d) Cleaning and disinfecting of all compounding areas and equipment.¶

(2) Records for compounding must utilize a master formulation record. All master formulation records must be approved by the pharmacist for compounded preparations, and records for all preparations, excluding those for patient specific IV admixture products, must contain, at a minimum:¶

(a) The name, strength and dosage form of the preparation; ¶

(b) Physical description of the final preparation;¶

(c) Ingredient identities and amounts;¶

(d) Complete instructions for preparing the product, including equipment, supplies, and a description by of the Board compounding steps;¶

~~(2e) The formula worksheets for compounding.~~ Calculations needed to determine and verify quantities of components and doses of ingredients; ¶

(f) Compatibility and stability information, including references;¶

(g) Beyond-use date (BUD) assignment and storage requirements, excluding those for patient specific IV admixture products, reference source;¶

(h) Sterilization method utilized, when applicable. Methods include steam, dry heat, radiation and filtration;¶

(i) Quality control procedures and expected results; and ¶

(j) Appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate.¶

(3) Each compounded product must be documented and the unique compounding record must include, but are is not limited to, the following:¶

(a) Drug name and strength, strength and dosage form of the preparation;¶

- (b) Physical description of the final preparation; ¶
 - (c) Master formulation record reference for the preparation; ¶
 - (d) Quantity prepared; ¶
 - (e) Date and time prepared; ¶
 - (f) Pharmacy unique lot number; ¶
 - (g) Name, quantity and manufacturers' lot numbers and expiration dates of for all ingredients used to prepare compounded product; ¶
 - (h) Beyond-use date; ¶
 - (i) Name/identity of verifying pharmacist; ¶
 - (j) Names of all technicians involved in the process; ¶
 - (k) Copy of the label used for the compounded product; ¶
 - (l) Mixing instructions; ¶
 - (m) Physical evidence/identity of all personnel involved in each step of the process; ¶
 - (n) Documentation of the proper weight of each dry chemical or drug used and measurement of each ingredient; ¶
 - (o) Pharmacist documented verification that the correct formula, calculations and the correct weights or volumes of chemical or drugs were used/measurements were used; ¶
 - (p) Total quantity compounded; ¶
 - (q) Beyond-use date assignment and storage requirements, including reference source, if differs from master formulation record; ¶
 - (r) Certification of completion of any additional testing, including endotoxin, required by the pharmacy's policies and procedures/Description of final preparation and Product Identification Label (PIL); ¶
 - (s) Documentation of any quality control issue and any adverse reaction or preparation problem, including those reported by the patient, caregiver or other person, to include corrective actions for any failures; ¶
 - (t) Any other information required by the pharmacy's policies and procedures. ¶
 - (34) Record of maintenance and certifications for all equipment must be retained for a minimum of three years/Non patient-specific drug compounding is permitted for; ¶
 - (a) Compounding in anticipation of a prescription drug order or an order to prepare for administration, based on routine, regularly observed patterns. Pharmacy shall retain documentation; or ¶
 - (b) Preparing veterinary non patient-specific drug compounding by a pharmacy located in Oregon for a veterinary practitioner located in Oregon only. Pharmacy shall submit a request on a form prescribed by the Board and retain all documentation, including Board acknowledgment to be made available for upon inspection by the Board.
- Statutory/Other Authority: ORS 689.205
 Statutes/Other Implemented: ORS 689.155