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27.01.05 – Rules Governing Drug Compounding

IDAPA 27
TITLE 01
CHAPTER 05

27.01.05 – RULES GOVERNING DRUG COMPOUNDING

000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; the Idaho Pharmacy Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act, Title 54, Chapter 17, Idaho Code; and specifically pursuant to Sections 37-2702, 37-2715, 54-1717, 54-1753, 54-1755, and 54-1763, Idaho Code. (7-1-18)

001. TITLE AND SCOPE.
In addition to the General Provisions set forth in IDAPA 27.01.01, "General Provisions," the following title and scope shall apply to these rules: (7-1-18)

01. Title. The title of this chapter is "Rules Governing Drug Compounding," IDAPA 27, Title 01, Chapter 05. (7-1-18)

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to regulate and control drug compounding. (7-1-18)

002. WRITTEN INTERPRETATIONS.
In accordance with Title 67, Chapter 52, Idaho Code, this agency may have written statements that pertain to the interpretation of, or to compliance with the rules of this chapter. Any such documents are available for public inspection and copying at cost at the Idaho Board of Pharmacy office. (7-1-18)

003. ADMINISTRATIVE PROCEEDINGS AND APPEALS.
Administrative proceedings and appeals are administered by the Board in accordance with the "Idaho Rules of Administrative Procedure of the Attorney General," IDAPA 04.11.01, Subchapter B -- Contested Cases, Rules 100 through 800. (7-1-18)

01. Place and Time for Filing. Documents in rulemakings or contested cases must be filed with the executive director of the Board at the Board office between the hours of 8 a.m. and 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (7-1-18)

02. Manner of Filing. One (1) original of each document is sufficient for filing; however, the person or officer presiding over a particular rulemaking or contested case proceeding may require the filing of additional copies. A document may be filed with the Board by e-mail or fax if legible, complete, and received during the Board's office hours. The filing party is responsible for verifying with Board staff that an e-mail or fax was successfully and legibly received. (7-1-18)

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into these rules. (7-1-18)

005. BOARD OFFICE INFORMATION.

01. Street Address. The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (7-1-18)

02. Mailing Address. The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (7-1-18)

03. Telephone Number. The telephone number is (208) 334-2356. (7-1-18)

04. Fax Number. The fax number is (208) 334-3536. (7-1-18)

05. Electronic Address. The website address is https://bop.idaho.gov. (7-1-18)

06. Office Hours. The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday,

excluding state holidays. (7-1-18)

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 74, Chapter 1, Idaho Code. (7-1-18)

007. OFFICIAL BOARD JOURNAL.
The official journal of the Board is the electronic Idaho State Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification. (7-1-18)

008. – 009. (RESERVED)

010. DEFINITIONS AND ABBREVIATIONS.
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the definitions and abbreviations found at IDAPA 27.01.01.010 through 012 are applicable to these rules. (7-1-18)

011. – 099. (RESERVED)

100. COMPOUNDING DRUG PRODUCTS.
Any compounding that is not permitted herein is considered manufacturing. (7-1-18)

01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: (7-1-18)

a. Compound positron emission tomography drugs; (7-1-18)

b. Radiopharmaceutics; (7-1-18)

c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; (7-1-18)

d. The addition of a flavoring agent to a drug product; and (7-1-18)

e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. (7-1-18)

02. General Compounding Standards. (7-1-18)

a. Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. (7-1-18)

b. Certificate of Analysis (COA). Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a COA must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is required on the COA: (7-1-18)

i. Product name; (7-1-18)

ii. Lot number; (7-1-18)

iii. Expiration date; and (7-1-18)

iv. Assay. (7-1-18)

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned,

sanitized, or sterilized as appropriate prior to use. (7-1-18)

d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction. (7-1-18)

03. Prohibited Compounding. Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited. (7-1-18)

04. Limited Compounding. (7-1-18)

a. Triad Relationship. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order. (7-1-18)

b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if: (7-1-18)

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (7-1-18)

ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (7-1-18)

c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product. (7-1-18)

05. Drug Compounding Controls. (7-1-18)

a. Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: (7-1-18)

i. Appropriate packaging, handling, transport, and storage requirements; (7-1-18)

ii. Accuracy and precision of calculations, measurements, and weighing; (7-1-18)

iii. Determining ingredient identity, quality, and purity; (7-1-18)

iv. Labeling accuracy and completeness; (7-1-18)

v. Beyond use dating; (7-1-18)

vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (7-1-18)

vii. Maintaining environmental quality control; and (7-1-18)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (7-1-18)

b. Accuracy. Components including, but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate. The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label. (7-1-18)

c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: (7-1-18)

i. Production date; (7-1-18)

ii. Beyond use date; (7-1-18)

iii. List and quantity of each ingredient; (7-1-18)

iv. Internal control or serial number; and (7-1-18)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (7-1-18)

101. STERILE PRODUCT PREPARATION.

01. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products, these rules apply to all persons, including any business entity, engaged in the practice of sterile compounding and sterile prepackaging in or into Idaho. (7-1-18)

02. Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug product must be sterilized when prepared in the following dosage forms: (7-1-18)

a. Aqueous bronchial and nasal inhalations, except sprays intended to treat bronchial mucosa only; (7-1-18)

b. Baths and soaks for live organs and tissues; (7-1-18)

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (7-1-18)

d. Irrigations for wounds and body cavities; (7-1-18)

e. Ophthalmic drops and ointments; and (7-1-18)

f. Tissue implants. (7-1-18)

03. Compounder Responsibilities. Compounders and sterile prepackagers are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter; (7-1-18)

a. Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows; (7-1-18)

i. Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile products shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; (7-1-18)

ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (7-1-18)

iii. Opened single-dose ampules shall not be stored for any time period; and (7-1-18)

iv. Multiple-dose containers (for example, vials) that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer; (7-1-18)

b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial endotoxins; (7-1-18)

c. Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared. (7-1-18)

04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. (7-1-18)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated. (7-1-18)

b. Filters must be inspected and replaced in accordance with the manufacturer's recommendations. (7-1-18)

05. Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following: (7-1-18)

a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required; (7-1-18)

b. A sink with hot and cold water in close proximity to the hood; (7-1-18)

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; and (7-1-18)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet. (7-1-18)

06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: (7-1-18)

a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (7-1-18)

b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (7-1-18)

c. Audits appropriate for the risk of contamination for the particular sterile product including: (7-1-18)

i. Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing; (7-1-18)

ii. Periodic hand hygiene and garbing competency; (7-1-18)

iii. Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager; (7-1-18)

iv. Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including: (7-1-18)

(1) Total particle counts; (7-1-18)

(2) Viable air sampling; (7-1-18)

(3) Gloved fingertip sampling; (7-1-18)

(4) Surface sampling; (7-1-18)

v. Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, etc.) before dispensing or distributing; (7-1-18)

d. Temperature, logged daily; (7-1-18)

e. Beyond use date and accuracy testing, when appropriate; and (7-1-18)

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (7-1-18)

07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including: (7-1-18)

a. Antiseptic hand cleansing; (7-1-18)

b. Disinfection of non-sterile compounding surfaces; (7-1-18)

c. Selecting and appropriately donning protective garb; (7-1-18)

d. Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients; (7-1-18)

e. Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; (7-1-18)

f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product; and (7-1-18)

g. Inspecting for quality standards before dispensing or distributing. (7-1-18)

102. HAZARDOUS DRUGS PREPARATION.

In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products and Sterile Product Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: (7-1-18)

01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation

to dilute and remove any airborne contaminants. (7-1-18)

02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. (7-1-18)

a. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; (7-1-18)

b. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. (7-1-18)

c. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: (7-1-18)

i. The hazardous drugs in use will not volatilize while they are being handled; or (7-1-18)

ii. The PIC can provide manufacturer written documentation attesting to the safety of such ventilation. (7-1-18)

03. Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs. (7-1-18)

04. Labeling. Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills. (7-1-18)

05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. (7-1-18)

06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit dose or unit-of-use packaging. (7-1-18)

07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste. (7-1-18)

08. Training. Ensure that personnel working with hazardous drugs are trained in hygiene, garbing, receipt, storage, handling, transporting, compounding, spill control, clean up, disposal, dispensing, medical surveillance, and environmental quality and control. (7-1-18)

09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule. (7-1-18)

103. OUTSOURCING FACILITY.

01. Federal Act Compliance. An outsourcing facility must ensure compliance with 21 U.S.C. Section 353b of the Federal Food, Drug and Cosmetic Act. (7-1-18)

02. Adverse Event Reports. Outsourcing facilities must submit a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with the content and format requirement established in Section 310.305 of Title 21 of the Code of Federal Regulations to the Board. (7-1-18)

03. Policies and Procedures. An outsourcing facility must adopt policies and procedures for maintaining records pertaining to compounding, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (7-1-18)

104. LABELING: DISTRIBUTED COMPOUNDED DRUG PRODUCT.

Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription drug order, solely as permitted for outsourcing facilities and pharmacies herein, must be labeled with the following information: (7-1-18)

01. **Drug Name**. The name of each drug included. (7-1-18)

02. **Strength or Concentration**. The strength or concentration of each drug included. (7-1-18)

03. **Base or Diluents**. If a sterile compounded drug product, the name and concentration of the base or diluents. (7-1-18)

04. **Administration**. If applicable, the dosage form or route of administration. (7-1-18)

05. **Quantity**. The total quantity of the drug product. (7-1-18)

06. **Expiration Date**. The expiration or beyond use date. (7-1-18)

07. **Compounder Identifier**. The initials or unique identifier of the compounder responsible for the accuracy of the drug product. (7-1-18)

08. **Resale Prohibited**. Resale is prohibited and products must be labeled as follows: (7-1-18)

a. A pharmacy that is distributing, the statement: “not for further dispensing or distribution;” and (7-1-18)

b. An outsourcing facility, the statement: “not for resale.” (7-1-18)

09. **Instructions, Cautions, and Warnings**. Handling, storage or drug specific instructions, cautionary information, and warnings as necessary or appropriate for proper use and patient safety. (7-1-18)

105. – 999. **(RESERVED)**

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