IDAPA 27 – BOARD OF PHARMACY

27.01.05 – RULES GOVERNING DRUG COMPOUNDING

DOCKET NO. 27-0105-1801

NOTICE OF RULEMAKING – PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: A public hearing concerning this rulemaking will be held as follows:

PUBLIC HEARING
Wednesday, October 24, 2018 – 1:00 p.m. (MDT)

Idaho State Capitol Building
Room WW53
700 W. Jefferson Street
Boise, ID 83702

Written comments received by October 15, 2018, will be included in the Board's distributed meeting materials for consideration. Written comments received between October 15, 2018, and October 24, 2018, will be printed and distributed to Board members at the meeting. For those planning to attend the open, public meeting, written and verbal comments will be accepted by and/or presented before the Board.

The hearing site will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

This docket makes several minor edits to the rules governing drug compounding to better align with federal law and current practice.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year as a result of this rulemaking: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018, Idaho Administrative Bulletin, **Vol. 18-7, pages 162-163**.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Alex Adams, Executive Director, at 208-334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 24, 2018, as described above.

Dated this 30th day of August 2018.

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Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0105-1801
(Only Those Sections With Amendments Are Shown.)

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 and irrigations intended to treat ~~*bronchial*~~ nasal 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. Gloved fingertip sampling testing at least annually for personnel who compound low- and medium-risk level compounded sterile preparations and every six (6) months for personnel who compound high-risk level compounded sterile preparations. ( )

vi. 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)