

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1503

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: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

The hearing site(s) 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 rulemaking docket streamlines, clarifies and adds missing or incomplete language. Current language is missing in the definitions associated with compounding of drugs. These changes clarify the language to add a hazardous drug definition, and definitions of USP 795 and USP 797. The changes clarify the components of a prescription drug order to include the prescriber phone number. These changes add language to allow certain product preparations to not be considered compounded if combined according to the manufacturer's labeling.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

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 resulting from this rulemaking: NA

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 under Docket No. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, [Vol. 15-7, page 71](#) and in the August 5, 2015 Idaho Administrative Bulletin, [Vol. 15-8, page 106](#).

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: NA

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 28, 2015.

DATED this 4th Day of September 2015.

Alex Adams
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Phone: 334-2356
Fax: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1503
(Only Those Sections With Amendments Are Shown.)

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

- 01. Accredited School or College of Pharmacy.** A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)
- 02. ACPE.** Accreditation Council for Pharmacy Education. (3-21-12)
- 03. Acute Care Hospital.** A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)
- 04. ADS -- Automated Dispensing and Storage.** A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)
- 05. Biological Product.** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (4-11-15)
- 06. Biosimilar.** A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (4-11-15)
- 07. CDC.** United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)
- 08. Central Drug Outlet.** A resident or nonresident pharmacy, drug outlet or business entity employing or contracting pharmacists to perform centralized pharmacy services. (7-1-13)
- 09. Central Pharmacist.** A pharmacist performing centralized pharmacy services. (7-1-13)
- 10. Central Pharmacy.** A pharmacy performing centralized pharmacy services. (7-1-13)
- 11. Centralized Pharmacy Services.** The processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations. (7-1-13)
- 12. Change of Ownership.** A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)
- 13. Charitable Clinic or Center -- Authorized Personnel.** A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)
- 14. Chart Order.** A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

15. **CME.** Continuing medical education. (3-21-12)
16. **COE -- Central Order Entry.** A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)
17. **Collaborative Pharmacy Practice.** A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)
18. **Collaborative Pharmacy Practice Agreement.** A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)
19. **Continuous Quality Improvement Program.** A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (3-21-12)
20. **Correctional Facility.** Any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order. (4-4-13)
21. **CPE.** Continuing pharmacy education. (3-21-12)
22. **DEA.** United States Drug Enforcement Administration. (3-21-12)
23. **Distributor.** A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)
24. **DME.** Durable medical equipment. (3-21-12)
25. **Drug Order.** A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)
26. **Drug Product Selection.** The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)
27. **Drug Product Substitution.** Dispensing a drug product other than prescribed. (4-4-13)
28. **DTM -- Drug Therapy Management.** Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)
29. **Emergency Drugs.** Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)
30. **Executive Director.** The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)
31. **FDA.** United States Food and Drug Administration. (3-21-12)
32. **Flavoring Agent.** An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)
33. **Floor Stock.** Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

34. FPGEC. Foreign Pharmacy Graduate Examination Committee. (4-4-13)
- ~~35.~~ **Hazardous Drug.** Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: ()
- a. Carcinogenicity: ()
 - b. Teratogenicity or developmental toxicity: ()
 - c. Reproductive toxicity in humans: ()
 - d. Organ toxicity at low doses in humans or animals: ()
 - e. Genotoxicity: or ()
 - f. New drugs that mimic existing hazardous drugs in structure or toxicity. ()
- ~~356.~~ **HIPAA.** Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)
- ~~367.~~ **Hospital System.** A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)
- ~~378.~~ **Idaho State Board of Pharmacy or Idaho Board of Pharmacy.** The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, “the Board” or “Board” also means the Idaho State Board of Pharmacy. (3-21-12)
- ~~389.~~ **Individually Identifiable Health Information.** Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)
- a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)
 - b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)
 - i. Identifies the individual; or (3-21-12)
 - ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)
- ~~3940.~~ **Institutional Pharmacy.** A pharmacy located in an institutional facility. (3-21-12)
- ~~401.~~ **Interchangeable Biosimilar.** A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (4-11-15)

(BREAK IN CONTINUITY OF SECTIONS)

012. DEFINITIONS AND ABBREVIATIONS (S -- Z).

01. **Sample.** A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (3-21-12)

- 02. Secured Pharmacy.** The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-21-12)
- 03. Skilled Nursing Facility.** An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (3-21-12)
- 04. Student Pharmacist.** A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. (3-21-12)
- 05. Technician.** Unless specifically differentiated, a term inclusive of pharmacy technician, certified pharmacy technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (3-21-12)
- 06. Telepharmacy.** The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (3-21-12)
- 07. Therapeutic Equivalent Drugs.** Products assigned an “A” code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). (4-4-13)
- 08. Unit Dose.** Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (3-21-12)
- 09. USP.** United States Pharmacopeia. (3-21-12)
- 10. USP-NF.** United State Pharmacopeia-National Formulary. (3-21-12)
- 11. USP 795.** The current edition of the United States Pharmacopeia-National Formulary, Chapter 795. ()
- 12. USP 797.** The current edition of the United States Pharmacopeia-National Formulary, Chapter 797. ()
- 13. VAWD -- Verified Accredited Wholesale Distributor.** An accreditation program for wholesale distributors offered through NABP. (3-21-12)
- 14. VDO -- Veterinary Drug Outlet.** A registered establishment that employs a qualified VDT to distribute prescription veterinary drugs pursuant to lawful orders of a veterinarian. (3-21-12)
- 15. VDT -- Veterinary Drug Technician.** A non-pharmacist qualified by registration with the Board to distribute prescription veterinary drugs in a VDO. (3-21-12)
- 16. Veterinary Drug Order.** A lawful order by a veterinarian issued pursuant to the establishment of a veterinarian-patient-client relationship as recognized by the American Veterinary Medical Association. (3-21-12)
- 17. VIS.** Vaccine Information Statement. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

111. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.

A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for a drug order, must include at least the following: (3-21-12)

- 01. Patient’s Name.** The patient’s name and: (3-21-12)

- a. If for a controlled substance, the patient's full name and address; and (3-21-12)
- b. If for an animal, the species. (3-21-12)
02. **Date.** The date issued. (3-21-12)
03. **Drug Information.** The drug name, strength, quantity, and if for a controlled substance, the dosage form. (3-21-12)
04. **Directions.** The directions for use. (3-21-12)
05. **Prescriber Information.** The name, address, and phone number, and, if for a controlled substance, the address and DEA registration number of the prescriber. ~~(3-21-12)~~()
06. **Signature.** If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, or if statutorily allowed, the prescriber's agent's signature, and if electronic, the prescriber's electronic signature. (3-20-14)

(BREAK IN CONTINUITY OF SECTIONS)

239. COMPOUNDING DRUG PRODUCTS.

Any compounding that is not permitted herein is considered manufacturing. (4-11-15)

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: (4-11-15)

- a. Compound positron emission tomography drugs; (4-11-15)
- b. Radiopharmaceuticals; (4-11-15)
- c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; ~~and~~ ~~(4-11-15)~~()
- d. The addition of a flavoring agent to a drug product; ~~and~~ ~~(4-11-15)~~()
- e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. ()

02. **General Compounding Standards.** (4-11-15)

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. (4-11-15)

b. **Certificate of Analysis.** Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a CO 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: (4-11-15)

- i. Product name; (4-11-15)
- ii. Lot number; (4-11-15)
- iii. Expiration date; and (4-11-15)

- iv. Assay. (4-11-15)
 - c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (4-11-15)
 - 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. (4-11-15)
- 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. (4-11-15)
- 04. Limited Compounding.** (4-11-15)
- 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. (4-11-15)
 - 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:
 - i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (4-11-15)
 - ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (4-11-15)
 - 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. (4-11-15)
- 05. Drug Compounding Controls.** (4-11-15)
- 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: (4-11-15)
 - i. Appropriate packaging, handling, transport, and storage requirements; (4-11-15)
 - ii. Accuracy and precision of calculations, measurements, and weighing; (4-11-15)
 - iii. Determining ingredient identity, quality, and purity; (4-11-15)
 - iv. Labeling accuracy and completeness; (4-11-15)
 - v. Beyond use dating; (4-11-15)
 - vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (4-11-15)

vii. Maintaining environmental quality control; and (4-11-15)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (4-11-15)

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. (4-11-15)

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: (4-11-15)

i. Production date; (4-11-15)

ii. Beyond use date; (4-11-15)

iii. List and quantity of each ingredient; (4-11-15)

iv. Internal control or serial number; and (4-11-15)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (4-11-15)