IDAPA 27 – BOARD OF PHARMACY

27.01.01 – GENERAL PROVISIONS

DOCKET NO. 27-0101-1801

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:

Over the past two years, the Board of Pharmacy has engaged in strategic efforts to promote regulatory reform and reduce obstacles to licensure. Last year, the Board of Pharmacy cut 55% of its rules by word count, 62% of restrictions, and eliminated six categories of licensure.

This year, the Board intends to continue with these efforts. In particular, the Board intends to eliminate IDAPA 27.01.06, Rules Governing DME, Manufacturing, and Distribution, as much of the chapter needlessly duplicates other state laws. The Board will carefully extract the few rules from the chapter that are needed to protect public health, and add them to other Board chapters as appropriate. To IDAPA 27.01.01, the Board intends to add a definition for "DME Outlet," remove the definition for "MPJE," and add distributing to the section of unprofessional conduct regarding misbranded or adulterated products. Lastly, the Board aims to make minor technical corrections.

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 154-155**.

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.

Alex J. Adams, Pharm D, MPH
Executive Director
Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1801
(Only Those Sections With Amendments Are Shown.)

010. DEFINITIONS AND ABBREVIATIONS (A – D).
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms shall have the meanings set forth below: (7-1-18)

01. **ACCME**. Accreditation Council for Continuing Medical Education. (7-1-18)

02. **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. (7-1-18)

03. **ACPE**. Accreditation Council for Pharmacy Education. (7-1-18)

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. (7-1-18)

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). (7-1-18)

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. (7-1-18)

07. **CDC**. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (7-1-18)

08. **Change of Ownership**. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (7-1-18)

09. **CLIA-Waived Test**. A test that is waived under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988. (7-1-18)

10. **Clinical Guidelines**. Recommendations from a reputable organization that are evidence-based and intended to optimize patient care in specific clinical circumstances. (7-1-18)

11. **CME**. Continuing medical education. (7-1-18)

12. **Collaborative Pharmacy Practice**. A pharmacy practice whereby one (1) or more pharmacists or pharmacies 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. (7-1-18)

13. **Collaborative Pharmacy Practice Agreement**. A written agreement between one (1) or more pharmacists or pharmacies and one (1) or more prescribers that provides for collaborative pharmacy practice. (7-1-18)

14. **Community Pharmacy**. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (7-1-18)

15. **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. (7-1-18)

16. **CPE**. Continuing pharmacy education. (7-1-18)

17. **CPE Monitor**. An NABP service that allows pharmacists to electronically keep track of CPE credits from ACPE-accredited providers. (7-1-18)

18. **DEA**. United States Drug Enforcement Administration. (7-1-18)

19. **Distributor**. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (7-1-18)

20. **DME**. Durable medical equipment. (7-1-18)

21. **DME Outlet**. A registered outlet that may hold for sale at retail DME and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection. ( )

2~~1~~2. **Drug Product Selection**. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (7-1-18)

2~~2~~3. **Drug Product Substitution**. Dispensing a drug product other than prescribed. (7-1-18)

2~~3~~4. **DTM – Drug Therapy Management**. Selecting, initiating, or modifying drug treatment pursuant to a collaborative pharmacy practice agreement or statewide protocol agreement. (7-1-18)

011. DEFINITIONS AND ABBREVIATIONS (E – N).
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms shall have the meanings set forth below: (7-1-18)

01. **Emergency Drugs**. Drugs necessary 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. (7-1-18)

02. **Executive Director**. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (7-1-18)

03. **FDA**. United States Food and Drug Administration. (7-1-18)

04. **Flavoring Agent**. An additive in food or drugs when used in accordance with the principles of

good pharmacy practices and in the minimum quantity necessary to produce its intended effect. (7-1-18)

05. 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. (7-1-18)

06. FPGEC. Foreign Pharmacy Graduate Examination Committee. (7-1-18)

07. 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: (7-1-18)

a. Carcinogenicity; (7-1-18)

b. Teratogenicity or developmental toxicity; (7-1-18)

c. Reproductive toxicity in humans; (7-1-18)

d. Organ toxicity at low doses in humans or animals; (7-1-18)

e. Genotoxicity; or (7-1-18)

f. New drugs that mimic existing hazardous drugs in structure or toxicity. (7-1-18)

08. HIPAA. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (7-1-18)

09. 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. (7-1-18)

10. Institutional Pharmacy. A pharmacy located in an institutional facility. (7-1-18)

11. 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. (7-1-18)

12. Limited Service Outlet. Limited service outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, durable medical equipment outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, mobile pharmacies, and analytical or research laboratories. ~~(7-1-18)~~( )

13. Maintenance Drug. A drug intended for the treatment of a health condition or disease that is persistent or otherwise expected to be long lasting in its effects. (7-1-18)

14. Medication Synchronization Program. An opt-in program provided by a pharmacy for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently. (7-1-18)

15. ~~***MPJE**. Multistate Pharmacy Jurisprudence Exam.*~~ ~~(7-1-18)~~

~~**16.**~~ **NABP**. National Association of Boards of Pharmacy. (7-1-18)

1~~7~~6. NAPLEX. North American Pharmacists Licensure Examination. (7-1-18)

1~~8~~7. NDC. National Drug Code. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

020. PRACTICE OF PHARMACY: GENERAL APPROACH.
To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, a licensee or registrant of the Board must independently determine whether: (7-1-18)

01. Express Prohibition. The act is expressly prohibited by: (7-1-18)

a. The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code; (7-1-18)

b. The Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; (7-1-18)

c. The rules of the Idaho State Board of Pharmacy; or (7-1-18)

d. Any other applicable state or federal laws, rules or regulations. (7-1-18)

02. Education ~~and~~, Training, and Experience. The act is consistent with licensee or registrant's education, training, ~~or practice~~ and experience. ~~(7-1-18)~~( )

03. Standard of Care. Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training and experience. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

023. UNPROFESSIONAL CONDUCT.
The following acts or practices by any licensee or registrant are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (7-1-18)

01. Unethical Conduct. Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (7-1-18)

02. Lack of Fitness. A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (7-1-18)

03. On-Duty Intoxication or Impairment. Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (7-1-18)

04. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (7-1-18)

05. Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (7-1-18)

06. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules.

(7-1-18)

07. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (7-1-18)

08. Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (7-1-18)

09. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. (7-1-18)

10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock. ~~(7-1-18)~~( )

11. Prescriber Incentives. Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (7-1-18)

12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (7-1-18)

13. Failure to Report. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (7-1-18)

14. Failure to Follow Board Order. Failure to follow an order of the Board. (7-1-18)

15. Use of False Information. Knowingly using false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (7-1-18)

16. Standard of Care. ~~*Providing health care services*~~ Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting. ~~(7-1-18)~~( )

17. Unnecessary Services or Products. Directly promoting or inducing for the provisions of health care services or products that are unnecessary or not medically indicated. (7-1-18)