Dear Senators HEIDER, Souza, Jordan, and
Representatives WOOD, Packer, Chew:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Board of Pharmacy:

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal) - Proposed Rule (Docket No. 27-0101-1701);

IDAPA 27.01.01 - General Provisions (New Chapter) - Proposed Rule (Docket No. 27-0101-1702);

IDAPA 27.01.02 - Rules Governing Licensure and Registration (New Chapter, Fee Rule) - Proposed Rule (Docket No. 27-0102-1701);

IDAPA 27.01.03 - Rules Governing Pharmacy Practice (New Chapter) - Proposed Rule (Docket No. 27-0103-1701);

IDAPA 27.01.04 - Rules Governing Pharmacist Prescriptive Authority (New Chapter) - Proposed Rule (Docket No. 27-0104-1701);

IDAPA 27.01.05 - Rules Governing Drug Compounding (New Chapter) - Proposed Rule (Docket No. 27-0105-1701);

IDAPA 27.01.06 - Rules Governing DME, Manufacturing, and Distribution (New Chapter) - Proposed Rule (Docket No. 27-0106-1701).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 11/06/2017. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 12/06/2017.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4834, or send a written request to the address on the memorandum attached below.

Eric Milstead
Director

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Senior Legislative Research Analyst - Elizabeth Bowen

DATE: October 18, 2017

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal) - Proposed Rule (Docket No. 27-0101-1701)

IDAPA 27.01.01 - General Provisions (New Chapter) - Proposed Rule (Docket No. 27-0101-1702)

IDAPA 27.01.02 - Rules Governing Licensure and Registration (New Chapter, Fee Rule) - Proposed Rule (Docket No. 27-0102-1701)

IDAPA 27.01.03 - Rules Governing Pharmacy Practice (New Chapter) - Proposed Rule (Docket No. 27-0103-1701)

IDAPA 27.01.04 - Rules Governing Pharmacist Prescriptive Authority (New Chapter) - Proposed Rule (Docket No. 27-0104-1701)

IDAPA 27.01.05 - Rules Governing Drug Compounding (New Chapter) - Proposed Rule (Docket No. 27-0105-1701)

IDAPA 27.01.06 - Rules Governing DME, Manufacturing, and Distribution (New Chapter) - Proposed Rule (Docket No. 27-0106-1701)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01, 27.01.02, 27.01.03, 27.01.04, 27.01.05, and 27.01.06.

27.01.01

The first rule, Docket No. 27-0101-1701, repeals the rules of the Board of Pharmacy in their entirety, so that replacement rules may be promulgated. The replacement rules will not add any new regulatory requirements; rather, they reorganize existing rules and eliminate outdated language. Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

The second rule, Docket No. 27-0101-1702, is the first chapter of the replacement rules and contains general provisions, such as definitions. Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

27.01.02

This rule establishes a new chapter of replacement rules regarding licensure and registration for individuals and facilities. The rule includes license and registration fees.

Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The new fee schedule is anticipated to decrease revenue to the Board's dedicated fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

27.01.03

This rule establishes a new chapter of replacement rules governing pharmacy practice. The new chapter substantially conforms to the existing chapter but eliminates some requirements relating to drug outlets, technology, and staffing changes.

Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

27.01.04

This rule establishes a new chapter of rules specifying the products that pharmacists may prescribe, as authorized by House Bill 191, enacted by the 2017 Legislature. Additionally, existing rules on collaborative pharmacy practice and statewide protocol agreements are incorporated.

Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

27.01.05

This rule establishes a new chapter of replacement rules on drug compounding. The new chapter substantially conforms to existing rules.

Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

27.01.06

This rule establishes a new chapter of replacement rules on durable medical equipment, drug manufacturing, and drug distribution. The new chapter substantially conforms to existing rules.

Negotiated rulemaking was conducted, and there is no anticipated negative fiscal impact on the state general fund. The Board states that this rulemaking is authorized pursuant to Section 54-1717, Idaho Code.

cc: Board of Pharmacy
Alex Adams, PharmD, MPH

IDAPA 27 – BOARD OF PHARMACY

27.01.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1701 (CHAPTER REPEAL)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The rules of the Idaho State Board of Pharmacy, IDAPA 27, Title 01, Chapter 01, are being repealed in their entirety effective July 1, 2018. New rules are being promulgated as six separate chapters as indicated below. The Board does not intend to add any new regulatory requirements as part of its rulemaking; instead, as the Board better organizes its rules into chapters, it aims to simultaneously eliminate outdated regulations and those that stifle the emergence of new technology or new practice models that can improve public health and safety.

1. General Provisions (Docket No. 27-0101-1702)
2. Rules Governing Licensing and Registration (Docket No. 27-0102-1701)
3. Rules Governing Pharmacy Practice (Docket No. 27-0103-1701)
4. Rules Governing Pharmacist Prescriptive Authority (Docket No. 27-0104-1701)
5. Rules Governing Drug Compounding (Docket No. 27-0105-1701)
6. Rules Governing DME, Manufacturing, and Distribution (Docket No. 27-0106-1701)

Detailed descriptions of each of the aforementioned chapters accompany the referenced rule dockets.

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 in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol.17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

IDAPA 27.01.01 IS BEING REPEALED IN ITS ENTIRETY

IDAPA 27 – BOARD OF PHARMACY

27.01.01 – GENERAL PROVISIONS

DOCKET NO. 27-0101-1702 (NEW CHAPTER)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The scope of Chapter 27.01.01. is to establish general provisions for the Board of Pharmacy, and to serve as a parent chapter for all subsequent chapters. This chapter is comprised of current rules as follows: definitions and abbreviations, criteria for obtaining a waiver or variance, the Board's authority to inspect and investigate, and acts that constitute unprofessional conduct. Changes made to the current rules include:

- Definitions that merely duplicate those already defined in Sections 54-1705 and 37-2701, Idaho Code, are removed;
- Definitions are added for 'ACCME,' 'CLIA-Waived Test,' 'Clinical Guidelines,' 'CPE Monitor,' and 'Student Technician'; and
- Unprofessional conduct is expanded to include provisions related to 'Standard of Care' and 'Unnecessary Services or Products.'

These rules will take effect in their entirety on July 1, 2018.

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 in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54-56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114-115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1702
(New Chapter)

IDAPA 27
TITLE 01
CHAPTER 01

27.01.01 – GENERAL PROVISIONS

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. ( )

001. TITLE AND SCOPE.

01. Title. The title of this chapter is "General Provisions," IDAPA 27, Title 01, Chapter 01. ( )

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to: ( )

a. Regulate and control the manufacture, distribution, and dispensing of controlled substances within or into the state, pursuant to the Uniform Controlled Substances Act, Section 37-2715, Idaho Code; ( )

b. Regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Section 54-1718, Idaho Code; and ( )

c. Carry out its duties in regard to drugs, devices and other materials used in the diagnosis, mitigation and treatment, or prevention of injury, illness, and disease, pursuant to Section 54-1719, Idaho Code, or in regard to professionals or other individuals licensed or registered by the Board or otherwise engaged in conduct subject to regulation under these Acts. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

008. – 009. (RESERVED)

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: ( )

01. ACCME. Accreditation Council for Continuing Medical Education. ( )

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. ( )

03. ACPE. Accreditation Council for Pharmacy Education. ( )

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. ( )

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). ( )

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. ( )

07. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. ( )

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

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

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

11. CME. Continuing medical education. ( )

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. ( )

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. ( )

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

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. ( )

16. **CPE**. Continuing pharmacy education. ( )

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

18. **DEA**. United States Drug Enforcement Administration. ( )

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

20. **DME**. Durable medical equipment. ( )

21. **Drug Product Selection**. The act of selecting either a brand name drug product or its therapeutically equivalent generic. ( )

22. **Drug Product Substitution**. Dispensing a drug product other than prescribed. ( )

23. **DTM -- Drug Therapy Management**. Selecting, initiating, or modifying drug treatment pursuant to a collaborative pharmacy practice agreement or statewide protocol agreement. ( )

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: ( )

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. ( )

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

03. **FDA**. United States Food and Drug Administration. ( )

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. ( )

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. ( )

06. **FPGEC**. Foreign Pharmacy Graduate Examination Committee. ( )

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: ( )

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. ( )

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

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. ( )

10. **Institutional Pharmacy**. A pharmacy located in an institutional facility. ( )

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. ( )

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, and analytical or research laboratories. ( )

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. ( )

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. ( )

15. **MPJE**. Multistate Pharmacy Jurisprudence Exam. ( )

16. **NABP**. National Association of Boards of Pharmacy. ( )

17. **NAPLEX**. North American Pharmacists Licensure Examination. ( )

18. **NDC**. National Drug Code. ( )

012. DEFINITIONS AND ABBREVIATIONS (O -- Z).
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: ( )

01. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. ( )

02. **Pharmaceutical Care Services**. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and also encompasses services provided by way of DTM under a collaborative practice agreement, statewide protocol agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and Medication Therapy Management. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: ( )

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; ( )

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; ( )

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; ( )

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; ( )

e. Documenting the care delivered; ( )

f. Communicating essential information or referring the patient when necessary or appropriate; ( )

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; ( )

h. Conducting a drug therapy review consultation with the patient or caregiver; ( )

i. Preparing or providing information as part of a personal health record; ( )

j. Identifying processes to improve continuity of care and patient outcomes; ( )

k. Providing consultative drug-related intervention and referral services; ( )

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; ( )

m. Ordering and interpreting laboratory tests; and ( )

n. Other services as allowed by law. ( )

03. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. ( )

04. PDMP. Prescription Drug Monitoring Program. ( )

05. Prepackaging. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. ( )

06. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. ( )

07. Purple Book. The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. ( )

08. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. ( )

09. Reconstitution. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. ( )

10. Restricted Drug Storage Area. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. ( )

11. Sample. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. ( )

12. 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. ( )

13. Student Technician. A student who is enrolled in a high school or college supervised program, and

who does not otherwise meet the requirements for registration as a technician-in-training or certified technician. ( )

14. **Technician**. Unless specifically differentiated, a term inclusive of pharmacy technician, certified 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. ( )

15. **Telepharmacy**. The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. ( )

16. **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). ( )

17. **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). ( )

18. **USP**. United States Pharmacopeia. ( )

19. **USP-NF**. United State Pharmacopeia-National Formulary. ( )

20. **USP 795**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 795. ( )

21. **USP 797**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 797. ( )

22. **VAWD -- Verified Accredited Wholesale Distributor**. An accreditation program for wholesale distributors offered through NABP. ( )

013. – 019. (RESERVED)

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: ( )

01. **Express Prohibition**. The act is expressly prohibited by: ( )

a. The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code; ( )

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

c. The rules of the Idaho State Board of Pharmacy; or ( )

d. Any other applicable state or federal laws, rules or regulations. ( )

02. **Education and Training**. The act is consistent with licensee or registrant's education, training or practice experience. ( )

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. ( )

021. WAIVERS OR VARIANCES.

01. **Criteria**. The board may grant or deny, in whole or in part, a waiver of, or variance from, specified rules if the granting of the waiver or variance is consistent with the Board's mandate to promote, preserve and protect

public health, safety and welfare, and based on consideration of one (1) or both of the following: ( )

a. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; or ( )

b. The waiver or variance requested would test an innovative practice or service delivery model. ( )

02. Content and Filing of a Waiver or Variance Petition. A written petition for waiver or variance should include at least the following: ( )

a. The name, address, and telephone number of the petitioner or petitioners; ( )

b. A specific reference to the rule or rules from which a waiver or variance is requested; ( )

c. A statement detailing the waiver or variance requested, including the precise scope and duration; and ( )

d. A description of how the waiver or variance, if granted, will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. ( )

03. Invalid Requests. A waiver or variance request that is contrary to federal law or Idaho Code or that seeks to delay or cancel an administrative deadline will not be considered or granted by the Board. ( )

04. Time Period of Waiver or Variance. Waivers or variances may be granted on a permanent or temporary basis. Temporary waivers or variances have no automatic renewal, but may be renewed if the Board finds that sufficient grounds to allow the waiver or variance continue to exist. ( )

05. Cancellation or Modification of a Waiver or Variance. A waiver or variance granted by the Board may be canceled or modified by the Board at any time. ( )

022. BOARD INSPECTIONS AND INVESTIGATIONS.

01. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. ( )

02. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. ( )

03. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, one (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection and must pay within ninety (90) days of inspection. ( )

04. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. ( )

05. Investigations. Licensees or registrants must also fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, to gather information pertinent to a complaint received by the Board, or to enforce disciplinary actions. ( )

023. UNPROFESSIONAL CONDUCT.
The following acts or practices by a pharmacist, pharmacist intern, or technician are declared to be specifically, but

not by way of limitation, unprofessional conduct and conduct contrary to the public interest. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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). ( )

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

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

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. ( )

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. ( )

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. ( )

14. Failure to Follow Board Order. Failure to follow an order of the Board. ( )

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. ( )

16. Standard of Care. Providing health care services which fail to meet the standard provided by other

qualified licensees or registrants in the same or similar setting. ( )

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. ( )

024. – 999. (RESERVED)

IDAPA 27 – BOARD OF PHARMACY

27.01.02 – RULES GOVERNING LICENSURE AND REGISTRATION

DOCKET NO. 27-0102-1701 (NEW CHAPTER, FEE RULE)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The scope of Chapter 27.01.02 is to establish the rules related to licensure and registration for both individuals and facilities. This chapter is comprised of rules from the existing Board rules as follows: general requirements, board fees, fee schedule, pharmacist licensure and registration, pharmacist intern registration, technician registration, practitioner controlled substance registration, and drug outlet licensure and registration. Changes made to the current rules include:

- Elimination of the following licensure or registration categories: nursing home, non-pharmacy retail outlet, veterinary drug technician, and inactive pharmacist license. Elimination of the license or registration does not mean that these activities cannot occur; it merely removes the need for a government permission slip prior to engaging in these activities as it relates to the practice of pharmacy;
- Consolidation of pharmacist controlled substance registration and distributor controlled substance registration into the main licenses for each category;
- Changes to the fee schedule for pharmacists, manufacturers, distributors, and prescriber drug outlets as outlined below;
- Annual renewal deadlines are changed for individuals (birth month) and facilities (now December 31);
- Continuing pharmacy education requirements are streamlined for pharmacists and Board-approved credits are removed as this duplicates a service provided commonly and more effectively by the private sector;
- Externs and interns are consolidated into a single license type, now called 'pharmacist interns;'
- The technician-in-training registration is capped at a period at two (2) years from the date of issuance, the employer requirement is removed for technicians-in-training, and a student technician category is created;

- Drug outlets may obtain a temporary license number so that pharmacies can start health plan contracting prior to opening provided certain criteria are met;
- Removes the requirement that a floor plan must be submitted to, and approved by, Board staff prior to a remodel; and
- Streamlines the process for permanently closing a pharmacy.

These rules will take effect in their entirety on July 1, 2018.

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

The following categories of licensure or registration are proposed to be eliminated:

Category	Current Fee(s)	Proposed Fee	Note
Nursing Home	$35	$0	Category proposed to be eliminated.
Non-Pharmacy Retail Outlet	$35	$0	Category proposed to be eliminated.
Veterinary Drug Technician	$35	$0	Category proposed to be eliminated.
Inactive Pharmacist License	$50	$0	Category proposed to be eliminated.

Currently, to practice pharmacy in Idaho, a pharmacist must obtain a license or registration (fees vary) and separately a controlled substance registration ($60). Idaho is among a minority of states that requires these separate licenses and registrations. The Board proposes to eliminate the separate controlled substance registration, and adjust the fees for pharmacists as follows:

Category	Current Fee(s)	Proposed Fee	Note
Pharmacist Controlled Substances Registration	$60	$0	Category proposed to be eliminated and bundled with the separate pharmacist license or registration, as described in the following columns.
Pharmacist License by Examination (Initial)	$100	$140	The fee would be adjusted to account for consolidation of the pharmacist controlled substances registration. Pharmacists who currently hold both a pharmacist license and controlled substance registration save $20 annually by consolidating the two. Otherwise there is a net $40 increase. As of April 2017, there were only 80 pharmacists in Idaho (3% of total pharmacist licensees) who held a pharmacist license but not a controlled substance registration. These pharmacists are generally in non-practice settings. In addition, 780 out-of-state pharmacists did not hold a controlled substance registration.
Pharmacist License (Renewal)	$90	$130	
Pharmacist License by Reciprocity (Initial)	$250	$140	The National Association of Boards of Pharmacy license transfer process has streamlined the staff work burden for license reciprocity applications; the proposed fee would now create parity with the fee for pharmacist licensure by exam.

In addition, the Board intends to increase the fee for its nonresident pharmacist registration category from $250 to $290, which also accounts for the consolidation of the pharmacist controlled substance registration. Currently, Section 54-1720, Idaho Code, caps the fee for pharmacists at $250, which prevents the Board from making this change as part of this rule docket. The Board intends to bring agency legislation to address this cap; if this agency legislation successfully passes, the Board intends to make this change via temporary rule after the conclusion of the 2018 legislative session and prior to the effective date of these rules (July 1, 2018).

Currently, to distribute medications in Idaho, a distributor must obtain a license or registration (fees vary) and separately a controlled substance registration ($100) if they are distributing controlled substances. Idaho is among a minority of states that requires these separate licenses and registrations. The Board proposes to eliminate the separate controlled substance registration, and adjust the fees for distributors as follows:

Category	Current Fee(s)	Proposed Fee	Note
Distributor Controlled Substances Registration	$100	$0	Category proposed to be eliminated and bundled with the separate distributor/ manufacturer license or registration.
Manufacturer	$100	$150	Distributors who currently hold both a distributor registration and controlled substance registration save $50 annually by consolidating the two. Otherwise there is a net $50 increase.
Wholesale Distributor	$130	$180	
Wholesale OTC	$100	$150	

Lastly, the Board proposes to modify the following fees for various reasons described in the table:

Category	Current Fee(s)	Proposed Fee	Note
Technician-in-Training	$35/year	$35/two years	Technicians-in-training will save $35 if their training period exceeds the first year.
Prescriber Drug Outlet	$35	$100	When the Board initially established the fee, it proved insufficient to cover the costs associated with licensing and inspections. The fee for all other drug outlets is $100, so this creates parity and accounts for the Board's actual expenses.

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:

The proposed changes have no impact on the state General Fund. The net revenue change to the Board of Pharmacy's dedicated fund is projected to be a net decrease of $18,503 on renewals as proposed in the current rules. If the Board's agency legislation also passes, enabling an increase in the nonresident pharmacist registration fee, the net impact on the Board's dedicated fund is projected to be an increase of $4,338 on renewals.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

THE FOLLOWING IS THE PROPOSED TEXT OF FEE DOCKET NO. 27-0102-1701
(New Chapter)

IDAPA 27
TITLE 01
CHAPTER 02

27.01.02. - RULES GOVERNING LICENSURE AND REGISTRATION

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. ( )

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

01. **Title**. The title of this chapter is "Rules Governing Licensure and Registration," IDAPA 27, Title 01, Chapter 02. ( )

02. **Scope**. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to license individuals and facilities engaged in the practice of pharmacy in or into Idaho, including pharmacists, technicians, pharmacist interns, practitioners, and drug outlets. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

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. ( )

011. – 019. (RESERVED)

020. BOARD OF PHARMACY LICENSURE AND REGISTRATION.
The Board will issue or renew a license or certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act, Idaho Controlled Substances Act, and any additional criteria specified by these rules for the license or registration classification. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions, except that the Board may suspend such requirements for the duration of a national, state or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, for individuals engaged in the scope of practice for which they are licensed in another state. ( )

021. LICENSURE AND REGISTRATION: GENERAL REQUIREMENTS.

01. Board Forms. Initial licensure and registration applications, annual renewal applications, and other forms used for licensure, registration, or other purposes must be in such form as designated by the Board. ( )

02. Incomplete Applications. Information requested on the application or other form must be provided and submitted to the Board office with the applicable fee or the submission will be considered incomplete and will not be processed. Applications that remain incomplete after six (6) months from the date of initial submission will expire. ( )

03. On-Time Annual Renewal Application. Licenses and registrations must be renewed annually to remain valid. Applications for renewal must be completed and submitted to the Board office prior to the license or registration expiration. Timely submission of the renewal application is the responsibility of each licensee or registrant. Licenses and certificates of registration issued to individuals will expire annually on the last day of the individual's birth month, and on December 31 for facilities, unless an alternate expiration term or date is stated in these rules. ( )

04. Late Renewal Application. Failure to submit a renewal application prior to the expiration date will cause the license or registration to lapse and will result in the assessment of a late fee and possible disciplinary action. A lapsed license or registration is invalid until renewal is approved by the Board and if not renewed within thirty (30) days after its expiration will require reinstatement. ( )

05. Exemption. New licenses and registrations issued ten (10) weeks or less prior to the renewal due date are exempt from the renewal requirements that year only. ( )

06. Cancellation and Registration. Failure to maintain the requirements for any registration will result in the cancellation of the registration. ( )

07. Reinstatement of License or Registration. Unless otherwise specified in Board rule, consideration of a request for reinstatement of a license or registration will require a completed application on a Board form, submission of a completed fingerprint card, as applicable, and payment of any applicable fees due or delinquent at the time reinstatement is requested. ( )

08. Parent or Legal Guardian Consent. No person under the age of eighteen (18), unless an emancipated minor, may submit an application for licensure or registration without first providing the Board with written consent from a parent or legal guardian. ( )

022. BOARD FEES.

01. Fee Determination and Collection. Pursuant to the authority and limitations established by Sections 37-2715 and 54-1720(5)(a), Idaho Code, the Board has determined and will collect fees for the issuance, annual renewal, or reinstatement of licenses and certificates of registration to persons and drug outlets engaged in acts or practices regulated by the Board. The Board may also charge reasonable fees for specified administrative services or publications. ( )

02. Time and Method of Payment. Fees are due and must be paid by cash, credit card, or by personal, certified, or cashier's check or money order payable to the "Idaho State Board of Pharmacy" at the time of application, submission, or request. Fees are nonrefundable and will not be prorated, except for the limited purpose of transitioning to the new renewal deadlines established by these rules. ( )

03. Fee for Dishonored Payment. A reasonable administrative fee may be charged for a dishonored check or other form of payment. If a license or registration application has been approved or renewed by the Board and payment is subsequently dishonored, the approval or renewal is immediately canceled on the basis of the submission of an incomplete application. The board may require subsequent payments to be made by cashier's check, money order, or other form of guaranteed funds. ( )

04. Overpayment of Fees. "Overpayment" refers to the payment of any fee in excess of the listed amount. Refunds issued will be reduced by a reasonable processing fee. ( )

05. Fee Exemption for Controlled Substance Registrations. Persons exempt pursuant to federal law from fee requirements applicable to controlled substance registrations issued by the DEA are also exempt from fees applicable to controlled substance registrations issued by the Board. ( )

023. FEE SCHEDULE.

01. Licenses and Registrations -- Professionals.

License/Registration	Initial Fee	Annual Renewal Fee
Pharmacist License	$140	$130
Nonresident Pharmacist Registration	$250	$250
Pharmacist Intern	$50	$50
Technician	$35	$35
Practitioner Controlled Substance Registration	$60	$60

( )

02. Certificates of Registration and Licensure -- Facilities.

License/Registration	Initial Fee	Annual Renewal Fee
Drug Outlet (unless otherwise listed)	$100	$100
Wholesale License	$180	$180
Wholesale Registration	$150	$150
Central Drug Outlet (Nonresident)	$500	$250
Mail Service Pharmacy	$500	$250
Durable Medical Equipment Outlet	$50	$50
Outsourcing Facility (Nonresident)	$500	$250
Manufacturer	$150	$150
Veterinary Drug Outlet	$35	$35

( )

03. Late Fees and Reinstatements.

Category	Fee
Late payment processing fee	$50
License or registration reinstatement fee	One-half (1/2) of the amount of the annual renewal

( )

04. Administrative Services.

Category	Fee
Experiential hours certification	$25

Category	Fee
Duplicate pharmacist certificate of licensure	$35

( )

024. -- 029. (RESERVED)

030. DETERMINATION OF NEED FOR PHARMACIST LICENSE, NONRESIDENT REGISTRATION, OR NEITHER.

01. Practice in Idaho. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws. ( )

02. Nonresident Pharmacists. All nonresident pharmacists practicing pharmacy into the state of Idaho must be licensed in their state of practice and must additionally be licensed or registered in Idaho as follows: ( )

a. Independent Practice. Pharmacists must be licensed if engaged in the independent practice of pharmacy across state lines and not practicing for an Idaho registered drug outlet. ( )

b. Practice for an Idaho Registered Drug Outlet. A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be licensed or registered to practice into Idaho. All other nonresident pharmacists who are employed by, or affiliated with, and practicing for the Idaho registered nonresident drug outlet, but who are not the PIC, are exempt from license and registration requirements for practice into Idaho. ( )

03. Exemption from Separate Controlled Substance Registration. All pharmacists who are practicing in or into Idaho are exempt from obtaining a separate controlled substance registration, but must maintain compliance with all requirements under Title 37, Chapter 27, Idaho Code. ( )

031. PHARMACIST LICENSURE BY EXAMINATION.
To be considered for licensure, a person must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, and submit to the Board an application for licensure by examination. ( )

01. Graduates of U.S. Pharmacy Schools. An applicant must be a graduate of an ACPE-accredited school or college of pharmacy within the United States. ( )

02. Graduates of foreign Pharmacy Schools. An applicant who is a graduate of a school or college of pharmacy located outside of the United States must submit certification by the FRGEC, and verification of completion of a minimum of seventeen hundred forty (1,740) experiential hours. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. ( )

03. Licensure Examinations. Qualified applicants must pass the NAPLEX and the MPJE in accordance with NABP standards. A candidate who fails the NAPLEX three (3) times must complete at least thirty (30) hours of continuing education accredited by an ACPE-accredited provider prior to being eligible to sit for each subsequent reexamination. Candidates are limited to five (5) total attempts to pass each exam. ( )

032. PHARMACIST LICENSURE BY RECIPROCITY.
An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and this rule to obtain an Idaho license. An applicant whose pharmacist license is currently restricted by a licensing entity in another state must appear before the Board to petition for licensure by reciprocity. ( )

01. Transfer Application. The applicant must submit a preliminary application for licensure transfer through NABP. ( )

02. MPJE. The applicant must pass the Idaho-based MPJE within five (5) total attempts. ( )

03. Intern Hours. An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may also be required to complete intern hours for each year away from the practice of pharmacy. ( )

033. PHARMACIST LICENSE RENEWAL: CPE REQUIREMENTS.
Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31. ( )

01. ACPE. At least twelve (12) of the CPE hours obtained must be from programs by an ACPE that have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ACPE credits must be reported to and documented in CPE Monitor in order to be accepted. ( )

02. CME. A maximum of three (3) of the hours may be obtained from CME, if the credits are: ( )

a. Obtained from an ACCME accredited provider; and ( )

b. A certificate is furnished that identifies the name of the ACCME accredited provider and a clear reference to its accreditation status, the title of the CME program, the completed hours of instruction, the date of completion, and the name of the individual obtaining the credit. All CME certificates must be submitted to the Board between December 1 and December 31. ( )

034. PHARMACIST LICENSE: REINSTATEMENT.
The Board may, at its discretion, consider reinstatement of a pharmacist license upon receipt of a completed application, background check, and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested. ( )

01. Satisfactory Evidence. Reinstatement applicants must provide satisfactory evidence of completion of a minimum of thirty (30) CPE hours within the twenty-four (24) months prior to reinstatement and compliance with any direct orders of the Board. ( )

02. Additional Requirements. A pharmacist reinstatement applicant may be required to appear before the Board. If a pharmacist license has lapsed for more than twenty-four (24) months, the applicant must pass the MPJE prior to returning to practice. The Board may also, at its discretion, impose additional requirements on a pharmacist reinstatement applicant who has not practiced as a pharmacist for the preceding twelve (12) months or longer that may include taking and passing an examination, completion of intern hours, completion of additional CPE hours, or other requirements determined necessary to acquire or demonstrate professional competency. ( )

035. NONRESIDENT PHARMACIST REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered to practice pharmacy into Idaho an applicant must submit an application on a Board form including, but not limited to: ( )

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; ( )

02. Facility License Information. The license or registration number of the facility for which the applicant will be practicing. ( )

036. PHARMACIST INTERN REGISTRATION.

01. Registration Requirements. To be approved for and maintain registration as a pharmacist intern, the applicant must: ( )

a. Currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy; or ( )

b. Be a graduate of an accredited school or college of pharmacy within the United States and awaiting examination for pharmacist licensure; or ( )

c. Be a graduate of a school or college of pharmacy located outside the United States, obtain certification by the FPGEC, and be awaiting examination for pharmacist licensure or obtaining practical experience as required under Board rule. ( )

02. Renewal. ( )

a. Current Students. A pharmacist intern registration must be renewed annually by July 15; however, the renewal fee will be waived, if renewed on time, for the duration of the student's enrollment in the school or college of pharmacy. Following graduation, if a pharmacist license application has been submitted, the pharmacist intern license will be extended at no cost for up to six (6) additional months from the date of application as a pharmacist, after which time the individual will need to submit a new application to continue to be a pharmacist intern. ( )

b. Pharmacy Graduates. A graduate pharmacist intern registration may be obtained and renewed once within one (1) year from the date of issuance. The Board may, at its discretion, grant additional time to complete internship experience if unique circumstances present. ( )

037. – 039. (RESERVED)

040. CERTIFIED TECHNICIAN REGISTRATION.
To be approved for registration as a certified technician, a person must satisfy the following requirements: ( )

01. Age. Be at least sixteen (16) years of age; ( )

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma;( )

03. Personal Characteristics. Be of good moral character and temperate habits; and ( )

04. Certification. Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the National Healthcareer Association (NHA), or their successors. ( )

041. TECHNICIAN-IN-TRAINING REGISTRATION.

01. Applying for Registration. A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a certified technician. ( )

02. Duration. An individual may register as a technician-in-training for a maximum of two (2) years from the date of issuance. ( )

042. STUDENT TECHNICIAN.

01. Registration Requirements. To be approved for registration as a student technician, an applicant must be at least sixteen (16) years of age, currently enrolled and in good standing in a high school or college supervised program, and not meet the requirement for registration as a technician-in-training or certified technician. ( )

02. Exemption from Criminal Background Check. Student technician candidates under the age of eighteen (18) are exempt from the fingerprint-based criminal history check requirement of Idaho Code. ( )

03. Renewal. A student technician registration must be renewed annually by July 15; however, the renewal fee will be waived, if renewed on time, for the duration of the student's enrollment in a technician training program. ( )

043. TECHNICIAN EXEMPTIONS.

01. Certification Exemption for Continuous Employment. A technician registered with the Board and employed as a technician on June 30, 2009, is not required to obtain or maintain certification as a condition of registration renewal after June 30, 2009, as long as the registrant remains continuously employed as a technician by the same employer. If a registrant that qualifies for this exemption disrupts continuous employment as a technician with one employer, or if any change of ownership occurs at the technician's place of employment, the technician registration will become invalid. ( )

02. Duration Exemption. The Board's executive director may grant a brief extension of duration of registration for a technician-in-training or a student technician for the purposes of employment continuity in the instance in which a technician is awaiting the completion of a requirement necessary to become a certified technician. No waiver may be granted in the instance in which the individual delayed sitting for the certification exam that the applicant was otherwise qualified to sit for. ( )

044. PRACTITIONER CONTROLLED SUBSTANCE REGISTRATION.
Any practitioner in Idaho who intends to prescribe, administer, dispense, or conduct research with a controlled substance must first obtain an Idaho practitioner controlled substance registration. ( )

01. State License. An applicant must hold a valid license or registration to prescribe medications from a licensing entity established under Title 54, Idaho Code. ( )

02. DEA Registration. An applicant must also hold a valid federal DEA registration, if required under federal law. ( )

045. -- 049. (RESERVED)

050. DRUG OUTLET LICENSURE AND REGISTRATION: GENERAL REQUIREMENTS.
A license or a certificate of registration is required for drug outlets prior to doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. ( )

01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location prior to satisfactory completion of a requisite opening inspection. A change of ownership of a currently registered pharmacy will not require an onsite inspection prior to issuance of a new pharmacy registration unless a structural remodel occurs. ( )

02. License and Registration Transferability. Drug outlet licenses and registrations are location and owner specific and are nontransferable as to person or place. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. ( )

03. Temporary Licenses. ( )

a. Temporary Pharmacy License Number Issued Prior to Operation. Upon request on a Board form, the Board may issue a temporary pharmacy license number prior to the pharmacy being open for business provided that the proposed location is in Idaho and has designated a PIC. ( )

b. Temporary Drug Outlet Facilities and Mobile Drug Outlets. To provide pharmacy services during a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, drug outlets may arrange to temporarily locate or relocate to a temporary drug outlet facility or mobile drug outlet. ( )

04. Nonresident Drug Outlet. The Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. ( )

05. Change of Ownership. The registrant must notify the Board of a drug outlet's change of ownership at least ten (10) days prior to the event on a Board form. ( )

06. Permanent Closing. A registrant must notify the Board and the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the proposed date of closure and the new location of the prescription files. Notice must be provided to the public by prominent posting in a public area of the pharmacy. The PIC must retain a closing inventory record of controlled substances. ( )

07. Exemption from Separate Controlled Substance Registration. All drug outlets doing business in or into Idaho who hold a valid license or registration from the Board are exempt from obtaining a separate controlled substance registration, but must maintain compliance with all requirements under Title 37, Chapter 27, Idaho Code. ( )

051. -- 059. (RESERVED)

060. STERILE PRODUCT DRUG OUTLET ENDORSEMENT.
A drug outlet engaged in sterile product preparation must obtain a single endorsement for one (1) or more hood or aseptic environmental control devices. ( )

061. OUTSOURCING FACILITY REGISTRATION.
An outsourcing facility must be registered with the Board in order to distribute compounded drug product for human use in or into Idaho. ( )

01. Application. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: ( )

a. A copy of a valid FDA registration as an outsourcing facility as required by 21 U.S.C. Section 353b; ( )

b. Identity of a pharmacist licensed or registered in Idaho who is designated as the PIC of the outsourcing facility; and ( )

c. An inspection report indicating compliance with applicable state and federal law. ( )

02. Coincidental Activity. An outsourcing facility applicant currently registered by the Board as a pharmacy or mail service pharmacy will be considered for an outsourcing facility registration with a supplemental pharmacy or mail service pharmacy registration at no additional fee. Exemption from registration fees does not excuse compliance with all laws and rules pertaining to pharmacies and mail service pharmacies. ( )

062. -- 069. (RESERVED)

070. WHOLESALER LICENSURE AND REGISTRATION.

01. Wholesaler Licensure. In addition to the information required pursuant to Section 54-1753, Idaho Code, the following information must be provided under oath by each applicant for wholesaler licensure as part of the initial licensing procedure and for each renewal on a Board form: ( )

a. Any felony conviction or any conviction of the applicant relating to wholesale or retail prescription drug distribution or distribution of controlled substances. ( )

b. Any discipline of the applicant by a regulatory agency in any state for violating any law relating to wholesale or retail prescription drug distribution or distribution of controlled substances. ( )

02. VAWD Accreditation. The Board will recognize a wholesaler's VAWD accreditation by NABP for purposes of reciprocity and satisfying the new drug outlet inspection requirements of these rules. ( )

03. Wholesaler Registration. Except when licensed pursuant to the Idaho Wholesale Drug Distribution Act and these rules, a wholesaler that engages in wholesale distribution of DME supplies, prescription medical devices, or non-prescription drugs in or into Idaho must be registered by the Board. ( )

071. -- 079. (RESERVED)

080. MANUFACTURER REGISTRATION.
A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing. Non-resident manufacturers that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident must be registered by the Board as a mail service pharmacy. ( )

081. -- 999. (RESERVED)

PROPOSED RULE COST/BENEFIT ANALYSIS

Section 67-5223(3), Idaho Code, requires the preparation of an economic impact statement for all proposed rules imposing or increasing fees or charges. This cost/benefit analysis, which must be filed with the proposed rule, must include the reasonably estimated costs to the agency to implement the rule and the reasonably estimated costs to be borne by citizens, or the private sector, or both.

Department or Agency: Board of Pharmacy

Agency Contact: Alex J. Adams, Executive Director **Phone:** (208) 334-2356

Date: August 31, 2017

IDAPA, Chapter and Title Number and Chapter Name: IDAPA 27.01.02 – Rules Governing Licensure and Registration

Fee Rule Status: **_x__ Proposed** **___ Temporary**

Rulemaking Docket Number: 27-0102-1701

STATEMENT OF ECONOMIC IMPACT:

The proposed changes have no impact on the state General Fund.

The net revenue change to the Board of Pharmacy's dedicated fund is projected to be a net decrease of $18,503 on renewals as proposed in the current rules. If the Board's agency legislation also passes, enabling an increase in the nonresident pharmacist registration fee, the net impact on the Board's dedicated fund is projected to be an increase of $4,338 on renewals.

The proposed changes have varying impacts on Board licensees and registrants. The Board has reviewed its fees relative to other states, and Idaho generally falls below the national median. Specific impacts, as described more fully in the fee rule, follow:

- Nursing homes save $35 annually;
- Non-pharmacy retail outlets save $35 annually;
- Veterinary drug technicians save $35 annually;
- Inactive pharmacist licensees save $50 annually;
- Pharmacists who currently hold both a license and a controlled substance registration save $20 annually; the 3% of Idaho pharmacists who hold only a license have a net increase of $40 annually;
- Manufacturers and distributors that hold both a license and a controlled substance registration save $50 annually; those that hold only a license have a net increase of $50 annually;
- Prescriber drug outlets have a net increase in $65 annually; and
- Technicians-in-training who exceed one year save $35.

IDAPA 27 – BOARD OF PHARMACY

27.01.03 – RULES GOVERNING PHARMACY PRACTICE

DOCKET NO. 27-0103-1701 (NEW CHAPTER)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The scope of Chapter 27.01.03 is to establish the rules governing the practice of pharmacy. This chapter is comprised of current rules as follows: professional practice standards, drug outlet practice standards, filling and dispensing prescription drugs, recordkeeping and reporting requirements, and prescription drug monitoring program requirements. Changes made to the current rules include:

- Specific requirements related to fixtures, books, equipment, or staffing patterns that drug outlets must have are removed;
- The rules emphasize "what" needs to occur as a means to improve public safety, as opposed to "how" or "where" it occurs. As such, the offsite pharmacy services rule is broadened;
- The rules clarify which drug outlets must have a person-in-charge;
- Specific technology requirements, such as those related to ADSs, are removed;
- Emergency refill authorizations for non-controlled substances are specified; and
- The requirement that all employment changes must be reported by the PIC has been removed.

These rules will take effect in their entirety on July 1, 2018.

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 in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0103-1701
(New Chapter)

IDAPA 27
TITLE 01
CHAPTER 03

27.01.03. - RULES GOVERNING PHARMACY PRACTICE

SUBCHAPTER A – STANDARD PROVISIONS
(Rules 000 through 099 – Standard Provisions)

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. ( )

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

01. Title. The title of this chapter is "Rules Governing Pharmacy Practice," IDAPA 27, Title 01, Chapter 03. ( )

02. Scope. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to: ( )

a. Regulate drug outlet practice standards; ( )

b. Regulate and control the filling and dispensing of prescription drugs; and ( )

c. Regulate drug outlet recordkeeping and reporting requirements. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

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. ( )

011. – 099. (RESERVED)

SUBCHAPTER B – PROFESSIONAL PRACTICE STANDARDS
(Rules 100 through 199 – Professional Practice Standards)

100. PRESCRIBER PERFORMANCE OF PHARMACY FUNCTIONS.

01. Prescriber Roles. for the purposes of this chapter, any function that a pharmacist may perform may similarly be performed by an Idaho prescriber in the course of filling or dispensing prescription drugs. ( )

02. Prescriber Delegation. For the purposes of this chapter, any function that a pharmacist may delegate to a technician or pharmacist intern may similarly be delegated by an Idaho prescriber to an appropriate support personnel in accordance with the prescriber's practice act. ( )

101. DELEGATION OF PHARMACY FUNCTIONS.
A pharmacist may delegate to and allow performance by a technician or pharmacist intern only those functions performed in pharmacy operations that meet the following criteria: ( )

01. Supervision. The function is performed under a pharmacist's supervision; ( )

02. Education, Skill and Experience. The function is commensurate with the education, skill, and experience of the technician or pharmacist intern; and ( )

03. Professional Judgment Restriction. Any function that requires the use of a pharmacist's professional judgment may be performed by a pharmacist intern. ( )

102. – 199. (RESERVED)

SUBCHAPTER C – DRUG OUTLET PRACTICE STANDARDS
(Rules 200 through 299 - Drug Outlet Practice Standards)

200. PIC: RESPONSIBILITIES AND LIMITATIONS.

01. Drug Outlets that Must Designate a PIC. The following drug outlets must have a designated PIC by the date of opening and must not thereafter allow a vacancy of a designated PIC to continue for more than thirty (30) sequential days: ( )

a. Any drug outlet that dispenses drugs to patients in Idaho; ( )

b. Any central drug outlet; and ( )

c. Any outsourcing facility. ( )

02. PIC and Drug Outlet Responsibility. The PIC is responsible for the management of every part of the drug outlet and its regulated operations. The PIC and the drug outlet each have corresponding and individual responsibility for compliance with applicable state and federal law and these rules. ( )

03. PIC Oversight Limitations. A person may neither be designated nor function as the PIC for more than two (2) drug outlets concurrently. ( )

201. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM FACILITY STANDARDS.
A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: ( )

01. Security. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. An alarm or other comparable monitoring system is required for any non-institutional drug outlet that stocks controlled substances and is new or remodeled after July 1, 2018. ( )

02. Patient Privacy. All protected health information must be stored and maintained in accordance with HIPAA. In addition, a community pharmacy that is new or remodeled after March 21, 2012 must provide and maintain a patient consultation area that affords the patient auditory and visual privacy and is compliant with the Americans with Disabilities Act. ( )

03. Equipment. A drug outlet must be properly equipped to ensure the safe, clean, and sanitary condition necessary and appropriate for proper operation, the safe preparation of prescriptions, and to safeguard product integrity. ( )

04. Staffing. A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business. ( )

05. Controlled Substances Storage. Controlled substances must be stored in a securely locked, substantially constructed cabinet or safe. However, a pharmacy may disperse substances listed in Schedules II, III, IV and V, in whole or in part, throughout the stock of non-controlled substances if doing so would be likely to obstruct the theft or diversion of the controlled substances. ( )

06. Controlled Substances Disposal. Expired, excess or unwanted controlled substances that are owned by the drug outlet must be properly disposed of through the services of a DEA-registered reverse distributor or by another method permitted by federal law. ( )

07. Authorized Access to the Restricted Drug Storage Area. ( )

a. Access to the restricted drug storage area can occur only when a pharmacist or prescriber is on duty. ( )

b. Access must be limited to pharmacists, technicians and pharmacist interns, or in the case of a prescriber drug outlet, to prescribers and appropriate support personnel in accordance with the prescriber's practice act. A pharmacist or prescriber may, however, authorize an individual temporary access to the restricted drug storage area to perform a legitimate non-pharmacy function if the individual remains under the direct supervision of the pharmacist or prescriber. ( )

c. An institutional facility may also develop an emergency drug access protocol in which a non-pharmacist health professional may enter into the restricted drug storage area of an institutional facility that is otherwise closed, and pursuant to a valid prescription drug order, remove a sufficient quantity of non-controlled drugs necessary to meet the immediate needs of a patient. ( )

202. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM PRESCRIPTION FILLING REQUIREMENTS.
Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: ( )

01. Valid Prescription Drug Order. Prescription drugs must only be dispensed pursuant to a valid prescription drug order as set forth in Subchapter D of these rules. ( )

02. Prospective Drug Review. Prospective drug review, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. ( )

03. Labeling. Each drug must bear a complete and accurate label as set forth in Subchapter D of these rules. ( )

04. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, an electronic verification system must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. A compounded drug may only be verified by a pharmacist or prescriber. ( )

05. Patient Counseling. Counseling, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. ( )

203. OFFSITE PHARMACY SERVICES.
A drug outlet may provide offsite pharmacy services at one (1) or more locations. When the services being performed are related to prescription fulfillment or processing, the drug outlet must comply with the following: ( )

01. Policies and Procedures. The originating drug outlet must have written policies and procedures outlining the offsite pharmacy services to be provided by the central drug outlet, or the offsite pharmacist or technician, and the responsibilities and accountabilities of each party. ( )

02. Secure Electronic File. The parties share a secure common electronic file or utilize other secure technology, including a private, encrypted connection that allows access by the central drug outlet or offsite pharmacist or technician to information necessary to perform offsite pharmacy services. ( )

03. Exemption. A single prescription drug order may be shared by an originating drug outlet and a central drug outlet, or offsite pharmacist or technician. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section will not be construed as the filling of a transferred prescription or as a wholesale distribution. ( )

204. DRUG OUTLETS THAT DISPENSE DRUGS TO PATIENTS WITHOUT AN ONSITE PHARMACIST OR PRESCRIBER.
In addition to all other preceding rules of this subchapter, a drug outlet that dispenses drugs to patients in Idaho that does not have a pharmacist or prescriber onsite to perform or supervise pharmacy operations must comply with the following requirements: ( )

01. Security and Access. ( )

a. The drug outlet must maintain video surveillance with an adequate number of views of the full facility and retain a high quality recording for a minimum of ninety (90) days. ( )

b. Proper identification controls of individuals accessing the restricted drug storage area must be utilized and access must be limited, authorized, and regularly monitored. ( )

02. Staffing Limitations. The ratio of pharmacists to support personnel may not exceed one (1) pharmacist for every six (6) technicians and pharmacist interns in total across all practice sites. ( )

03. Technology. The video and audio communication system used to counsel and interact with each

patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. ( )

04. Controlled Substances Inventories. ( )

a. A perpetual inventory must be kept for all Schedule II controlled substances; and ( )

b. If a perpetual inventory is not kept for all Schedule III through V substances, the pharmacist or prescriber must inventory and audit at least three (3) random controlled substances quarterly. ( )

05. Self-Inspection. A pharmacist or prescriber must complete and retain a monthly in-person self-inspection of the drug outlet using a form designated by the Board. ( )

06. Emergency Situations. ( )

a. A pharmacist or prescriber must be capable of being on site at the drug outlet within twelve (12) hours if an emergency arises. ( )

b. The drug outlet must be, or remain, closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, until system corrections or repairs are completed. ( )

07. Exemption for Self-Service Systems. A self-service ADS that is operating as a drug outlet is exempt from the video surveillance requirement and the self-inspection requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADS is exempt from the video and audio communication system requirements of this rule. ( )

08. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act are exempt from this rule. ( )

205. DRUGS STORED OUTSIDE OF A DRUG OUTLET FOR RETRIEVAL BY A LICENSED HEALTH PROFESSIONAL.
Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, floor stock, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: ( )

01. Supervising Drug Outlet. Drugs stored in such a manner must remain under the control of, and be routinely monitored by, the supervising drug outlet. ( )

02. Policies and Procedures. The supervising drug outlet must develop and implement policies and procedures regarding authorized access to drugs stored in the alternative designated area, documentation of drugs used, drug returns and wastage, and regular inventory procedures. ( )

03. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. ( )

04. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. ( )

05. Stocking and Replenishing. Stocking or replenishing drugs in an alternative designated area may be performed by a pharmacist or prescriber, or by appropriate support personnel using either an electronic verification system or a two (2) person checking system. ( )

206. – 299. (RESERVED)

SUBCHAPTER D – FILLING AND DISPENSING PRESCRIPTION DRUGS
(Rules 300 through 399 - Filling and Dispensing Prescription Drugs)

300. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. ( )

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued: ( )

a. In good faith; ( )

b. For a legitimate medical purpose; ( )

c. By a licensed prescriber; ( )

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; ( )

e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; or ( )

f. In the form and including the elements specified in this Subchapter D. ( )

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. ( )

03. Tampering. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. ( )

04. Prescriber Self-Use. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. ( )

05. Family Members. A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession. ( )

06. Expiration. A prescription drug order is invalid after its expiration date as follows: ( )

a. A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than ninety (90) days after its date of issue. ( )

b. A prescription drug order for a controlled substance listed in Schedules III, IV or V must not be filled or refilled more than six (6) months after its date of issue. ( )

c. A prescription drug order for a non-controlled drug must not be filled or refilled more than fifteen (15) months after its date of issue, unless if extended in accordance with these rules. ( )

07. Prescriber Change of Status. A prescription drug order is invalid after ninety (90) days from the date the pharmacist learns of a change in status that precludes a continued prescriber-patient relationship. ( )

301. PRESCRIPTION DRUG ORDER: SCHEDULE II DRUG LIMITATIONS

01. Faxed and Verbal Prescriptions. A Schedule II prescription must not be dispensed pursuant to a faxed or verbal prescription drug order, except as permitted by federal law. ( )

02. Multiple Prescription Drug Orders. A prescriber may issue and a pharmacy may fill multiple prescription drug orders, written on and dated with the same date, that allow the patient to receive up to a ninety (90)-day supply of a Schedule II controlled substance in accordance with federal law. ( )

302. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.
A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, must include at least the following: ( )

01. Patient's Name. The patient's or authorized entity's name and: ( )

a. If for a controlled substance, the patient's full name and address; and ( )

b. If for an animal, the species. ( )

02. Date. The date issued. ( )

03. Drug Information. The drug name, strength, quantity and, if for a controlled substance, the dosage form. ( )

04. Directions. The directions for use. ( )

05. Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. ( )

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. ( )

07. Institutional Drug Order Exemptions. An institutional drug order may exempt the patient's address, the dosage form, quantity, prescriber's address, and prescriber's DEA registration number. ( )

303. FILLING PRESCRIPTION DRUG ORDERS: PRACTICE LIMITATIONS.

01. Drug Product Selection. Drug product selection is allowed only between therapeutic equivalent drugs. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug product selection is permitted. ( )

02. Partial Filling. A prescription drug order may be partially filled within the limits of federal law. The total quantity dispensed in partial fillings must not exceed the total quantity prescribed. ( )

03. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal law and only as specifically authorized by the prescriber, except as follows: ( )

a. A pharmacist acting in good faith and exercising reasonable care may dispense or refill a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills. ( )

b. A pharmacist may refill a prescription for a non-controlled drug one (1) time in a six (6)-month period when the prescriber is not available for authorization. In such cases, a pharmacist may dispense a refill up to the quantity on the most recent fill or a thirty (30)-day supply, whichever is less. ( )

304. FILLING PRESCRIPTION DRUG ORDERS: ADAPTATION.
Upon patient consent, a pharmacist acting in good faith and exercising reasonable care may adapt drugs as specified in this rule, provided that the drug is not for a controlled substance, compounded drug, or biological product, and provided that the prescriber has not indicated by any means necessary that adaptation is not permitted. ( )

01. Change Quantity. A pharmacist may change the quantity of medication prescribed if: ( )

a. The prescribed quantity or package size is not commercially available; or ( )

b. The change in quantity is related to a change in dosage form. ( )

02. Change Dosage Form. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. ( )

03. Complete Missing Information. A pharmacist may complete missing information on a

prescription if there is sufficient evidence to support the change. ( )

04. Medication Synchronization. A pharmacist may extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. ( )

05. Documentation. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record. ( )

305. FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION.
Drug product substitutions are allowed only as follows: ( )

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; ( )

02. Skilled Nursing Facility. At the direction of the quality assessment and assurance committee of a skilled nursing facility; ( )

03. Drug Shortage. Upon a drug shortage, a pharmacist may exercise professional judgment, without contacting the prescriber, and may substitute an alternative dose of a prescribed drug, so long as the prescriber's directions are also modified, to equate to an equivalent amount of drug dispensed as prescribed; or ( )

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: ( )

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; ( )

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and ( )

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. ( )

306. FILLING PRESCRIPTION DRUG ORDERS: TRANSFERS.

01. Communicating Prescription Drug Order Transfers. A prescription drug order may be transferred within the limits of federal law. A controlled substance listed in Schedules III, IV or V may be transferred only from the drug outlet where it was originally filled and never from the drug outlet that received the transfer. ( )

02. Pharmacies Using Common Electronic Files. Drug outlets using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other drug outlets sharing the common electronic file. ( )

307. LABELING: STANDARD PRESCRIPTION DRUG.
Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: ( )

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business). ( )

02. Serial Number. The serial number. ( )

03. Date. The date the prescription is filled. ( )

04. Prescriber. The name of the prescriber. ( )

05. Name. ( )

a. If a person, the name of the patient or other person authorized to possess a legend drug in accordance with Idaho Code; ( )

b. If an animal, the name and species of the patient; or ( )

c. If a facility or other entity is authorized to possess a legend drug in accordance with Idaho Code, the name of the facility or entity. ( )

06. Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of each drug included (the generic name and its manufacturer's name or the brand name). ( )

07. Quantity. The quantity of item dispensed. ( )

08. Directions. The directions for use. ( )

09. Cautionary Information. Cautionary information as necessary or deemed appropriate for proper use and patient safety. ( )

10. Expiration. An expiration date that is either: ( )

a. The lesser of: ( )

i. One (1) year from the date of dispensing; ( )

ii. The manufacturer's original expiration date; ( )

iii. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or ( )

iv. A shorter period if warranted. ( )

b. If dispensed in the original, unopened manufacturer packaging, the manufacturer's original expiration date. ( )

11. Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable. ( )

12. Warning. A warning sufficient to convey that state or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed, except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. ( )

13. Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. ( )

308. LABELING: INSTITUTIONAL FACILITY DRUGS.
Except if dispensed in unit dose packaging, a drug dispensed for patient use while in a hospital must be dispensed in an appropriate container that bears at least the following information: ( )

01. Date. The date filled; ( )

02. Patient. The name of the patient; ( )

03. Drug. The name and strength of the drug; ( )

04. Quantity. The quantity of item dispensed; ( )

05. **Directions**. The directions for use, including the route of administration; ( )

06. **Caution**. Cautionary information as necessary or deemed appropriate for proper use and patient safety; ( )

07. **Expiration Date**. The expiration or beyond use date, if appropriate; and ( )

08. **Pharmacist**. The initials or other unique identifier of the dispensing pharmacist. ( )

309. LABELING: PARENTERAL ADMIXTURE.
If one (1) or more drugs are added to a parenteral admixture, the admixture's container must include a distinctive, supplementary label with at least the following information: ( )

01. **Ingredient Information**. The name, amount, strength and, if applicable, the concentration of the drug additive and the base solution or diluent; ( )

02. **Date and Time**. The date and time of the addition, or alternatively, the beyond use date; ( )

03. **Identification**. The initials or other unique identifier of the pharmacist or preparing prescriber responsible for its accuracy; ( )

04. **Prescribed Administration Regimen**. The rate or appropriate route of administration or both, as applicable; and ( )

05. **Special Instructions**. Any special handling, storage, or device-specific instructions. ( )

310. LABELING: PREPACKAGED PRODUCT.
The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label with at least the following information: ( )

01. **Drug Name and Strength**. The name and strength of the drug; ( )

02. **Expiration Date**. An expiration date that is the lesser of: ( )

a. The manufacturer's original expiration date; ( )

b. One (1) year from the date the drug is prepackaged; or ( )

c. A shorter period if warranted (A prepackaged drug returned unopened from an institutional facility and again prepackaged must be labeled with the expiration date used for the initial prepackaging.); ( )

03. **Conditional Information**. If not maintained in a separate record, the manufacturer's name and lot number and the identity of the pharmacist or provider responsible for the prepackaging. ( )

311. DISPENSING CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.
A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. ( )

01. **Positive Identification Presumed**. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: ( )

a. The controlled substance will be paid for, in whole or in part, by an insurer; ( )

b. The patient is being treated at an institutional facility or is housed in a correctional facility; or ( )

c. The filled prescription is delivered to the patient or patient's provider. ( )

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: ( )

a. The recipient's name (if other than the patient); ( )

b. A notation indicating that the recipient was known to the staff member; and ( )

c. The identity of the staff member making the personal identification. ( )

03. Acceptable Identification. A valid government-issued identification must include an unaltered photograph and signature to be acceptable. ( )

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and include: ( )

a. A copy of the identification presented; or ( )

b. A record that includes: ( )

i. The recipient's name; ( )

ii. A notation of the type of identification presented; ( )

iii. The government entity that issued the identification; and ( )

iv. The unique identification number. ( )

312. DISPENSING CONTROLLED SUBSTANCES: NON-PRESCRIPTION DISPENSING LIMITATIONS.
Limited quantities of a Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted by federal law. ( )

313. PRESCRIPTION DELIVERY: RESTRICTIONS.

01. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions to the following, as long as appropriate measures are taken to ensure product integrity: ( )

a. To the patient or the patient's residence, the institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed; ( )

b. To the patient's licensed or registered healthcare provider, as follows: ( )

i. If the drug is not a controlled substance; or ( )

ii. If the drug is a controlled substance that is intended for direct administration by the prescriber or prescriber's delegate. ( )

c. To another licensed drug outlet. ( )

02. Pick-up or Return by Authorized Personnel. Filled prescriptions may be picked up for or returned from delivery by authorized personnel when the drug outlet is closed for business if the prescriptions are placed in a secured delivery area outside of the restricted drug storage area that is equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion under

policies and procedures developed by the PIC. ( )

314. DESTRUCTION OR RETURN OF DRUGS OR DEVICES: RESTRICTIONS.
A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise a dispensed drug or prescription device must only be accepted for return as follows: ( )

01. Error. Those that were dispensed in a manner inconsistent with the prescriber's instructions may be returned for quarantine and destruction purposes only. ( )

02. Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care. ( )

03. Donation. Those that qualify for return under the provisions of the Idaho Legend Drug Donation Act as specified in Section 54-1762, Idaho Code. ( )

315. REPACKAGING DRUG PREVIOUSLY DISPENSED.
A drug outlet may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: ( )

01. Pharmacist Verification. The repackaging pharmacist verifies the identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within. ( )

02. Intermingled Drugs. The drugs are never intermingled with the repackaging pharmacy's regular stock. ( )

03. Labeling. The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes: ( )

a. The original dispensed prescription's serial number; ( )

b. The name, address, and phone number of the original dispensing pharmacy; and ( )

c. A statement that indicates that the drug has been repackaged, such as the words "repackaged by" followed by the name of the repackaging pharmacy. ( )

316. – 399. (RESERVED).

SUBCHAPTER E – DRUG OUTLET RECORDKEEPING AND REPORTING REQUIREMENTS
(Rules 400 through 499 - Drug Outlet Recordkeeping and Reporting Requirements)

400. RECORDKEEPING: MAINTENANCE AND INVENTORY REQUIREMENTS.

01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. ( )

02. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained as follows: ( )

a. Schedule II Prescriptions. Paper prescription drug orders for Schedule II controlled substances

must be maintained at the registered location in a separate prescription file. ( )

b. Schedule III through V Prescriptions. Paper prescription drug orders for Schedules III, IV and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV and V controlled substances only or in a readily retrievable manner from other prescription records as required by federal law. ( )

c. Electronic Prescriptions. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location. The electronic application must be capable of printing or otherwise converting the records into a readily understandable format at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filled. ( )

03. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An inventory must be conducted as follows: ( )

a. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. A separate controlled substances inventory must be taken and retained at each DEA-registered location. ( )

b. Inventory on PIC Change. A complete controlled substance inventory must be conducted by the incoming PIC or his delegate on or by the first day of employment of the incoming PIC. ( )

c. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory. ( )

d. Drugs Stored Outside a Drug Outlet. In addition to the annual inventory requirements, drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. ( )

e. Closing of Pharmacy. A closing inventory must be conducted and retained. ( )

04. Rebuttal Presumption of Violation. Evidence of an amount of a controlled substance that differs from the amount reflected on a record or inventory required by state or federal law creates a rebuttable presumption that the registrant has failed to keep records or maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law. ( )

05. Central Records Storage. Financial and shipping records of controlled substances including invoices, but excluding controlled substance order forms and inventories, may be retained at a central location if the registrant has provided DEA notification of central recordkeeping as required by federal law. ( )

06. Electronic Records Storage. Any record required to be kept under this section may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. ( )

401. RECORDKEEPING: ELECTRONIC SYSTEM FOR PATIENT MEDICATION RECORDS.
A drug outlet that is new or remodeled after the effective date of this rule must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. ( )

01. Real-time Online Retrieval of Information. The electronic recordkeeping system must be capable of real-time, online retrieval of information stored therein for a minimum of fifteen (15) months from the date

of entry. ( )

02. Immediately Retrievable Refill Data. The electronic recordkeeping system must have functionality that allows refill data to be immediately retrievable and produced upon request; for example, a refill-by-refill audit trail for a specified strength and dosage form of a drug. ( )

03. Audit Trail Documentation. The electronic recordkeeping system must also have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of these processes. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited. Drug outlets that utilize offsite pharmacy services for product fulfillment or processing must track the identity and location of each individual involved in each step of the offsite pharmacy services. ( )

04. System Security. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: ( )

a. Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and ( )

b. Functionality that documents any alteration of prescription drug order information after a prescription drug order is dispensed, including the identification of the individual responsible for the alteration. ( )

05. System Downtime, Backup and Recovery. The pharmacy must have policies and procedures in place for system downtime, backup and recovery. ( )

06. Exemption. Drug outlets are exempt from this section if they fill on average fewer than twenty (20) prescriptions per business day, and paper records must be maintained. ( )

402. REPORTING REQUIREMENTS.

01. PIC Change. Both an outgoing and incoming PIC must report to the Board a change in a PIC designation within ten (10) days of the change. ( )

02. Theft or Loss of Controlled Substances. A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law. ( )

03. Individual Information Changes. Changes in employment or changes to information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change. ( )

04. Reporting Adulteration or Misappropriation. A licensee or registrant must report to the Board any adulteration or misappropriation of a controlled drug in accordance with Section 37-117A. Idaho Code. ( )

403. – 499. (RESERVED)

SUBCHAPTER F – PRESCRIPTION DRUG MONITORING PROGRAM REQUIREMENTS (Rules 500 through 999 – Prescription Drug Monitoring Program Requirements)

500. CONTROLLED SUBSTANCES: PDMP.
Specified data on controlled substances must be reported by the end of the next business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. ( )

01. Online Access to PDMP. Online access to the Board's PDMP is limited to licensed prescribers and

pharmacists, or their delegates, for treatment purposes. To obtain online access, a prescriber or pharmacist, or their delegate must complete and submit a registration application and agree to adhere to the access restrictions and limitations established by law. ( )

02. Use Outside Scope of Practice Prohibited. Information obtained from the PDMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. A delegate may not access the PDMP outside of their supervisor's scope of professional practice. ( )

03. Profile Requests. Authorized persons without online access may obtain a profile by completing a Board form and submitting it to the Board office with proof of identification and other credentials required to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. ( )

04. Suspension, Revocation, or Restriction of PDMP Access. Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's, pharmacist's, or delegate's authorization for online access to the PDMP. ( )

501. – 999. (RESERVED)

IDAPA 27 – BOARD OF PHARMACY

27.01.04 – RULES GOVERNING PHARMACIST PRESCRIPTIVE AUTHORITY

DOCKET NO. 27-0104-1701 (NEW CHAPTER)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The scope of Chapter 27.01.04 is to specify which products pharmacists may prescribe. This chapter implements House Bill 191, which passed in the 2017 Idaho Legislature. House Bill 191 amended Section 54-1704, Idaho Code, and provided the Board of Pharmacy with rulemaking authority to designate drugs, drug categories, and devices that pharmacists may prescribe, provided certain conditions are met. In addition, existing rules related to collaborative pharmacy practice and statewide protocol agreements are organized into this chapter.

These rules will take effect in their entirety on July 1, 2018.

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 in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0104-1701
(New Chapter)

IDAPA 27
TITLE 01
CHAPTER 04

27.01.04. - RULES GOVERNING PHARMACIST PRESCRIPTIVE AUTHORITY

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. ( )

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

01. **Title**. The title of this chapter is "Rules Governing Pharmacist Prescriptive Authority," IDAPA 27, Title 01, Chapter 04. ( )

02. **Scope**. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to determine which drugs or devices pharmacists can prescribe independently, and further establish criteria for collaborative pharmacy practice and statewide protocol agreements. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

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. ( )

011. – 019. (RESERVED).

020. PHARMACIST PRESCRIBING: GENERAL REQUIREMENTS.
In addition to all nonprescription drugs and devices and the statutorily authorized drug products and categories set forth in Section 54-1704, Idaho Code, a pharmacist acting in good faith and exercising reasonable care may independently prescribe drugs, drug categories and devices as set forth in this chapter provided the following general requirements are met: ( )

01. Education. The pharmacist may only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained. ( )

02. Patient-Prescriber Relationship. The pharmacist may only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code. ( )

03. Patient Assessment. The pharmacist must obtain adequate information about the patient's health status to make appropriate decisions based on clinical guidelines or evidence-based research findings and mitigate potential contraindications and interactions, among other potential adverse health outcomes. ( )

a. At a minimum, for each drug or drug category the pharmacist intends to prescribe, the pharmacist must maintain a patient assessment protocol based on current clinical guidelines, when available, or evidence-based research findings that specifies the following: ( )

b. Patient inclusion and exclusion criteria; and ( )

c. Explicit medical referral criteria. ( )

d. The pharmacist must revise the patient assessment protocol when necessary to ensure continued compliance with clinical guidelines or evidence-based research findings. The pharmacist's patient assessment protocol, and any related forms, must be made available to the Board upon request. ( )

04. Collaboration with Other Health Care Professionals. The pharmacist must recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate. ( )

05. Follow-Up Care Plan. The pharmacist must develop and implement an appropriate follow-up care plan, including any monitoring parameters, in accordance with clinical guidelines. ( )

06. Notification. The pharmacist must inquire about the identity of the patient's primary care provider; and, if one is identified by the patient, provide notification within five (5) business days following the prescribing of a drug. In the instance in which the pharmacist is prescribing to close a gap in care or to supplement a valid prescription drug order, the pharmacist must alternatively notify the provider of record. ( )

07. Documentation. The pharmacist must maintain documentation adequate to justify the care provided, including, but not limited to the information collected as part of the patient assessment, the prescription record, any notification provided as required under this section, and the follow-up care plan. ( )

021. PHARMACIST PRESCRIBING FOR MINOR CONDITIONS.
A pharmacist may prescribe any drug approved by the FDA that is indicated for the following conditions: ( )

01. Lice; ( )

02. Cold Sores; ( )

03. Motion Sickness; ( )

04. Nausea; and ( )

05. Uncomplicated Urinary Tract Infections. ( )

022. PHARMACIST PRESCRIBING OF DEVICES.
A pharmacist may prescribe any of the following devices approved by the FDA: ( )

01. Inhalation Spacer; ( )

02. Nebulizer; ( )

03. Diabetes Blood Sugar Testing Supplies; ( )

04. **Insulin Pen Needles**; and ( )

05. **Syringes**. Syringes for patients with diabetes. ( )

023. PHARMACIST PRESCRIBING BASED ON CLIA-WAIVED TEST.
A pharmacist may prescribe any antimicrobial drug approved by the FDA that is indicated for the following conditions, provided the symptomatic patient first tests positive to a CLIA-waived test indicated for the condition: ( )

01. **Influenza**. When a person has tested positive for influenza, a pharmacist may additionally prescribe an antiviral medication to an individual who has been exposed to the infectious person and for whom clinical guidelines recommend chemoprophylaxis; and ( )

02. **Group A Streptococcal Pharyngitis**. ( )

024. PHARMACIST PRESCRIBING FOR CLINICAL GAPS IN CARE.
A pharmacist may prescribe any drug approved by the FDA for the purposes of closing a gap in clinical guidelines as follows: ( )

01. **Statins**. Statins, for patients with diabetes; and ( )

02. **Short-Acting Beta Agonists**. Short-acting beta agonists (SABA), for patients with asthma who have had a prior prescription for a SABA, and who have a current prescription for a long-term asthma control medication. ( )

025. PHARMACIST PRESCRIBING OF TRAVEL DRUGS.
A pharmacist who successfully completes an accredited CPE or CME course on travel medicine may prescribe any non-controlled drug recommended for individuals traveling outside the United States that are specifically listed in the federal CDC Health Information for International Travel (e.g., Yellow Book). The pharmacist may only prescribe drugs that are indicated for the patient's intended destination for travel. ( )

026. PHARMACIST PRESCRIBING TO SUPPLEMENT AN INFUSION ORDER.
A pharmacist may prescribe any of the following FDA approved drugs or devices to supplement a valid prescription drug order or institutional drug order for drugs intended to be administered to a patient via infusion; ( )

01. **Flush**. Heparin, in concentrations of 100 units per milliliter or less, and saline; ( )

02. **Devices**. Infusion pumps and other rate control devices; ( )

03. **Supplies**. Tubing, filters, catheters, intravenous (IV) start kits, central line dressing kits, and injection caps; and ( )

04. **Local Anesthetics for IV Port Access**. ( )

027. PHARMACIST PRESCRIBING IN EMERGENCY SITUATIONS.
If a situation exists that, in the professional judgment of the pharmacist, threatens the health or safety of the patient, a pharmacist may prescribe the following FDA approved drugs in the minimum quantity necessary until the patient is able to be seen by another provider. As soon as possible, the prescribing pharmacist must contact emergency medical services. ( )

01. **Diphenhydramine**; ( )

02. **Epinephrine**; and ( )

03. **Short-Acting Beta Agonists**. ( )

028. PHARMACIST PRESCRIBING FOR LYME DISEASE PROPHYLAXIS.
After a recognized tick bite, a pharmacist may prescribe antimicrobial prophylaxis, for the prevention of Lyme disease in accordance with clinical guidelines. ( )

029. – 199. (RESERVED).

200. COLLABORATIVE PHARMACY PRACTICE AND STATEWIDE PROTOCOL AGREEMENTS.

01. Collaborative Agreement. Pharmacists or pharmacies and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. ( )

a. Agreement Elements. The collaborative pharmacy practice agreement must include: ( )

i. Identification of the parties to the agreement; ( )

ii. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; ( )

iii. The drug name, class or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; ( )

iv. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; ( )

v. A provision allowing any party to cancel the agreement by written notification; ( )

vi. An effective date; and ( )

vii. Signatures of the parties to the agreement and dates of signing. ( )

b. Agreement Review. The collaborative pharmacy practice agreement must be reviewed and revised when necessary or appropriate. ( )

02. Statewide Protocol Agreement. A pharmacist may perform DTM or other patient care services according to a statewide protocol agreement issued by the director of the Idaho Department of Health and Welfare, in conjunction with the Board, for the purpose of improving public health. The protocol agreement must include: ( )

a. An effective date range; ( )

b. The geographical portion of the state where the protocol agreement is to be effective; and ( )

c. The drug name, class or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM or other patient care services. ( )

03. Prescribing Exemption. The general requirements set forth in Section 020 of these rules do not apply to collaborative agreements and statewide protocol agreements. ( )

201. – 999. (RESERVED).

IDAPA 27 – BOARD OF PHARMACY

27.01.05 – RULES GOVERNING DRUG COMPOUNDING

DOCKET NO. 27-0105-1701 (NEW CHAPTER)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing.

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:

The scope of Chapter 27.01.05 is to establish rules related to drug compounding. This chapter is comprised of current rules related to compounding drug products, sterile product preparation, hazardous drug preparation, outsourcing facilities, and labeling of distributed compounded drug products. No substantive changes were made to these rules relative to the current ones, though the Board did correct some minor typos from existing rules.

These rules will take effect in their entirety on July, 1, 2018.

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 in two separate open, public meetings on August 1, 2017 and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0105-1701
(New Chapter)

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. ( )

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

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

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

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. ( )

011. – 099. (RESERVED).

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

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: ( )

a. Compound positron emission tomography drugs; ( )

b. Radiopharmaceutics; ( )

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

d. The addition of a flavoring agent to a drug product; and ( )

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

02. General Compounding Standards. ( )

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. ( )

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: ( )

i. Product name; ( )

ii. Lot number; ( )

iii. Expiration date; and ( )

iv. Assay. ( )

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. ( )

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. ( )

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. ( )

04. Limited Compounding. ( )

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. ( )

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 ( )

ii. The commercial product is not reasonably available in the market in time to meet the patient’s needs. ( )

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. ( )

05. Drug Compounding Controls. ( )

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: ( )

i. Appropriate packaging, handling, transport, and storage requirements; ( )

ii. Accuracy and precision of calculations, measurements, and weighing; ( )

iii. Determining ingredient identity, quality, and purity; ( )

iv. Labeling accuracy and completeness; ( )

v. Beyond use dating; ( )

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

vii. Maintaining environmental quality control; and ( )

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

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. ( )

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: ( )

i. Production date; ( )

ii. Beyond use date; ( )

iii. List and quantity of each ingredient; ( )

iv. Internal control or serial number; and ( )

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

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. ( )

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: ( )

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

b. Baths and soaks for live organs and tissues; ( )

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); ( )

d. Irrigations for wounds and body cavities; ( )

e. Ophthalmic drops and ointments; and ( )

f. Tissue implants. ( )

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; ( )

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; ( )

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; ( )

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

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

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; ( )

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; ( )

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. ( )

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. ( )

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. ( )

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

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

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; ( )

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

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

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

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

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

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

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

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; ( )

ii. Periodic hand hygiene and garbing competency; ( )

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

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: ( )

(1) Total particle counts; ( )

(2) Viable air sampling; ( )

(3) Gloved fingertip sampling; ( )

(4) Surface sampling; ( )

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

d. Temperature, logged daily; ( )

e. Beyond use date and accuracy testing, when appropriate; and ( )

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

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: ( )

a. Antiseptic hand cleansing; ( )

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

c. Selecting and appropriately donning protective garb; ( )

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

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

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

g. Inspecting for quality standards before dispensing or distributing. ( )

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: ( )

01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. ( )

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

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; ( )

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

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

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

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

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

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

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

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. ( )

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

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. ( )

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

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. ( )

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. ( )

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. ( )

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: ( )

01. Drug Name. The name of each drug included. ( )

02. Strength or Concentration. The strength or concentration of each drug included. ( )

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

04. Administration. If applicable, the dosage form or route of administration. ( )

05. Quantity. The total quantity of the drug product. ( )

06. Expiration Date. The expiration or beyond use date. ( )

07. Compounder Identifier. The initials or unique identifier of the compounder responsible for the accuracy of the drug product. ( )

08. Resale Prohibited. Resale is prohibited and products must be labeled as follows: ( )

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

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

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. ( )

105. – 999. (RESERVED).

IDAPA 27 – BOARD OF PHARMACY

27.01.06 – RULES GOVERNING DME, MANUFACTURING, AND DISTRIBUTION

DOCKET NO. 27-0106-1701 (NEW CHAPTER)

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 25, 2017 – 9:00 a.m. (MDT)

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

For those planning to attend the open public hearing, the Board will accept written and verbal comments. For all others not planning to attend the public hearing, written comments will be accepted by the Executive Director on or before close of business on October 24, 2017 as follows:

- Written comments received by October 20, 2017 will be included in the Board's distributed meeting material for consideration in advance of the hearing.
- Written comments received between October 21, 2017 and October 24, 2017 will be printed and provided to the Board at the open public hearing

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:

The scope of Chapter 27.01.06 is to establish rules to regulate durable medical equipment (DME), manufacturing, and distribution. This chapter is comprised of current rules as follows: DME outlet standards, drug distribution, wholesaler standards, and drug manufacturer standards. No substantive changes were made to these rules relative to the current ones, though the following conforming edits have been made:

- The Board proposes to remove the transaction restriction on non-prescription drugs, which coincides with the removal of registration of non-pharmacy retail outlets specified in Chapter 02, IDAPA 27.01.02; and
- The Board proposes to amend the restriction on delivering drugs only to "the premises listed on the authorized receiving person's license or registration" to "the registered address" to reflect recent changes in what is on a state license and registration.

These rules will take effect in their entirety on July 1, 2018.

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 in two separate open, public meetings on August 1, 2017and August 30, 2017. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1701 in the June 7, 2017 Idaho Administrative Bulletin, **Vol. 17-6, pages 54 through 56**, and in the August 2, 2017 Idaho Administrative Bulletin, **Vol. 17-8, pages 114 through 115**.

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 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 25, 2017.

DATED this 30th day of August, 2017.

Alex J. Adams, Pharm D, MPH
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0106-1701
(New Chapter)

IDAPA 27
TITLE 01
CHAPTER 06

27.01.06. - RULES GOVERNING DME, MANUFACTURING, AND DISTRIBUTION

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. ( )

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

01. **Title**. The title of this chapter is "Rules Governing DME, Manufacturing, and Distribution," IDAPA 27, Title 01, Chapter 06. ( )

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 manufacturing and distribution. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

005. BOARD OFFICE INFORMATION.

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

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

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

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

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

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

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. ( )

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. ( )

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. ( )

011. – 019. (RESERVED).

020. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: ( )

a. Operational procedures for the appropriate provision and delivery of equipment; ( )

b. Operational procedures for maintenance and repair of equipment; and ( )

c. Recordkeeping requirements for documenting the acquisition and provision of products. ( )

02. Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: ( )

a. Pure oxygen for human application; ( )

b. Nitrous oxide; ( )

c. Sterile sodium chloride; and ( )

d. Sterile water for injection. ( )

03. Prescriber's Order Required. Prescription drugs and devices may only be sold or delivered by a DME outlet upon the lawful order of a prescriber. ( )

021. -- 029. (RESERVED)

030. DRUG DISTRIBUTION.

01. Authorized Distributors. The following drug outlets may distribute legend drugs in or into Idaho, in compliance with these rules, pursuant to the following restrictions: ( )

a. A licensed or registered wholesale distributor and a registered manufacturer in compliance with the Idaho Wholesale Distribution Act and the Idaho Pharmacy Act; ( )

b. An FDA and Idaho registered outsourcing facility in compliance with 21 U.S.C. Section 353b of the Food, Drug and Cosmetic Act; ( )

c. A dispenser without being licensed or registered as a wholesale distributor according to the following restrictions: ( )

i. A dispenser may distribute to authorized recipients for an emergency medical purpose in which an alternative source for a drug is not reasonably available in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining a drug. The amount of the drug distributed in an emergency must not reasonably exceed the amount necessary for immediate use; ( )

ii. A dispenser may distribute intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity; ( )

iii. A dispenser may distribute to another dispenser pursuant to a sale, transfer, merger or consolidation of all or a part of a dispenser, whether accomplished as a sale of stock or business assets; ( )

iv. A dispenser may distribute compound positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; and ( )

v. A dispenser may distribute minimal quantities of prescription drugs to a prescriber for in-office administration, including the distribution of compounded drug product in the absence of a patient specific prescription drug order if: ( )

(1) The compounded drug product is not sterile and not intended to be sterile; ( )

(2) The compounded drug product is not further dispensed or distributed by the practitioner; and ( )

(3) The quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the dispenser, which may include a drug compounded for the purpose of, or incident to, research, teaching or chemical analysis. ( )

02. Distribution. Unless statutorily exempted, an authorized distributor must furnish: ( )

a. Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs; ( )

b. Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law; ( )

c. Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and ( )

d. Drug product only to the registered address of the authorized receiving person. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery. ( )

03. Controlled Substance Distribution Invoice. Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: ( )

a. The date of the transaction; ( )

b. The name, address, and DEA registration number of the distributing dispenser; ( )

c. The name, address, and DEA registration number or the receiving dispenser; ( )

d. The drug name, strength, and quantity for each product distributed; and ( )

e. The signature of the person receiving the drugs. ( )

04. Monitoring Purchase Activity. An authorized distributor must have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, and orders of unusual frequency. ( )

05. Reporting. An authorized distributor must report specified data on controlled substances distributed at least monthly to the Board in a form and manner prescribed by the Board, except when distributing intracompany. ( )

06. Prohibited Acts. The following acts are prohibited: ( )

a. Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit; and ( )

b. Failing to obtain a license or registration when one is required to distribute in or into Idaho. ( )

031. -- 039. (RESERVED)

040. WHOLESALER: STANDARDS.
These wholesaler rules establish the minimum standards for the storage and handling of drugs by wholesalers and their officers, designated representative, agents, and employees and for the establishment and maintenance of records required for persons engaged in wholesale drug distribution. ( )

041. WHOLESALER: FACILITY REQUIREMENTS.
Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must: ( )

01. Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations; ( )

02. Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; ( )

03. Quarantine Area. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened; ( )

04. Maintenance Requirements. Be maintained in a clean and orderly condition; and ( )

05. Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind. ( )

042. WHOLESALER: FACILITY SECURITY.
Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: ( )

01. Access from Outside. Access from outside the premises must be kept to a minimum and well controlled; ( )

02. Perimeter Lighting. The outside perimeter of the premises must be well lighted; ( )

03. Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel; ( )

04. Alarm Systems. Facilities must be equipped with an alarm system to detect entry after hours; and ( )

05. Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering. ( )

043. WHOLESALER: DRUG STORAGE REQUIREMENTS.
Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs. ( )

044. WHOLESALER DRUG SHIPMENT INSPECTION REQUIREMENTS.

01. Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. ( )

02. Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents. ( )

045. WHOLESALER: QUARANTINE.
Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. ( )

01. Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. ( )

02. Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that

causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards. ( )

046. WHOLESALER: RECORDKEEPING REQUIREMENTS.
Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. ( )

01. Record Contents. The records must include at least: ( )

a. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; ( )

b. The identity and quantity of the drugs received and distributed or disposed of; and ( )

c. The dates of receipt and distribution or other disposition of the drugs. ( )

02. Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location. ( )

047. WHOLESALER: PERSONNEL.

01. Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. ( )

02. Adequate Personnel. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities. ( )

03. Designated Representative Continuing Education. A wholesaler's designated representative must complete training and continuing education on state and federal laws pertaining to wholesale distribution of prescription drugs provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. ( )

048. WHOLESALER: POLICIES AND PROCEDURES.
Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following: ( )

01. Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation. ( )

02. Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: ( )

a. A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; ( )

b. A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or ( )

c. An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design. ( )

03. Crisis Preparation. Wholesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency. ( )

049. (RESERVED)

050. DRUG MANUFACTURERS.
These rules are applicable to drug manufacturers located within the state of Idaho. Non-resident manufacturers engaged in wholesale drug distribution in or into Idaho must comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. ( )

01. Standards. A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements. ( )

02. Records. A manufacturer must adopt policies and procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. ( )

053. -- 999. (RESERVED)