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 - General Provisions - Proposed Rule (Docket No. 27-0101-1801);

IDAPA 27.01.03 - Rules Governing Pharmacy Practice - Proposed Rule (Docket No. 27-0103-1801);

IDAPA 27.01.04 - Rules Governing Pharmacist Prescriptive Authority - Proposed Rule (Docket No. 27-0104-1802).

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 12/03/2018. 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 01/02/2019.

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 334-4854, or send a written request to the address on the memorandum attached below.



Legislative Services Office Idaho State Legislature

Eric Milstead Director Serving klaho's Citizen Legislature

MEMORANDUM

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

& Welfare Committee

FROM: Principal Legislative Drafting Attorney - Elizabeth Bowen

DATE: November 13, 2018

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - General Provisions - Proposed Rule (Docket No. 27-0101-1801)

IDAPA 27.01.03 - Rules Governing Pharmacy Practice - Proposed Rule (Docket No. 27-0103-1801)

IDAPA 27.01.04 - Rules Governing Pharmacist Prescriptive Authority - Proposed Rule (Docket No. 27-0104-1802)

Summary and Stated Reasons for the Rule

Docket No. 27-0101-1801: In another proposed rule, Docket No. 27-0106-1801, the Board of Pharmacy is repealing a chapter of rules as part of an ongoing effort to minimize regulation. In this proposed rule, the Board is adding language from the repealed chapter that is necessary to retain, including a definition of "DME Outlet." A definition for an examination that will no longer be required for licensure is being eliminated, and technical corrections are made as well.

Docket No. 27-0103-1801: This rule changes existing language to conform to HB 339 and HB 351, enacted by the 2018 Legislature. Specifically, language on authorized drug substitutions is added, while obsolete or unnecessary language regarding drug outlets is removed. Additionally, several technical corrections are made, and some language that is being repealed under Docket No. 27-0106-1801 is being added in this rule.

Docket No. 27-0104-1802: This rule allows a pharmacist to prescribe certain approved medications for allergic rhinitis, mild acne, and mild cough. Additionally, the rule allows pharmacists to prescribe agents for catheter occlusion and emergency kit drugs (methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline) to supplement drug orders for drugs intended to be administered by infusion. The purpose of this rule is to conform to the provisions of HB 191 (2017) and to make a temporary rule permanent.

Negotiated Rulemaking / Fiscal Impact

Negotiated rulemaking was conducted for all three rules, and none of the rules is expected to have a negative fiscal impact on the state general fund.

Statutory Authority

I.C. 54-1717.

Kristin Ford, Manager Research & Legislation Paul Headlee, Manager Budget & Policy Analysis April Renfro, Manager Legislative Audits Glenn Harris, Manager Information Technology

ce: Board of Pharmacy Alex Adams, PharmD, MPH

*** PLEASE NOTE ***

Per the Idaho Constitution, all administrative rules must be reviewed by the Legislature during the next legislative session. The Legislature has 3 options with this rulemaking docket: 1) Approve the docket in its entirety; 2) Reject the docket in its entirety; or 3) Reject the docket in part.

IDAPA 27 – BOARD OF PHARMACY

27.01.01 – GENERAL PROVISIONS DOCKET NO. 27-0101-1801

NOTICE OF RULEMAKING - PROPOSED RULE

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

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

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

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

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

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

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

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

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

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018 Idaho Administrative Bulletin, **Vol. 18-7**, pages 154-155.

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

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

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

Dated this 30th day of August, 2018.

Alex J. Adams, Pharm D, MPH Executive Director Board of Pharmacy 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. 27-0101-1801 (Only Those Sections With Amendments Are Shown.)

010. DEFINITIONS AND ABBREVIATIONS (A – D).

The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms shall have the meanings set forth below:

(7-1-18)

- **01.** ACCME. Accreditation Council for Continuing Medical Education. (7-1-18)
- **02.** Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (7-1-18)
 - **03.** ACPE. Accreditation Council for Pharmacy Education. (7-1-18)
- **04. ADS Automated Dispensing and Storage**. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (7-1-18)
- **O5. Biological Product**. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (7-1-18)
- **06. Biosimilar**. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (7-1-18)
- **07. CDC**. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (7-1-18)
- **08. Change of Ownership**. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (7-1-18)
- **09. CLIA-Waived Test.** A test that is waived under the federal Clinical Laboratory Improvement Amendments (CLIA) of 1988. (7-1-18)
- **10.** Clinical Guidelines. Recommendations from a reputable organization that are evidence-based and intended to optimize patient care in specific clinical circumstances. (7-1-18)

11. CME. Continuing medical education.

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

(7-1-18)

- Community Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (7-1-18)
- Continuous Quality Improvement Program. A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (7-1-18)
 - 16. **CPE**. Continuing pharmacy education.

(7-1-18)

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

(7-1-18)

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

(7-1-18)

- DME Outlet. A registered outlet that may hold for sale at retail DME and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection.
- Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (7-1-18)
 - 2<mark>23</mark>. **Drug Product Substitution**. Dispensing a drug product other than prescribed. (7-1-18)
- 234. **DTM** – **Drug Therapy Management**. Selecting, initiating, or modifying drug treatment pursuant to a collaborative pharmacy practice agreement or statewide protocol agreement. (7-1-18)
- **DEFINITIONS AND ABBREVIATIONS (E N).**

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

- Emergency Drugs. Drugs necessary to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (7-1-18)
- Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (7-1-18)
 - FDA. United States Food and Drug Administration. (7-1-18)03.
 - Flavoring Agent. An additive in food or drugs when used in accordance with the principles of 04.

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

- **05. Floor Stock.** Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (7-1-18)
 - **06. FPGEC.** Foreign Pharmacy Graduate Examination Committee. (7-1-18)
- **07. Hazardous Drug**. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: (7-1-18)
 - a. Carcinogenicity; (7-1-18)
 - **b.** Teratogenicity or developmental toxicity; (7-1-18)
 - c. Reproductive toxicity in humans; (7-1-18)
 - **d.** Organ toxicity at low doses in humans or animals; (7-1-18)
 - e. Genotoxicity; or (7-1-18)
 - **f.** New drugs that mimic existing hazardous drugs in structure or toxicity. (7-1-18)
 - **08. HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (7-1-18)
- **09. Idaho State Board of Pharmacy or Idaho Board of Pharmacy**. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (7-1-18)
 - **10. Institutional Pharmacy**. A pharmacy located in an institutional facility. (7-1-18)
- 11. Interchangeable Biosimilar. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (7-1-18)
- 12. Limited Service Outlet. Limited service outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, durable medical equipment outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, mobile pharmacies, and analytical or research laboratories.
- **13. Maintenance Drug**. A drug intended for the treatment of a health condition or disease that is persistent or otherwise expected to be long lasting in its effects. (7-1-18)
- 14. Medication Synchronization Program. An opt-in program provided by a pharmacy for aligning the refill dates of a patient's prescription drugs so that drugs that are refilled at the same frequency may be refilled concurrently.

 (7-1-18)
 - 15. MPJE. Multistate Pharmacy Jurisprudence Exam. (7-1-18)
 - 16. NABP. National Association of Boards of Pharmacy. (7-1-18)
 - 176. NAPLEX. North American Pharmacists Licensure Examination. (7-1-18)
 - **187. NDC**. National Drug Code. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

020. PRACTICE OF PHARMACY: GENERAL APPROACH.

To evaluate whether a specific act is within the scope of pharmacy practice in or into Idaho, a licensee or registrant of the Board must independently determine whether:

(7-1-18)

- **01. Express Prohibition.** The act is expressly prohibited by: (7-1-18)
- a. The Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code; (7-1-18)
- **b.** The Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; (7-1-18)
- c. The rules of the Idaho State Board of Pharmacy; or (7-1-18)
- **d.** Any other applicable state or federal laws, rules or regulations. (7-1-18)
- **O2.** Education and Training and Experience. The act is consistent with licensee or registrant's education, training or practice and 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. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

023. UNPROFESSIONAL CONDUCT.

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

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

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

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

 (7-1-18)
- **04. Diversion of Drug Products and Devices**. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (7-1-18)
- **05.** Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (7-1-18)
- **06. Prescription Drug Order Noncompliance.** Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules.

(7-1-18)

- **07. Failure to Confer.** Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (7-1-18)
- **08.** Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (7-1-18)
- **09. Failure to Counsel or Offer Counseling.** Failing to counsel or offer counseling, unless specifically exempted or refused. (7-1-18)
- 10. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock.

 (7-1-18)
- 11. Prescriber Incentives. Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (7-1-18)
- 12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare.

 (7-1-18)
- 13. Failure to Report. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (7-1-18)
 - **14. Failure to Follow Board Order**. Failure to follow an order of the Board. (7-1-18)
- 15. Use of False Information. Knowingly using false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (7-1-18)
- 16. Standard of Care. Providing health care services Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting.

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

IDAPA 27 – BOARD OF PHARMACY

27.01.03 – RULES GOVERNING PHARMACY PRACTICE DOCKET NO. 27-0103-1801 NOTICE OF RULEMAKING – PROPOSED RULE

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

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

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

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

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

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

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

With the proposed repeal of IDAPA 27.01.06, "Rules Governing Durable Medical Equipment (DME), Manufacturing, and Distribution," updates are needed in this chapter to retain critical rules from that chapter. This docket also makes changes in accordance with House Bills 339 and 351, which passed the 2018 Idaho Legislature unanimously. Lastly, this docket makes several technical corrections and other changes to better align with federal law and existing practice.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules – Negotiated Rulemaking was published in the July 4, 2018 Idaho Administrative Bulletin, **Vol. 18-7**, pages 158-159.

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

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

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

Dated this 30th day of August 2018.

Alex J. Adams, Pharm D, MPH Executive Director Board of Pharmacy 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. 27-0103-1801 (Only Those Sections With Amendments Are Shown.)

200. PIC: RESPONSIBILITIES AND LIMITATIONS.

- 91. 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:

 (7-1-18)
 - **a.** Any drug outlet that dispenses drugs to patients in Idaho; (7-1-18)
 - b. Any central drug outlet; and (7 1-18
 - e. Any outsourcing facility. (7-1-18)
- **92. 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. (7-1-18)
- 93. PIC Oversight Limitations. A person may neither be designated nor function as the PIC for more than two (2) drug outlets concurrently. (7 1-18)

2010. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS: MINIMUM FACILITY STANDARDS.

- **91. 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. (7-1-18)
- **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. (7-1-18)
- **03.** Equipment and Storage. 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.

 (7-1-18)(_____)

- **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. (7-1-18)
- **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. (7-1-18)
 - 07. Authorized Access to the Restricted Drug Storage Area.
- Access to the restricted drug storage area ean occur only when a pharmacist or prescriber is on duty.

 (7-1-18)
- e. An institutional facility may also develop an emergency drug access protocol in which a nonpharmacist 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.

2021. 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: (7-1-18)

- **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. (7-1-18)
- **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. (7-1-18)
- **03. Labeling.** Each drug must bear a complete and accurate label as set forth in Subchapter D of these rules. (7-1-18)
- **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. (7-1-18)
- **05. Patient Counseling.** Counseling, as defined in Section 54-1705, Idaho Code, must be provided as set forth in Section 54-1739, Idaho Code. (7-1-18)

2032. 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: (7-1-18)

- **O1. 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. (7-1-18)
- **O2. 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. (7-1-18)
- **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. (7-1-18)

2043. 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:

(7-1-18)

01. Security and Access.

- (7-1-18)
- **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. (7-1-18)
- **b.** Proper identification controls of individuals accessing the restricted drug storage area must be utilized and access must be limited, authorized, and regularly monitored. (7-1-18)
- **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. (7-1-18)
- **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. (7-1-18)

04. Controlled Substances Inventories.

- (7-1-18)
- a. A perpetual inventory must be kept for all Schedule II controlled substances; and (7-1-18)
- **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. (7-1-18)
- **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. (7-1-18)

06. Emergency Situations.

- (7-1-18)
- **a.** A pharmacist or prescriber must be capable of being on site at the drug outlet within twelve (12) hours if an emergency arises. (7-1-18)
- **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. (7-1-18)
- **O7. 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.

 (7-1-18)
 - **08. Exemption for Veterinarians.** Veterinarians practicing in accordance with their Idaho practice act

are exempt from this rule.

(7-1-18)

2054. 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:

(7-1-18)

- **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. (7-1-18)
- **O2. 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. (7-1-18)
- **03. Secure Storage**. The area is appropriately equipped to ensure security and protection from diversion or tampering. (7-1-18)
- **04. Controlled Substances**. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. (7-1-18)
- **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. (7-1-18)

2065. – 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. (7-1-18)

- **01. Invalid Prescription Drug Orders.** A prescription drug order is invalid if not issued: (7-1-18)
- **a.** In good faith; (7-1-18)
- **b.** For a legitimate medical purpose; (7-1-18)
- **c.** By a licensed prescriber; (7-1-18)
- **d.** Within the course and scope of the prescriber's professional practice and prescriptive authority; (7-1-18)
- e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; or (7-1-18)
- **f.** In the form and including the elements specified in this Subchapter D. (7-1-18)
- **02.** Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. (7-1-18)
- **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. (7-1-18)
- **04. Prescriber Self-Use**. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (7-1-18)

- 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. (7-1-18)
 - **065. Expiration.** A prescription drug order is invalid after its expiration date as follows: (7-1-18)
- **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. (7-1-18)
- **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. (7-1-18)
- e. 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. (7-1-18)
- 076. Prescriber Change of Status Digital Image Prescriptions. 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 A digital image of a prescription drug order is invalid if it is for a controlled substance or if the patient intends to pay cash for the drug in whole.

(BREAK IN CONTINUITY OF SECTIONS)

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: (7-1-18)

- **01. Patient's Name**. The patient's or authorized entity's name and: (7-1-18)
- **a.** If for a controlled substance, the patient's full name and address; and (7-1-18)
- **b.** If for an animal, the species. (7-1-18)
- **02. Date**. The date issued. (7-1-18)
- **O3. Drug Information**. The drug name, strength, quantity and, if for a controlled substance, the dosage form.
 - **04. Directions.** The directions for use. (7-1-18)
- **05. Prescriber Information**. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (7-1-18)
- 06. Signature. If paper, the pre-printed, stamped or hand printed name and written Δ signature sufficient to evidence a valid prescription of either the prescriber or, if statutorily allowed, a renewal of a previous prescription, the prescriber's agent's signature and, if electronic, when authorized by 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. (7-1-18)
- **O8.** Exemptions for Non-Controlled Substances. A prescriber may omit the required drug information and directions if the prescriber makes a clear indication that the pharmacist is to finalize the patient's drug therapy plan.

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

 (7-1-18)
- that Aa 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. (7-1-18)

- **01.** Change Quantity. A pharmacist may change the quantity of medication prescribed if: (7-1-18)
- a. The prescribed quantity or package size is not commercially available; or (7.1.18)(
- b. The change in quantity is related to a change in dosage form.: (7-1-18)(
- <u>c.</u> The change is intended to dispense up to the total amount authorized by the prescriber including refills; or
- <u>d.</u> The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.
- **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. (7-1-18)
- **03. Complete Missing Information**. A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change. (7-1-18)
- 94. 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. (7-1-18)
- **054. Documentation**. A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record. (7-1-18)
- **305.** FILLING PRESCRIPTION DRUG ORDERS: DRUG PRODUCT SUBSTITUTION.
 Drug product substitutions are allowed only as follows: (7-1-18)
- **01. Hospital**. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (7-1-18)
- **02.** Skilled Nursing Institutional Facility. At the direction of the quality assessment and assurance committee of an skilled nursing institutional facility; (7-1-18)(______)

| | | Drug Shortage. Upon a drug shortage, a pharmacist may exercise professional judgment, without rescriber, and may substitute an alternative dose of a prescribed drug, so long as the prescriber of modified, to equate to an equivalent amount of drug dispensed as prescribed; or (7-1-18) | | | |
|-----------------------------------|-----------------------------|--|--|--|--|
| biologic | 04. cal produc | Biosimilars . A pharmacist may substitute an interchangeable biosimilar product for a prescribed tif: (7-1-18) | | | |
| Book; | a. | The biosimilar has been determined by the FDA to be interchangeable and published in the Purple (7-1-18) | | | |
| dispense | b. ed; and | The prescriber does not indicate by any means that the prescribed biological product must be (7-1-18) | | | |
| medical | c. record. | The name of the drug and the manufacturer or the NDC number is documented in the patien (7-1-18) | | | |
| with and | 05. other drug | Prescriber-Authorized Substitution. A prescriber may authorize a pharmacist to substitute a drug in the same therapeutic class provided the following conditions are met: | | | |
| substitu | <u>a.</u> tion allov | The prescriber has clearly indicated that substitution is permissible by indicating "therapeutic ved" or a similar designation; | | | |
| plan, or. | b. in the ca | The substitution is intended to ensure formulary compliance with the patient's health insurance se of a patient without insurance, to lower the cost to the patient while maintaining safety; | | | |
| differen | <u>c.</u> ces in the | The patient opts-in to the substitution, and the pharmacist clearly informs the patient of the drug products and specifies that the patient may refuse the substitution; and | | | |
| | <u>d.</u> | If a substitution is made: | | | |
| as is pre | <u>i.</u> escribed; a | The prescriber's directions are also modified to equate to an equivalent amount of drug dispensed and | | | |
| days of | <u>ii.</u> dispensin | The pharmacist notifies the patient's original prescriber of the substitution within five (5) business the prescription. | | | |
| drugs. | <u>e.</u> | Prescriber-authorized substitution does not apply to biological products or narrow therapeutic index | | | |
| (BREAK IN CONTINUITY OF SECTIONS) | | | | | |
| 313. | PRESC | RIPTION DELIVERY: RESTRICTIONS. | | | |
| | | Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled the following in accordance with federal law, as long as appropriate measures are taken to ensure and safety. (7-1-18)(| | | |
| - convale | a. scing, the | To the patient or the patient's residence, the institutional facility in which the patient is correctional facility in which a patient is housed; (7-1-18) | | | |
| | b. | To the patient's licensed or registered healthcare provider, as follows: (7-1-18) | | | |
| | i. | If the drug is not a controlled substance; or (7-1-18) | | | |
| | ii. | If the drug is a controlled substance that is intended for direct administration by the prescriber of | | | |

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prescriber's delegate. (7-1-18)

e. To another licensed drug outlet.

(7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

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

400. RECORDKEEPING: MAINTENANCE AND INVENTORY REQUIREMENTS.

- **O1.** 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.

 (7-1-18)
- **02. Prescription Retention**. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained as follows: (7-1-18)
- **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. (7-1-18)
- **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. (7-1-18)
- 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. (7-1-18)
- **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:

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

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| invento | ry of the | substance on hand, and thereafter, include the substance in each inventory. | (7-1-18) | | | |
|--|--|--|--|--|--|--|
| | | Drugs Stored Outside a Drug Outlet. In addition to the annual inventory requirements, druutlet in accordance with these rules must be regularly inventoried and inspected to ensure red, secured, and accounted for. | | | | |
| | <u>€d</u> . | Closing of Pharmacy. A closing inventory must be conducted and retained. | (7-1-18) | | | |
| that the | registra | Rebuttal Presumption of Violation . Evidence of an amount of a controlled substance the reflected on a record or inventory required by state or federal law creates a rebuttable present has failed to keep records or maintain inventories in conformance with the recordkeep ements of state and federal law. | sumption | | | |
| | | Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distributories and records or transactions pertaining to the receipt and distribution or other disponce with federal law. The records must include at least: | | | | |
| address | a. of the lo | The source of the drugs, including the name and principal address of the seller or transferor cation from which the drugs were shipped; | r, and the | | | |
| | <u>b.</u> | The identity and quantity of the drugs received and distributed or disposed of: | () | | | |
| | <u>c.</u> | The dates of receipt and distribution or other disposition of the drugs; and | () | | | |
| <u>law.</u> | <u>d.</u> | Controlled substance distribution invoices, in the form and including the requirements of | of federal () | | | |
| law. | 0 <u>56</u> . | Central Records Storage. Records may be retained at a central location in compliance with | th federal (7-1-18) | | | |
| 067. 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. (7-1-18) | | | | | | |
| (BREAK IN CONTINUITY OF SECTIONS) | | | | | | |
| 402. | REPOI | RTING REQUIREMENTS. | | | | |
| designa | 01. tion with | PIC Change. Both an outgoing and incoming PIC must report to the Board a change in ten (10) days of the change. | in a PIC (7-1-18) | | | |
| reported | 0<mark>21</mark>. d to the D | Theft or Loss of Controlled Substances. A registrant must report to the Board on the specific at the specific to the Board on the specific at the specific to the Board on the specific at the specific to the Board on the specific to the Board on the specific at the specific to the Board on the specific to the specific to the Board on the specific to the specific to the Board on the specific to the specific to the Board on the specific to the Board on the specific to the specific to the Board on the specif | same day ıl law. (7-1-18) | | | |
| or with | 0 <mark>32</mark> . the initia | Individual Information Changes . Changes in employment or changes to information prol or renewal application must be reported to the Board within ten (10) days of the change. | | | | |
| any adu | 043. | Reporting Adulteration or Misappropriation . A licensee or registrant must report to the or misappropriation of a controlled drug in accordance with Section 37-117A. Idaho Code. | | | | |
| distribu | 04. ted at lea | <u>Drug Distributor Monthly Reports</u> . An authorized distributor must report specified data set monthly to the Board in a form and manner prescribed by the Board. | on drugs | | | |

IDAPA 27 – BOARD OF PHARMACY

27.01.04 - RULES GOVERNING PHARMACIST PRESCRIPTIVE AUTHORITY **DOCKET NO. 27-0104-1802**

NOTICE OF RULEMAKING - PROPOSED RULE

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

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

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

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

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

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

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

This docket further implements House Bill 191, which passed the Idaho Legislature in 2017. In addition, during the 2018 rules review, members of the legislature suggested an edit to one of the rules as drafted, and this change was made via temporary rule and published in the June 2018 Administrative Bulletin. This docket would make the temporary rule permanent.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the July 4, 2018, Idaho Administrative Bulletin, Vol. 18-7, pages 160-161.

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

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

Dated this 30th day of August 2018.

Alex J. Adams, Pharm D, MPH Executive Director Board of Pharmacy 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. 27-0104-1802 (Only Those Sections With Amendments Are Shown.)

021. PHARMACIST PRESCRIBING FOR MINOR CONDITIONS.

A pharmacist may prescribe any drug approved by the FDA, unless otherwise specified, that is indicated for the following conditions:

(7 1 18)(_____)

| 01. | Lice; | (7-1-18) |
|------------|---|------------------------|
| 02. | Cold Sores; | (7-1-18) |
| 03. | Motion Sickness Prevention; and | (7 1 18) () |
| 04. | Uncomplicated Urinary Tract Infections: | (7-1-18) () |
| <u>05.</u> | Allergic Rhinitis. Prescribing is limited to intranasal drugs only; | () |
| <u>06.</u> | Mild Acne. Prescribing is limited to topical drugs only; and | () |
| <u>07.</u> | Mild Cough. Only benzonatate may be prescribed for cough suppression. | <u>()</u> |

(BREAK IN CONTINUITY OF SECTIONS)

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:

(7-1-18)

- 01. Statins. Statins, for patients who have a current prescription for a drug for been diagnosed with diabetes; and (7-1-18)(_____)
- **O2. 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. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

BOARD OF PHARMACY Rules Governing Pharmacist Prescriptive Authority

Docket No. 27-0104-1802 Proposed Rulemaking

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; (7-1-18)

- **01. Flush**. Heparin, in concentrations of one hundred (100) units per milliliter or less, and saline; (7-1-18)
- **02. Devices**. Infusion pumps and other rate control devices; (7-1-18)
- **03.** Supplies. Tubing, filters, catheters, intravenous (IV) start kits, central line dressing kits, and injection caps; and
 - 04. Local Anesthetics for IV Port Access: (7-1-18)(
 - <u>05.</u> <u>Catheter Occlusion</u>. Agents for catheter occlusion; and
- <u>06.</u> normal saline. <u>Emergency Kit Drugs.</u> Methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and (_____)