IDAPA 27 – BOARD OF PHARMACY

27.01.03 – RULES GOVERNING PHARMACY PRACTICE

DOCKET NO. 27-0103-1802

NOTICE OF RULEMAKING – ADOPTION OF TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is September 28, 2018.

AUTHORITY: In compliance with Sections 67-5226, Idaho Code, notice is hereby given this agency has adopted a temporary rule. The action is authorized pursuant to Sections 37-2702 and 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule:

On June 25, 2018, The U.S. Food and Drug Administration (FDA) approved Epidiolex (cannabidiol – CBD) oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy. On September 27, 2018, the U.S. Drug Enforcement Administration (DEA) made a scheduling determination that removes this specific drug product from Schedule I of the Controlled Substances Act and places it in Schedule V. This temporary rule ensures conformity between federal law and Idaho law. As a result, Epidiolex can be prescribed and dispensed to patients in accordance with the other provisions of the Controlled Substances Act.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons:

Per Section 37-2702, Idaho Code, if any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the board, the board shall similarly control the substance under this act by promulgating a temporary rule or proposing a statutory amendment, or both, within thirty (30) days from publication in the federal register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that thirty (30) day period, the board objects to inclusion, rescheduling, or deletion.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

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

Dated this 27th day of September, 2018.

Alex J. Adams, Pharm D, MPH
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
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THE FOLLOWING IS THE TEXT OF THE TEMPORARY RULE FOR DOCKET NO. 27-0103-1802
(Only Those Sections With Amendments Are Shown.)

316. CONTROLLED SUBSTANCES: TEMPORARY SCHEDULING.
Cannabidiol in a drug product approved by the FDA, specifically derived from cannabis and containing no more than one tenth percent (0.1%) tetrahydrocannabinols, is removed from Schedule I, under Article II, Title 37, Chapter 27, Idaho Code, and placed in Schedule V, under Article II, Title 37, Chapter 27, Idaho Code. (9-28-18)T

317. – 399. (RESERVED).

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
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1801
(Only Those Sections With Amendments Are Shown.)

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

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

02. **Accredited School or College of Pharmacy**. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (7-1-18)

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

04. **ADS – Automated Dispensing and Storage**. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (7-1-18)

05. **Biological Product**. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (7-1-18)

06. **Biosimilar**. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (7-1-18)

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

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

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

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

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

12. **Collaborative Pharmacy Practice**. A pharmacy practice whereby one (1) or more pharmacists or pharmacies jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (7-1-18)

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

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

15. **Continuous Quality Improvement Program**. A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (7-1-18)

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

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

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

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

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

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

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

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

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

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

01. **Emergency Drugs**. Drugs necessary to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (7-1-18)

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

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

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

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

05. Floor Stock. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (7-1-18)

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

07. Hazardous Drug. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: (7-1-18)

a. Carcinogenicity; (7-1-18)

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

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

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

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

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

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

09. Idaho State Board of Pharmacy or Idaho Board of Pharmacy. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (7-1-18)

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

11. Interchangeable Biosimilar. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (7-1-18)

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

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

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

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

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

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

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

(BREAK IN CONTINUITY OF SECTIONS)

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

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

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

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

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

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

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

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

(BREAK IN CONTINUITY OF SECTIONS)

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

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

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

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

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

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

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

(7-1-18)

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

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

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

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

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

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

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

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

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

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

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

IDAPA 27 – BOARD OF PHARMACY

27.01.02 – RULES GOVERNING LICENSURE AND REGISTRATION

DOCKET NO. 27-0102-1802 (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 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 the chapter related to pharmaceutical manufacturer registration. The rules also eliminate the Multistate Pharmacy Jurisprudence Exam (MPJE) as a precondition to pharmacist licensure, a change that is consistent with nearly every other Idaho health profession. Additional technical corrections are made.

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

This fee is being imposed pursuant to Section 54-1720, Idaho Code. The fee for a nonresident pharmacist registration is being increased from $250 to $290. The Board eliminated the requirement for pharmacists to obtain a controlled substances registration as of July 1, 2018. This proposed rule adjusts the nonresident pharmacist registration to $290. Nonresident pharmacists who previously held both the pharmacist registration and a separate controlled substance registration will still realize a net savings of $20 per year.

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 156-157**.

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
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Boise, ID 83720-0067
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0102-1802
(Only Those Sections With Amendments Are Shown.)

023. FEE SCHEDULE.

01. Licenses and Registrations -- Professionals.

License/Registration	Initial Fee	Annual Renewal Fee
Pharmacist License	$140	$130
Nonresident ~~*Pharmacist*~~ PIC Registration	$2~~5~~90	$2~~5~~90
Pharmacist Intern	$50	$50
Technician	$35	$35
Practitioner Controlled Substance Registration	$60	$60

~~(7-1-18)~~( )

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

License/Registration	Initial Fee	Annual Renewal Fee
Durable Medical Equipment Outlet	$50	$50
Outsourcing Facility (Nonresident)	$500	$250
Manufacturer	$150	$150
Veterinary Drug Outlet	$35	$35

(7-1-18)

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

(7-1-18)

04. Administrative Services.

Category	Fee
Experiential hours certification	$25
Duplicate pharmacist certificate of licensure	$35

(7-1-18)

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. (7-1-18)

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:(7-1-18)

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. (7-1-18)

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

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. (7-1-18)

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. (7-1-18)

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. (7-1-18)

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. (7-1-18)

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 NAPLEX attempts ~~*to pass each exam*~~.
~~*(7-1-18)*~~( )

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. (7-1-18)

01. Transfer Application. The applicant must submit a preliminary application for licensure transfer through NABP. (7-1-18)

~~***02. MPJE**. The applicant must pass the Idaho-based MPJE within five (5) total attempts.* *(7-1-18)***~~

0~~3~~2. **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. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

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. (7-1-18)

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. (7-1-18)

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

035. NONRESIDENT ~~*PHARMACIST*~~ PIC REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered ~~*to practice pharmacy into Idaho*~~ as a nonresident PIC, an applicant must submit an application on a Board form including, but not limited to: ~~*(7-1-18)*~~( )

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (7-1-18)

02. Facility License Information. The license or registration number of the facility for which the applicant will be practicing. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

080. MANUFACTURER REGISTRATION.

01. Resident Manufacturers. A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing. ( )

02. Nonresident Manufacturers. Non-resident manufacturers must be registered as follows: ( )

a. Those 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. ~~(7-1-18)~~( )

b. Those engaged in wholesale distribution must be registered as a manufacturer and comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. ( )

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.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0103-1801
(Only Those Sections With Amendments Are Shown.)

~~***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: (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)*~~

~~***c.** Any outsourcing facility. (7-1-18)*~~

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

~~***03. 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)*~~

20~~1~~0. 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: ~~*(7-1-18)*~~( )

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. (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)

05. Controlled Substances Storage. ~~*Controlled substances*~~ Drug outlets that dispense prescription drugs must ~~*be*~~ store~~*d*~~ controlled substances 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. ~~*(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. ~~*(7-1-18)*~~

~~***a.***~~ Access to the restricted drug storage area ~~*can occur only when a pharmacist or prescriber is on duty.*~~ ~~*(7-1-18)*~~

~~***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*~~ authorized 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*~~. ~~*(7-1-18)*~~( )

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

20~~2~~1. 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)

20~~3~~2. 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)

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. (7-1-18)

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. (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)

20~~4~~3. 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)

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. (7-1-18)

08. Exemption for Veterinarians. Veterinarians practicing in accordance with their Idaho practice act

are exempt from this rule. (7-1-18)

20~~5~~4. 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)

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. (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)

20~~6~~5. – 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)~~

0~~6~~5. **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)

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

0~~7~~6. ~~*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. ~~(7-1-18)~~( )

(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)

03. Drug Information. The drug name, strength, quantity and, if for a controlled substance, the dosage form. (7-1-18)

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*~~ A 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*~~. ~~(7-1-18)~~( )

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)

08. 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)*~~

~~***b.***~~ that ~~*A*~~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. ~~*(7-1-18)*~~( )

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)*~~( )

c. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or ( )

d. 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)

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

0~~5~~4. **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)*~~( )

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 (7-1-18)

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (7-1-18)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (7-1-18)

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and (7-1-18)

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (7-1-18)

05. Prescriber-Authorized Substitution. A prescriber may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class provided the following conditions are met: ( )

a. The prescriber has clearly indicated that substitution is permissible by indicating "therapeutic substitution allowed" or a similar designation; ( )

b. The substitution is intended to ensure formulary compliance with the patient's health insurance plan, or, in the case of a patient without insurance, to lower the cost to the patient while maintaining safety; ( )

c. The patient opts-in to the substitution, and the pharmacist clearly informs the patient of the differences in the drug products and specifies that the patient may refuse the substitution; and ( )

d. If a substitution is made: ( )

i. The prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as is prescribed; and ( )

ii. The pharmacist notifies the patient's original prescriber of the substitution within five (5) business days of dispensing the prescription. ( )

e. Prescriber-authorized substitution does not apply to biological products or narrow therapeutic index drugs. ( )

(BREAK IN CONTINUITY OF SECTIONS)

313. PRESCRIPTION DELIVERY: RESTRICTIONS.

01. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions *to the following* in accordance with federal law, as long as appropriate measures are taken to ensure product integrity: and safety. *(7-1-18)*( )

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; (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 or

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

~~***c.*** *To another licensed drug outlet.*~~ ~~*(7-1-18)*~~

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*~~. ~~*(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.

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. (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)*~~

~~***c***~~**b.** 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. (7-1-18)

~~d~~**c.** 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. (7-1-18)

~~e~~**d.** Closing of Pharmacy. A closing inventory must be conducted and retained. (7-1-18)

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. (7-1-18)

05. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law. 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; ( )

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

d. Controlled substance distribution invoices, in the form and including the requirements of federal law. ( )

0~~5~~**6. Central Records Storage**. Records may be retained at a central location in compliance with federal law. (7-1-18)

0~~6~~**7. 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. 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.* *(7-1-18)*~~

0~~1~~**1. 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. (7-1-18)

0~~2~~**2. 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. (7-1-18)

0~~3~~**3. 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. (7-1-18)

04. Drug Distributor Monthly Reports. An authorized distributor must report specified data on drugs distributed at least monthly to the Board in a form and manner prescribed by the Board. ( )

IDAPA 27 – BOARD OF PHARMACY

27.01.03 – RULES GOVERNING PHARMACY PRACTICE

DOCKET NO. 27-0103-1802

NOTICE OF RULEMAKING – ADOPTION OF TEMPORARY RULE

EFFECTIVE DATE: The effective date of the temporary rule is September 28, 2018.

AUTHORITY: In compliance with Sections 67-5226, Idaho Code, notice is hereby given this agency has adopted a temporary rule. The action is authorized pursuant to Sections 37-2702 and 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is the required finding and concise statement of its supporting reasons for adopting a temporary rule:

On June 25, 2018, The U.S. Food and Drug Administration (FDA) approved Epidiolex (cannabidiol – CBD) oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy. On September 27, 2018, the U.S. Drug Enforcement Administration (DEA) made a scheduling determination that removes this specific drug product from Schedule I of the Controlled Substances Act and places it in Schedule V. This temporary rule ensures conformity between federal law and Idaho law. As a result, Epidiolex can be prescribed and dispensed to patients in accordance with the other provisions of the Controlled Substances Act.

TEMPORARY RULE JUSTIFICATION: Pursuant to Section 67-5226(1)(b), Idaho Code, the Governor has found that temporary adoption of the rule is appropriate for the following reasons:

Per Section 37-2702, Idaho Code, if any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the board, the board shall similarly control the substance under this act by promulgating a temporary rule or proposing a statutory amendment, or both, within thirty (30) days from publication in the federal register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that thirty (30) day period, the board objects to inclusion, rescheduling, or deletion.

FEE SUMMARY: Pursuant to Section 67-5226(2), the Governor has found that the fee or charge being imposed or increased is justified and necessary to avoid immediate danger and the fee is described herein: N/A

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

Dated this 27th day of September, 2018.

Alex J. Adams, Pharm D, MPH
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
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THE FOLLOWING IS THE TEXT OF THE TEMPORARY RULE FOR DOCKET NO. 27-0103-1802
(Only Those Sections With Amendments Are Shown.)

316. CONTROLLED SUBSTANCES: TEMPORARY SCHEDULING.
Cannabidiol in a drug product approved by the FDA, specifically derived from cannabis and containing no more than one tenth percent (0.1%) tetrahydrocannabinols, is removed from Schedule I, under Article II, Title 37, Chapter 27, Idaho Code, and placed in Schedule V, under Article II, Title 37, Chapter 27, Idaho Code. (9-28-18)T

317. – 399. (RESERVED).

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 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
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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)~~( )

05. Allergic Rhinitis. Prescribing is limited to intranasal drugs only; ( )

06. Mild Acne. Prescribing is limited to topical drugs only; and ( )

07. Mild Cough. Only benzonatate may be prescribed for cough suppression. ( )

(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)~~( )

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. (7-1-18)

(BREAK IN CONTINUITY OF SECTIONS)

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*~~ ~~*(7-1-18)*~~( )

04. Local Anesthetics for IV Port Access~~.~~**;** ~~*(7-1-18)*~~( )

05. Catheter Occlusion. Agents for catheter occlusion; and ( )

06. Emergency Kit Drugs. Methylprednisolone, hydrocortisone, diphenhydramine, epinephrine, and normal saline. ( )

IDAPA 27 – BOARD OF PHARMACY

27.01.05 – RULES GOVERNING DRUG COMPOUNDING

DOCKET NO. 27-0105-1801

NOTICE OF RULEMAKING – PROPOSED RULE

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dated this 30th day of August 2018.

Alex J. Adams, Pharm D, MPH
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0105-1801
(Only Those Sections With Amendments Are Shown.)

101. STERILE PRODUCT PREPARATION.

01. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products, these rules apply to all persons, including any business entity, engaged in the practice of sterile compounding and sterile prepackaging in or into Idaho. (7-1-18)

02. Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug product must be sterilized when prepared in the following dosage forms: (7-1-18)

a. Aqueous bronchial and nasal inhalations, except sprays and irrigations intended to treat ~~*bronchial*~~ nasal mucosa only; ~~*(7-1-18)*~~( )

b. Baths and soaks for live organs and tissues; (7-1-18)

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (7-1-18)

d. Irrigations for wounds and body cavities; (7-1-18)

e. Ophthalmic drops and ointments; and (7-1-18)

f. Tissue implants. (7-1-18)

03. Compounder Responsibilities. Compounders and sterile prepackagers are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter; (7-1-18)

a. Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows; (7-1-18)

i. Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile products shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; (7-1-18)

ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (7-1-18)

iii. Opened single-dose ampules shall not be stored for any time period; and (7-1-18)

iv. Multiple-dose containers (for example, vials) that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer; (7-1-18)

b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial endotoxins; (7-1-18)

c. Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared. (7-1-18)

04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. (7-1-18)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated. (7-1-18)

b. Filters must be inspected and replaced in accordance with the manufacturer's recommendations. (7-1-18)

05. Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following: (7-1-18)

a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required; (7-1-18)

b. A sink ~~*with hot and cold water in close proximity to the hood*~~; ~~*(7-1-18)*~~( )

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; and (7-1-18)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet. (7-1-18)

06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: (7-1-18)

a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (7-1-18)

b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (7-1-18)

c. Audits appropriate for the risk of contamination for the particular sterile product including: (7-1-18)

i. Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing; (7-1-18)

ii. Periodic hand hygiene and garbing competency; (7-1-18)

iii. Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager; (7-1-18)

iv. Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including: (7-1-18)

(1) Total particle counts; (7-1-18)

(2) Viable air sampling; (7-1-18)

(3) ~~*Gloved fingertip sampling;*~~ ~~*(7-1-18)*~~

~~*(4)*~~ Surface sampling; (7-1-18)

v. Gloved fingertip sampling testing at least annually for personnel who compound low- and medium-risk level compounded sterile preparations and every six (6) months for personnel who compound high-risk level compounded sterile preparations. ( )

vi. Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, etc.) before dispensing or distributing; (7-1-18)

d. Temperature, logged daily; (7-1-18)

e. Beyond use date and accuracy testing, when appropriate; and (7-1-18)

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (7-1-18)

07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including: (7-1-18)

a. Antiseptic hand cleansing; (7-1-18)

b. Disinfection of non-sterile compounding surfaces; (7-1-18)

c. Selecting and appropriately donning protective garb; (7-1-18)

d. Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients; (7-1-18)

e. Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; (7-1-18)

f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product; and (7-1-18)

g. Inspecting for quality standards before dispensing or distributing. (7-1-18)

IDAPA 27 – BOARD OF PHARMACY

27.01.06 – RULES GOVERNING DME, MANUFACTURING, AND DISTRIBUTION

DOCKET NO. 27-0106-1801 (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 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:

The Board of Pharmacy intends to eliminate this chapter as described more fully in Rule Docket No. 27-0101-1801.

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 164-165**.

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
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IDAPA 27.01.06 IS BEING REPEALED IN ITS ENTIRETY