Dear Senators HEIDER, Nuxoll, Bock, and
Representatives WOOD, Perry, Rusche:

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

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - HB 017 (CPE) (Docket No. 27-0101-1207);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Compounding standards (Docket No. 27-0101-1301);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions (Docket No. 27-0101-1302).

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 10/09/2013. 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 11/07/2013.

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 334-4845, or send a written request to the address on the memorandum attached below.

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Jeff Youtz
Director

MEMORANDUM

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

FROM: Senior Legislative Research Analyst - Ryan Bush

DATE: September 20, 2013

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - HB 017 (CPE) (Docket No. 27-0101-1207)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Compounding standards (Docket No. 27-0101-1301)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions (Docket No. 27-0101-1302)

(1) 27.01.01 - Rules of the Idaho State Board of Pharmacy - HB 017 (CPE) (Docket No. 27-0101-1207)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - HB 017 (CPE). The Board states that this rulemaking brings 27.01.01 into conformity with House Bill 17 (2013). Specifically, this rulemaking accomplishes the following:

(1) Reduces the amount of Board-approved continuing pharmacy education (CPE) and provides more structure for such CPE;

(2) Requires more CPE that is accredited by the Accreditation Counsel for Pharmacy Education or Continuing Medical Education;

(3) Mandates one hour of CPE for all pharmacists engaged in the practice of sterile compounding;

(4) Clarifies that four ounces is the maximum allowable quantity of a CV scheduled controlled substance that can be dispensed by a pharmacist without prescription;

(5) Provides for information that must be included in an application to the Board for approval of a CPE program;

(5) Allows drugs to be stored and removed from a secured area adjacent to a pharmacy pursuant to security restrictions; and

(6) Clarifies that pharmacy structural security rules pertain to all pharmacies.

The Board states that negotiated rulemaking was conducted and Notices of Intent to Promulgate Rules were published in the December 2012, January, February, March, May, July and August issues of the Idaho Administrative Bulletin. The Board states that there will be a minimal positive fiscal impact in the form of saved personnel time.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(2) 27.01.01 - Rules of the Idaho State Board of Pharmacy - Compounding standards (Docket No. 27-0101-1301)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - Compounding standards. The Board states that this rulemaking establishes standards for the compounding of drugs in the following ways:

(1) Provides general compounding standards that regulate ingredients, prohibited acts, equipment, compromised drugs and hazardous drugs;

(2) Provides a scope of practice that regulates compounding of commercially available drugs, anticipatory compounding, compounding and distributing for office use, compounding for research and reconstitution exceptions; and

(3) Establishes drug compounding controls that regulate policies and procedures, compounding accuracy, certain records and labeling.

The Board further states that this rulemaking expands sterile product preparation rules by defining products that require sterilization, compounding responsibilities, environmental controls, equipment, sterile hazardous drugs, documentation requirements and policy and procedures. The FDA's Compliance Policy Guideline relating to compounding is incorporated by reference into these rules.

The Board states that negotiated rulemaking was conducted and Notices of Intent to Promulgate Rules were published in the December 2012, January, February, March, May, July and August issues of the Idaho Administrative Bulletin. The Board states that there will be a fiscal impact of approximately ten thousand dollars ($10,000) from its request for funding to send Board inspectors to sterile compounding training.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

(3) 27.01.01 - Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions (Docket No. 27-0101-1302)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 Rules of the Idaho State Board of Pharmacy - Acceptable ID for controlled substance prescriptions. The Board states that this rulemaking updates the list of acceptable forms of identification required to receive controlled substances prescriptions. These new forms of identification include a U.S. passport card (PASS Card) and Western Hemisphere Travel Initiative (WHTI) documents, including an Enhanced Driver's License or Nexus Air Card.

The Board states that negotiated rulemaking was not conducted because the rule is simple in nature. There is no fiscal impact associated with this rulemaking.

The proposed rule appears to be within the statutory authority granted to the Board in Section 54-1717, Idaho Code.

cc: Board of Pharmacy
Mark Johnston, R.Ph.

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1207

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 16, 2013.

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

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

These rules would create harmony with 2013's House Bill No. 017 and other sections of Idaho Code, reduce the amount of and place more structure around Board approved continuing pharmacy education (CPE) thus requiring more CPE that is accredited with the Accreditation Counsel for Pharmacy Education or Continuing Medical Education, which are the two national agencies recognized by the federal Department of Education for such activities, mandate one (1) hour of CPE for all pharmacists engaged in the practice of sterile compounding, clarify that four (4) ounces is the maximum allowable quantity of a CV scheduled controlled substance that can be dispensed by a pharmacist without prescription, allow drugs to be stored and removed from a secured area adjacent to a pharmacy pursuant to many restrictions, and clarify that pharmacy structural security rules pertain to all pharmacies.

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

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

Minimal positive impact in the form of saved personnel time approving continuing pharmacy education.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the December 5, 2012 Idaho Administrative Bulletin, **Vol. 12-12**, page 62; January 2, 2013 Idaho Administrative Bulletin, **Vol. 13-1**, page 182; February 6, 2013 Idaho Administrative Bulletin, **Vol. 13-2**, page 28; March 6, 2013 Idaho Administrative Bulletin, **Vol. 13-3**, page 13; May 1, 2013 Idaho Administrative Bulletin, **Vol. 13-5**, page 83; July 3, 2013 Idaho Administrative Bulletin, **Vol. 13-7**, page 79; and August 7, 2013 Idaho Administrative Bulletin, **Vol. 13-8**, page 293.

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 Mark Johnston, 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 23, 2013.

DATED this 30th day of August, 2013.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Telephone: (208) 334-2356
FAX: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1207

029. PHARMACIST LICENSE OR REGISTRATION.

01. Practice in Idaho. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws. (7-1-13)

02. Practice Into Idaho. Unless statutorily exempted, all pharmacists practicing pharmacy into the state of Idaho must be licensed or registered as follows: (7-1-13)

a. The following pharmacists must be licensed to provide centralized pharmacy services into Idaho: (7-1-13)

i. Pharmacists engaged in the independent practice of pharmacy across state lines as defined by the Pharmacist Independent Practice Rule. (7-1-13)

ii. Pharmacists practicing from a central drug outlet that is not a pharmacy. (7-1-13)

iii. Pharmacists practicing from a remote office location. ( )

b. The following pharmacists not licensed in Idaho must be registered to practice pharmacy into Idaho. (7-1-13)

i. The PIC or director of a nonresident central drug outlet or mail service pharmacy. (7-1-13)

ii. Pharmacists practicing from a pharmacy or its COE. (7-1-13)

(BREAK IN CONTINUITY OF SECTIONS)

035. PHARMACIST REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered to practice pharmacy into Idaho an applicant must submit an application in the manner and form prescribed by the Board including, but not limited to: (7-1-13)

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (7-1-13)

02. Facility License Information. The license or registration number of the facility ~~*from*~~ for which the applicant will be practicing. ~~*(7-1-13)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

050. CPE: PROGRAM CRITERIA.

01. Board Approval of CPE Programs. The Board recognizes CPE program accreditation by ACPE and CME. CPE programs not accredited by either ACPE or CME must be approved by the Board. ~~*Application for approval will require provision of the following information*~~ A sponsoring organization, presenter or continuing education coordinator may apply to the Board for accreditation of a CPE program. An application must be submitted twenty-one (21) days in advance of the program and must include: ~~*(3-21-12)*~~( )

a. The name of ~~*provider or sponsor*~~ the sponsoring organization, if applicable; ~~*(3-21-12)*~~( )

b. The ~~type~~ title of the program offered; ~~(3-21-12)~~( )

c. The learning objectives and ~~A~~a description of the subject matter; ~~(3-21-12)~~( )

d. The ~~number of clock hours offered~~ method and materials for assessing the learning objectives; ~~(3-21-12)~~( )

e. The method of evaluating satisfactory completion of the program; ~~(3-21-12)~~( )

f. The dates, time schedule, number of clock hours and location of the program; and ~~(3-21-12)~~( )

g. The names and ~~qualifications~~ curriculum vitae or resume of instructors or other persons responsible for the delivery and content of the program~~.~~; and ~~(3-21-12)~~( )

h. A copy of the materials to be offered to the participants and the program to be presented (electronic or hard copy), if applicable. ( )

02. Postgraduate Education. A CPE program must consist of postgraduate education in one or more of the following general areas: (3-21-12)

a. The socioeconomic and legal aspects of health care; (3-21-12)

b. The properties and actions of drugs and dosage forms; or (3-21-12)

c. The etiology, characteristics, and therapeutics of a disease state. (3-21-12)

03. Evidence of Satisfactory Completion. A CPE program must provide evidence of satisfactory completion by participants. (3-21-12)

04. Qualified Instruction. The program presenter must be qualified in the subject matter by education or experience. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

052. CPE: REQUIREMENTS.
Each pharmacist applicant for license renewal must annually complete fifteen (15) CPE hours. (4-4-13)

01. ACPE or CME. At a minimum, ~~eight~~ twelve (~~8~~12) of the CPE hours obtained must be all or a combination of ACPE or CME accredited programs. ACPE accredited activities must have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ~~(4-4-13)~~( )

02. Pharmacy Law. One (1) of the CPE hours obtained must ~~be ACPE accredited or Board approved jurisprudence (pharmacy law) programs~~ address federal, state or local law effecting the practice of pharmacy. ~~(4-4-13)~~( )

03. Board Approved. A maximum of ~~six~~ three (~~6~~3) of the CPE hours obtained may be Board-approved programs not accredited through ACPE or CME. ~~(4-4-13)~~( )

04. Live Attendance. Three (3) of the CPE hours obtained must be by attendance at live or synchronous online CPE programs. (4-4-13)

05. Immunizer Qualification. To maintain qualification to administer immunizations, a minimum of

one (1) of the ACPE-approved CPE hours must be related to vaccines, immunizations, or their administration. (4-4-13)

06. Sterile Compounding Requirement. To engage in the practice of sterile compounding a minimum of one (1) of the CPE hours must be ACPE accredited and related to the practice of sterile compounding. ( )

0~~6~~7. Carryover of Certain Unused Units. CPE hours accrued during June of a licensing period may be carried over into the next licensing period to the extent that a pharmacist's total CPE hours for the current licensing period exceed the total CPEs hours required by these rules. (4-4-13)

0~~7~~8. New Pharmacist Exemption. Recent pharmacist graduates applying for the first license renewal are not required to complete or certify the annual CPE requirements. (3-21-12)

~~053~~9. ***~~CPE:~~*** **Requirements for Dual Licenses**. ( )

~~01~~a. ***~~Idaho Licensee.~~*** An Idaho-licensed pharmacist residing in another state must meet Idaho CPE requirements to be granted an Idaho license renewal. ***~~(3-21-12)~~***( )

~~02~~b. ***~~Approval.~~*** CPE programs attended by an Idaho-licensed pharmacist for purposes of satisfying licensing requirements of another state must be accredited by either ACPE or CME or must be approved by the Board to also be recognized for purposes of renewal of the pharmacist's Idaho license. ***~~(3-21-12)~~***( )

05~~4~~3. -- 059. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

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

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

a. If for a controlled substance, the patient's full name and address; and (3-21-12)

b. If for an animal, the species. (3-21-12)

02. Date. The date issued. (3-21-12)

03. Drug Information. The drug name, strength, quantity, and if for a controlled substance, the dosage form. (3-21-12)

04. Directions. The directions for use. (3-21-12)

05. Prescriber Information. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (3-21-12)

06. Signature. If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, or if statutorily allowed, the prescriber's agent's signature, and if electronic, the prescriber's electronic signature. ***~~(3-21-12)~~***( )

112. DRUG ORDER: MINIMUM REQUIREMENTS.
A drug order must comply with applicable requirements of federal law and must include at least the following: (3-21-12)

01. **Patient's Name**. The patient's name. (3-21-12)

02. **Date**. The date issued. (3-21-12)

03. **Drug Information**. The drug name, strength, and route of administration. (3-21-12)

04. **Directions**. The directions for use. (3-21-12)

05. **Prescriber Information**. The name of the prescriber. (3-21-12)

06. **Signature**. If written, the signature of the prescriber or if statutorily allowed, the prescriber's agent. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

202. CONTROLLED SUBSTANCES: NON-PRESCRIPTION DISPENSING.
A Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted or restricted by these rules. (3-21-12)

01. **Dispensing by a Technician Prohibited**. Technicians are prohibited from dispensing a non-prescription controlled substance even if under the direct supervision of a pharmacist, but may transact the sale and deliver the product after the pharmacist has fulfilled his professional and legal responsibilities. (3-21-12)

02. **Restricted Quantity**. No more than four (4) ounces of liquid containing a maximum of two hundred (200) milligrams of codeine per one hundred (100) milliliters or per one hundred (100) grams may be distributed at retail to the same purchaser in any forty-eight (48) hour period. ~~(3-21-12)~~( )

03. **Purchaser's Age**. A purchaser of a non-prescription controlled substance must be at least eighteen (18) years of age. (3-21-12)

04. **Identification Required for Purchase**. The pharmacist must obtain positive identification as required by these rules that, if appropriate, includes proof of age of the purchaser of a non-prescription Schedule V controlled substance. (3-21-12)

05. **Bound Record Book and Patient Signature Required**. A bound record book must be used to document sales of non-prescription Schedule V controlled substances and must record the following: (3-21-12)

a. The name and address of the purchaser; (3-21-12)

b. The name and quantity of the controlled substance purchased; (3-21-12)

c. The date of the purchase; (3-21-12)

d. The name or initials of the pharmacist who dispensed the substance to the purchaser; and (3-21-12)

e. The signature of the purchaser. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

604. PHARMACY PRODUCT STORAGE AND REMOVAL.
Prescription drugs, devices, and other products restricted to sale or dispensing by, or under the supervision of, a pharmacist must be stored in the pharmacy and must not be sold, delivered, or otherwise removed from a pharmacy

unless a pharmacist is present, except: ( )

01. Emergency Drug Access and Pharmacist Absence. ~~a~~As allowed by these rules for emergency access to an institutional pharmacy~~.~~: ( )

02. Institutional Facility Alternative Storage. In an institutional facility these restricted products may also be stored in an alternative designated area that is appropriately equipped to ensure compliance with drug product storage requirements, to provide adequate security and protection from diversion, and that otherwise complies with applicable requirements of these rules~~.~~: ~~(3-21-12)~~( )

03. Storage for Delivery. Filled prescriptions may be picked up for delivery from a pharmacy when the pharmacy is closed for business if: ( )

a. The prescriptions are placed in a secured delivery area equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversions; ( )

b. The secured delivery area has walls that extend to the roof, solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner that the hinge hardware is accessible only from inside the secured delivery area; ( )

c. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements; ( )

d. The secured delivery area is attached or located adjacent to the pharmacy that filled the prescriptions; ( )

e. The PIC, or a pharmacist designated by the PIC, and the approved transport agent solely have access to the secure delivery area. Two (2) factor credentialing is required for entry, which must include two (2) of the following: ( )

i. Something you know (a knowledge factor); ( )

ii. Something you have (a hard token stored separately from the computer being accessed); and ( )

iii. Something you are (biometric information); ( )

f. The pharmacy has a means of recording the time of entry and the identity of all persons who access the secured delivery area; ( )

g. The pharmacy maintains immediately retrievable records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery; ( )

h. The pharmacy maintains written policies and procedures for the secured delivery storage and removal of prescriptions; and ( )

i. The PIC of a pharmacy that ships drugs by common carrier shall require the common carrier to conduct criminal background checks on its employees who have access to the secured delivery area; and ( )

04. Qualified Returns to the Secured Delivery Area. A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area: ( )

a. Emergency kits; ( )

b. Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and ( )

c. Those deemed qualified for return pursuant to Section 262 (Restricted Return of Drugs or Devices) of these rules. ( )

605. PHARMACY SECURITY.

01. Basic Security Standards. A pharmacy must be constructed and equipped with adequate security, and at least while closed, utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. Pharmacies without an alarm or other monitoring system as of the effective date of this rule must comply with this rule upon completion of a structural remodel. (3-21-12)

02. Non-Institutional Pharmacy Security During Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except: (4-4-13)

a. If a technician or student pharmacist is on to duty, to allow brief pharmacist absences within the business establishment; or (4-4-13)

b. To perform professional services in the peripheral areas immediately outside of the pharmacy. (4-4-13)

03. Structural Security Requirements. If a pharmacy is located within an establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All pharmacies must meet the following security requirements: ~~(3-21-12)~~( )

a. Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (3-21-12)

b. Solid core or metal doors are required for new or remodeled pharmacies after the effective date of this rule. (4-4-13)

c. Doors and other access points must be constructed in a manner that the hinge hardware is accessible only from inside of the pharmacy and must be equipped with locking devices. (3-21-12)

d. If used, a “drop box” or “mail slot” allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment. (3-21-12)

04. Restricted Access to the Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist or except as permitted by these rules for an institutional pharmacy. (3-21-12)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1301

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 16, 2013.

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

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

The New England Compounding Center tragedy, whereby 52 Americans have died so far from tainted injectible compounded product, has highlighted the need for tighter compounding regulation. This rulemaking establishes standards for the compounding of drugs, including general compounding standards that regulate ingredients, prohibited acts, equipment, compromised drugs, and hazardous drugs, scope of practice that regulates compounding of commercially available drugs, anticipatory compounding, compounding and distributing for office use, compounding for research, and reconstitution exceptions, and drug compounding controls that regulates policies and procedures, compounding accuracy, certain records, and labeling. These rule changes also expand sterile product preparation rules, including defining products that require sterilization, compounding responsibilities, environmental controls, equipment, sterile hazardous drugs, documentation requirements, and policy and procedures.

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

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

The Board envisions requesting about ten thousand dollars ($10,000) to send the Board's inspectors to sterile compounding training.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted under Docket No. 27-0101-1207. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the December 5, 2012 Idaho Administrative Bulletin, **Vol. 12-12**, page 62; January 2, 2013 Idaho Administrative Bulletin, **Vol. 13-1**, page 182; February 6, 2013 Idaho Administrative Bulletin, **Vol. 13-2**, page 28; March 6, 2013 Idaho Administrative Bulletin, **Vol. 13-3**, page 13; May 1, 2013 Idaho Administrative Bulletin, **Vol. 13-5**, page 83; July 3, 2013 Idaho Administrative Bulletin, **Vol. 13-7**, page 79; and August 7, 2013 Idaho Administrative Bulletin, **Vol. 13-8**, page 293.

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:

The New England Compounding Center tragedy, whereby 52 Americans have died so far from tainted injectible compounded product, has highlighted the need for tighter compounding regulation. The FDA's Compliance Policy Guidance for FDA Staff and Industry, Sec. 460.200, Pharmacy Compounding, Appendix A (Reissued May 29, 2002) has been incorporated by reference into these rules to prohibit the compounding of drugs for human use that were withdrawn or removed from the market for safety reasons.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, 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 23, 2013.

DATED this 30th day of August, 2013.

Mark Johnston, R.Ph.
Executive Director
Board of Pharmacy
1199 W. Shoreline Ln., Ste. 303
P. O. Box 83720
Boise, ID 83720-0067
Telephone: (208) 334-2356
FAX: (208) 334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1301

004. INCORPORATION BY REFERENCE.

~~*No documents have*~~ FDA's Compliance Policy Guidance for FDA Staff and Industry, Sec. 460.200, Pharmacy Compounding, Appendix A (Reissued May 29, 2002) has been incorporated by reference into these rules.

~~*(3-21-12)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

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

01. Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)

02. ACPE. Accreditation Council for Pharmacy Education. (3-21-12)

03. Acute Care Hospital. A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)

04. ADS -- Automated Dispensing and Storage. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

05. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

06. Central Drug Outlet. A resident or nonresident pharmacy, drug outlet or business entity employing or contracting pharmacists to perform centralized pharmacy services. (7-1-13)

07. Central Pharmacist. A pharmacist performing centralized pharmacy services. (7-1-13)

08. Central Pharmacy. A pharmacy performing centralized pharmacy services. (7-1-13)

09. Centralized Pharmacy Services. The processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons

and at the same or different locations. (7-1-13)

10. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)

11. Charitable Clinic or Center -- Authorized Personnel. A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)

12. Chart Order. A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

13. CME. Continuing medical education. (3-21-12)

14. COE -- Central Order Entry. A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)

15. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

16. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

17. Continuous Quality Improvement Program. A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (3-21-12)

18. Correctional Facility. Any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order. (4-4-13)

19. CPE. Continuing pharmacy education. (3-21-12)

20. DEA. United States Drug Enforcement Administration. (3-21-12)

21. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

22. DME. Durable medical equipment. (3-21-12)

23. Drug Order. A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)

24. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

25. Drug Product Substitution. Dispensing a drug product other than prescribed. (4-4-13)

26. DTM -- Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

27. Emergency Drugs. Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)

28. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

29. FDA. United States Food and Drug Administration. (3-21-12)

30. Flavoring Agent. An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)

31. Floor Stock. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

32. FPGEC. Foreign Pharmacy Graduate Examination Committee. (4-4-13)

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

a. Carcinogenicity; ( )

b. Teratogenicity or developmental toxicity; ( )

c. Reproductive toxicity in humans; ( )

d. Organ toxicity at low doses in humans or animals; ( )

e. Genotoxicity; or ( )

f. New drugs that mimic existing hazardous drugs in structure or toxicity. ( )

34. High Risk Sterile Product Preparation. A sterile drug product that is compounded from nonsterile components, containers, or equipment and requires terminal sterilization. ( )

3~~3~~5. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

3~~4~~6. **Hospital System**. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

3~~5~~7. **Idaho State Board of Pharmacy or Idaho Board of Pharmacy**. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (3-21-12)

3~~6~~8. **Individually Identifiable Health Information**. Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)

b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)

i. Identifies the individual; or (3-21-12)

ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)

3~~7~~9. Institutional Pharmacy. A pharmacy located in an institutional facility. (3-21-12)

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. LTCF -- Long-Term Care Facility. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. Mail Service Pharmacy. A nonresident pharmacy that ships, mails, or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law. (7-1-13)

03. MPJE. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

04. MTM -- Medication Therapy Management. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

05. NABP. National Association of Boards of Pharmacy. (3-21-12)

06. NAPLEX. North American Pharmacists Licensure Examination. (3-21-12)

07. NDC. National Drug Code. (3-21-12)

08. Non-Institutional Pharmacy. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

09. Parenteral Admixture. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

10. Pharmaceutical Care Services. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Except as permitted pursuant to a collaborative practice agreement, nothing in these rules allows a pharmacist, beyond what is statutorily allowed, to engage in the unlicensed practice of medicine or to diagnose, prescribe, or conduct physical examinations. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (4-4-13)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; and (3-21-12)

m. Other services as allowed by law. (3-21-12)

11. Pharmacist Extern. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)

12. Pharmacist Intern. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

13. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

14. PHI -- Protected Health Information. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR

160.103) in its role as an employer. (3-21-12)

15. PIC. Pharmacist-in-charge. (3-21-12)

16. PMP. Prescription Monitoring Program. (3-21-12)

17. Prepackaging. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order or prior to distributing a sterile product as allowed by these rules. ~~(3-21-12)~~( )

18. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

19. Prescriber Drug Outlet. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

20. Readily Retrievable. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

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

2~~1~~**2. Relative Contraindication**. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

2~~2~~**3. Remote Dispensing Site**. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

2~~3~~**4. Remote Office Location**. A secured area that is restricted to authorized personnel, adequately protects private health information, and shares a secure common electronic file or a private, encrypted connection with a pharmacy, from which a pharmacist who is contracted or employed by a central drug outlet performs centralized pharmacy services. (7-1-13)

2~~4~~**5. Retail Non-Pharmacy Drug Outlet**. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

2~~5~~**6. Retail Pharmacy**. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

2~~6~~**7. R.N**. Registered nurse. (3-21-12)

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

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

(BREAK IN CONTINUITY OF SECTIONS)

231. -- 23~~9~~8. (RESERVED)

239. COMPOUNDING DRUG PRODUCTS.

01. Application. These rules apply to any person, including any business entity, authorized to engage

in the practice of non-sterile compounding, sterile compounding and sterile prepackaging of drug products in or into Idaho. ( )

a. USP. Strict application of or adherence to the guidelines of USP 795 and USP 797 is not mandated; however, it is expected that all persons and business entities will strive to practice in accordance with those guidelines that apply to their practice settings and in all situations comply with the spirit of USP 797 and USP 795. ( )

b. Manufacturing. Any compounding that is not permitted herein is considered manufacturing. ( )

02. General Compounding Standards. ( )

a. Certificate of Analysis. A COA issued by a firm located in the United States must be obtained for all active ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied. If a COA is not available from the vendor, the pharmacist must procure one from a laboratory located in the United States. COAs are not required if the active ingredient utilized is designated USP-NF. If the product is not designated as USP-NF, then the following minimum information is required on the COA: ( )

i. Product name; ( )

ii. Lot number; ( )

iii. Expiration date; and ( )

iv. Assay. ( )

b. Prohibited Compounding. Compounding any drug for human use that the FDA, in its Compliance Policy Guidance for FDA Staff and Industry, Sec. 460.200 Pharmacy Compounding, Appendix A (Reissued May 29, 2002), has identified as prohibited for compounding or withdrawn or removed from the market for safety reasons is prohibited. ( )

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

d. Disposing Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampules, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be disposed of immediately. ( )

e. Hazardous Drugs. Drug outlets must ensure the storage area has sufficient general exhaust ventilation to dilute and remove any airborne contaminants and use a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless the hazardous drugs in use will not volatilize while they are being handled. Additionally, a drug outlet that prepares hazardous drugs must: ( )

i. Clearly identify prepared doses of hazardous drugs, label them with proper precautions, and dispense them in a manner to minimize risk of hazardous spills; ( )

ii. Comply with applicable local, state, and federal laws in the disposal of hazardous waste; and ( )

iii. Include procedures for handling hazardous spills in the policies and procedures manual. ( )

iv. Supplies necessary for handling hazardous spills and disposal of wastes must be available and maintained in the area at all times. ( )

03. Scope of Practice. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order. ( )

a. Commercially Available Products. Compounding a drug product that is commercially available is prohibited, provided however, that a pharmacist may compound a drug product that is essentially a copy of an available FDA-approved drug product if: ( )

i. Pursuant to a valid pharmacist/patient/prescriber relationship and valid prescription drug order, it is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or ( )

ii. Commercial product is not reasonably available in the market in time to meet the patient's needs. ( )

b. Anticipatory Compounding. A pharmacist may compound very limited quantities of a drug product prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders generated solely within an established pharmacist/patient/prescriber relationship. ( )

c. Office Use. A pharmacist may distribute non-patient specific drug products in the absence of a valid prescription drug order to licensed practitioners to administer (and not for resale) to their patients in the course of their professional practice. The quantity shall be limited to five percent (5%) of the total number of compounded or sterile prepackaged drug products dispensed and distributed on an annual basis by the pharmacy, except that this limit shall not apply to nuclear pharmacies. ( )

d. Research. A drug may be compounded for the purpose of, or incident to, research, teaching, or chemical analysis and not for resale or dispensing. ( )

e. Reconstitution. Compounding does not include reconstituting of a nonsterile drug or a sterile drug for immediate administration. ( )

04. Drug Compounding Controls. ( )

a. Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must be written to ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of practice: ( )

i. Appropriate packaging and storage requirements; ( )

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

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

iv. Labeling accuracy and completeness; ( )

v. Beyond use date assignment; ( )

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

vii. Maintaining environmental quality control; ( )

viii. Packaging, storage, handling, and transport; ( )

ix. Environmental sampling testing; ( )

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

b. Accuracy. Components, including but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate. The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label. If any drug potency analysis is conducted, records must be maintained in a readily retrievable manner. ( )

c. Non-Patient Specific Records. A production record of drug products compounded or sterile prepackaged for office use and prepared in anticipation of receiving prescription drug orders that are not for immediate administration, solely as permitted herein, must be prepared and kept for each drug product prepared, including: ( )

i. Production date; ( )

ii. Beyond use date; ( )

iii. List and quantity of each ingredient; ( )

iv. Internal control or serial number; and ( )

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

d. Labeling. The label affixed to the container of a compounded or sterile prepackaged drug product that is: ( )

i. Dispensed must comply with the standard prescription drug labeling requirements. ( )

ii. Distributed in the absence of a patient specific prescription drug order, solely as permitted herein, must contain the following information: ( )

(1) The name of each drug included; ( )

(2) The strength or concentration of each drug included; ( )

(3) If applicable, the name and concentration of the base or diluents; ( )

(4) If applicable, the dosage form or route of administration; ( )

(5) The total quantity of the drug product; ( )

(6) The expiration or beyond use date; ( )

(7) The initials or unique identifier of the pharmacists responsible for the accuracy of the drug product; ( )

(8) The statement "not for resale;" and ( )

(9) Handling, storage or drug specific instructions, cautionary information, and warnings as required or deemed appropriate for proper use and patient safety. ( )

240. 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. ( )

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

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

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

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

d. Irrigations for wounds and body cavities; ( )

e. Ophthalmic drops and ointments; and ( )

f. Tissue implants. ( )

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

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

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

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

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

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

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

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

0~~1~~4. 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. (3-21-12)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every ~~twelve~~ six (~~12~~6) months or if relocated. ~~(3-21-12)~~( )

b. ~~Pref~~Filters must be inspected and replaced in accordance with the manufacturer's recommendations. ~~(3-21-12)~~( )

0~~2~~5. Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following: (3-21-12)

a. Protective apparel including non-vinyl gloves, gowns, and masks unless the PIC or director can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required; ~~(3-21-12)~~( )

b. A sink with hot and cold water in close proximity to the hood; (3-21-12)

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; (3-21-12)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet~~;~~. ~~(3-21-12)~~( )

~~**e.** *A separate vertical flow biohazard safety hood, if hazardous materials are prepared; and* (3-21-12)~~

~~**f.** *Supplies necessary for handling both hazardous and biohazardous spills and disposal of wastes must be available and maintained in the area at all times.* (3-21-12)~~

0~~3~~6. ~~*Cytotoxic*~~ Sterile Hazardous Drug~~s~~ Preparation Equipment. ~~*A drug outlet in which cytotoxic*~~ Sterile hazardous drugs ~~*are prepared*~~ must ~~*also:*~~ ~~(3-21-12)~~

~~**a.** *B*~~be ~~*equipped with and*~~ prepared ~~*the drugs*~~ in a ~~*vented*~~ dedicated class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets~~;~~. ~~(3-21-12)~~( )

~~**b.** *Require appropriate containment techniques;* (3-21-12)~~

~~**c.** *Clearly identify prepared doses of cytotoxic drugs, label them with proper precautions, and dispense them in a manner to minimize risk of cytotoxic spills;* (3-21-12)~~

~~**d.** *Comply with applicable local, state, and federal laws in the disposal of cytotoxic waste; and* (3-21-12)~~

~~**e.** *Include procedures for handling cytotoxic spills in the policies and procedures manual.* (3-21-12)~~

0~~4~~7. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: (3-21-12)

a. Justification of ~~*expiration*~~ beyond use dates ~~*chosen*~~ assigned, pursuant to direct testing or extrapolation from reliable literature sources; ~~(3-21-12)~~( )

b. ~~*Employee t*~~Training records, ensuring that personnel are adequately skilled, educated, and instructed; ~~(3-21-12)~~( )

c. ~~*Technique a*~~Audits~~; *and*~~ appropriate for the risk of contamination for the particular sterile product

including: ~~(3-21-12)~~( )

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

ii. Initial hand hygiene and garbing competency; ( )

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

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

(1) Total particle counts; ( )

(2) Viable air sampling; ( )

(3) Gloved fingertip sampling; ( )

(4) Surface sampling; ( )

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

d. Temperature, logged daily; ( )

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

~~**d.**~~**f.** Measuring, mixing, sterilizing and purification ~~E~~equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. ~~(3-21-12)~~( )

0~~5~~8. **Policies and Procedures**. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet ~~*compounding*~~ preparing sterile pharmaceutical products and must~~:~~ ~~(3-21-12)~~

~~*a. Be designed and sufficiently detailed to protect the health and safety of persons preparing or receiving sterile products; and*~~ ~~(3-21-12)~~

~~**b.**~~ ~~I~~include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, ~~*product storage, stability standards, and infection control.*~~ including: ~~(3-21-12)~~( )

a. Antiseptic hand cleansing; ( )

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

c. Appropriately selecting and donning protective garb; ( )

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

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

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

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

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1302

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 16, 2013.

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

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

This rulemaking updates the list of acceptable forms of identification required to receive controlled substance prescriptions, to include those issued in compliance with the Western Hemisphere Travel Initiative (WHTI). The rulemaking extends the acceptable forms of positive identification to obtain controlled substance prescriptions to include Enhanced Drivers Licenses (EDLs), Nexus Cards, and PASS Cards.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted because the rule is simple in nature.

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 Mark Johnston, 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 23, 2013.

DATED this 30th day of August, 2013.

Mark Johnston, R.Ph.
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THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1302

200. CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.
A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. (3-21-12)

01. Positive Identification Presumed. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: (3-21-12)

a. The controlled substance will be paid for, in whole or in part, by an insurer; or (3-21-12)

b. The patient is being treated at an institutional facility or is housed in a correctional facility. (4-4-13)

c. The filled prescription is delivered to the patient's residence either by mail, common carrier, or an employee of the pharmacy. (4-4-13)

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a pharmacy or prescriber drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: (3-21-12)

a. The recipient's name (if other than the patient); (3-21-12)

b. A notation indicating that the recipient was known to the staff member; and (3-21-12)

c. The identity of the staff member making the personal identification. (3-21-12)

03. Acceptable Identification. The identification presented must include an unaltered photograph and signature and acceptable forms include: ( )

a. ~~a~~A valid U.S. state or U.S. military driver's license or identification card; ~~and~~ ( )

b. A Western Hemisphere Travel Initiative (WHTI) compliant document (i.e., Enhanced Driver's License (EDL) or Nexus Air Card); ( )

c. ~~a~~A valid passport.; and ~~(3-21-12)~~( )

d. A U.S. passport card (PASS Card). ( )

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and must include: (3-21-12)

a. A copy of the identification presented; or (3-21-12)

b. A record that includes: (3-21-12)

i. The recipient's name; (3-21-12)

ii. A notation of the type of identification presented; (3-21-12)

iii. The ~~*state, military branch, or other*~~ government entity that issued the identification; and ~~(3-21-12)~~( )

iv. The unique identification number ~~*of the driver's license, identification card, or passport*~~. ~~(3-21-12)~~( )