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 Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401);

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402);

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403);

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404);

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405).

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 10/20/2014. 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 11/18/2014.

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

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

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Eric Milstead
Director

MEMORANDUM

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

FROM: Legislative Research Analyst - Elizabeth Bowen

DATE: September 30, 2014

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404)

IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405)

(1) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1401)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule would allow biosimilar products to be substituted for a prescribed biological product, in order to be consistent with federal law. There is no negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

(2) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy (Fee Rule) - Temporary and Proposed Rule (Docket No. 27-0101-1402)

The Board of Pharmacy submits notice of temporary and proposed rulemaking at IDAPA 27.01.01. The temporary and proposed rule defines outsourcing facilities, creates a new registration category for outsourcing facilities, establishes a registration fee, and establishes practice standards for outsourcing facilities. The purpose of the temporary and proposed rule is to make Idaho's regulatory scheme consistent with the federal Drug Quality and Security Act. There is no apparent negative fiscal impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

(3) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1403)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule relates to compounded drug product and is intended to protect public safety. The rule creates labeling requirements for compounded drug product, establishes general compounding standards, limits pharmacy distribution of non-sterile compounded drug product, and expands a sterile compounding rule and a hazardous drug sub-rule. The Board received $14,000 in appropriations for FY2015 in order to train inspectors; otherwise, there is no apparent negative impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

(4) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1404)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule provides clarification of several matters in order to be consistent with statutory changes made in 2014. The clarifications include the number of student pharmacist hours required for foreign graduates, the number of renewals for which a technician-in-training may qualify, the period of time when a controlled substance inventory must be conducted, and the security requirements for pharmacies. Additionally, the rule updates standard drug labeling requirements, creates a new limited pharmacy repackaging rule, allows pharmacist immunizers to use all forms of injectable epinephrine, combines various pharmacy authorized entry rules, and updates remote dispensing site security and training requirements. There is no negative impact on the state general fund, and negotiated rulemaking was conducted. The rule is consistent with the Board's authority under Section 54-1717, Idaho Code.

(5) IDAPA 27.01.01 - Rules Pertaining To The Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1405)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. The proposed rule, which relates to wholesale distribution of drugs, is being updated to be consistent with the federal Drug Quality and Security Act. There is no apparent negative impact on the state general fund. Negotiated rulemaking was conducted. The rule is consistent with the Board's authority under 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. 27-0101-1401

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:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

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:

Federal law has created a new drug category, biosimilars, which are federally allowed to be substituted for a prescribed biological product. Idaho law is currently more restrictive than federal law, so such substitution is not permissible without this rule promulgation. This proposed rule allows a biosimilar product to be substituted for a prescribed biological product, upon the determination by the FDA that the biosimilar product is interchangeable.

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:

There is no fiscal impact of this proposed rule to the Board of Pharmacy; however, the State of Idaho will save money when biosimilars are dispensed to Health and Welfare recipients and state employees.

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 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

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: NA

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, Executive Director, (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 22, 2014.

DATED this 29th Day of August, 2014.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1401
(Only those Sections being amended are shown.)

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. 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. ( )

06. Biosimilar. A biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. ( )

05~~7~~. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

06~~8~~. 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~~9~~. Central Pharmacist. A pharmacist performing centralized pharmacy services. (7-1-13)

~~08~~10. Central Pharmacy. A pharmacy performing centralized pharmacy services. (7-1-13)

~~09~~11. 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)

1~~0~~2. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet

licensed or registered by the Board. (3-21-12)

1~~1~~3. 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)

1~~2~~4. 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)

1~~3~~5. CME. Continuing medical education. (3-21-12)

1~~4~~6. 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)

1~~5~~7. 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)

1~~6~~8. 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)

1~~7~~9. 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~~20. 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~~21. CPE. Continuing pharmacy education. (3-21-12)

2~~0~~2. DEA. United States Drug Enforcement Administration. (3-21-12)

2~~1~~3. Distributor. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

2~~2~~4. DME. Durable medical equipment. (3-21-12)

2~~3~~5. 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)

2~~4~~6. Drug Product Selection. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

2~~5~~7. Drug Product Substitution. Dispensing a drug product other than prescribed. (4-4-13)

2~~6~~8. DTM -- Drug Therapy Management. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

2~~7~~9. 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~~30. Executive Director. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

~~29~~31. **FDA**. United States Food and Drug Administration. (3-21-12)

30~~1~~2. **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~~2~~3. **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~~3~~4. **FPGEC**. Foreign Pharmacy Graduate Examination Committee. (4-4-13)

33~~4~~5. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

34~~5~~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)

35~~6~~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)

36~~7~~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)

37~~8~~9. **Institutional Pharmacy**. A pharmacy located in an institutional facility. (3-21-12)

40. **Interchangeable**. A biological product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. ( )

(BREAK IN CONTINUITY OF SECTIONS)

130. DRUG PRODUCT: SUBSTITUTION.
Drug product substitutions are allowed only as follows: (4-4-13)

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (4-4-13)

02. Skilled Nursing Facility. At the direction of the quality assessment and assurance committee of a skilled nursing facility consisting of the director of nursing services, a physician designated by the facility, a consultant pharmacist, and at least two (2) other members of the facility's staff; or (4-4-13)

03. Drug Shortage. Upon a drug shortage, a pharmacist, using his best professional judgment, without contacting the prescriber, 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 is prescribed. (4-4-13)

04. Biosimilars. Upon the determination by the FDA that the biosimilar product is interchangeable with the prescribed biological product, provided however, no substitution is permitted if the prescriber orders by any means that the prescribed biological product must be dispensed. If a biological product is substituted, the name of the drug and the manufacturer or the NDC number must be documented in the patient medication record. ( )

PROPOSED RULE COST/BENEFIT ANALYSIS

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

Department or Agency: Board of Pharmacy

Agency Contact: Mark Johnston, Executive Director Phone: (208) 334-2356

Date: 9/2/14

IDAPA, Chapter and Title Number and Chapter Name: IDAPA 27.01.01 – Rules of the Idaho Board of Pharmacy

Fee Rule Status: _X__ Proposed _X__ Temporary

Rulemaking Docket Number: 27-0101-1402

STATEMENT OF ECONOMIC IMPACT:

These rules will generate a small increase in the number of Board of Pharmacy registrants at either five hundred dollars ($500) or two hundred fifty dollars ($250) per initial registration and two hundred fifty dollars ($250) per renewal. Currently the number of federally registered outsourcing facilities that are not already registered in another category appears to be three (3) — and the federal law has been in place since November of 2013.

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1402 (FEE RULE)

NOTICE OF RULEMAKING - TEMPORARY AND PROPOSED RULE

EFFECTIVE DATE: The effective date of the temporary rule is September 1, 2014.

AUTHORITY: In compliance with Sections 67-5221(1) and 67-5226, Idaho Code, notice is hereby given that this agency has adopted a temporary rule, and proposed rulemaking procedures have been initiated. 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:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

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 the required finding and concise statement of its supporting reasons for adopting a temporary rule and a nontechnical explanation of the substance and purpose of the proposed rulemaking:

The federal Drug Quality and Security Act created a new type of drug outlet doing business into Idaho and potentially in Idaho: the outsourcing facility. This rulemaking defines outsourcing facilities, creates a new registration category, establishes a fee, and establishes practice standards for such outsourcing facilities.

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

The federal Drug Quality and Security Act created a new category of drug outlet registration: outsourcing facilities. As of July 14, 2014, fifty-one (51) outsourcing facilities are registered federally; all are nonresident, distributing into Idaho. Waiting until sine die of the 2015 Legislature will cause confusion and force the Board to register outsourcing facilities at a lower fee without practice standards. This rulemaking protects public safety by properly registering, including a registration fee, and instituting practice standards for outsourcing facilities.

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

This rulemaking is being promulgated due to the federal change that necessitates a state change and protects public safety by properly registering, including a registration fee, and instituting practice standards for outsourcing facilities. Pursuant to the board's authority set forth in Section 54-1720, Idaho Code, this rulemaking establishes fees for outsourcing facility registrations: five hundred dollar ($500) initial nonresident registration; two hundred fifty dollar ($250) initial resident registration; and two hundred fifty-dollar ($250) registration annual renewal.

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:

These rules will generate a small increase in the number of Board of Pharmacy registrants at either five hundred dollars ($500) or two hundred fifty dollars ($250) per initial registration and two hundred fifty dollars ($250) per renewal. Currently the number of federally registered outsourcing facilities that are not already registered in another category appears to be three (3) - and the federal law has been in place since November of 2013.

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 under Docket No. 27-0101-1401 in the July 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

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: NA

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

Anyone may submit written comments regarding the proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 22, 2014.

DATED this 29th Day of August, 2014.

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

THE FOLLOWING IS THE TEMPORARY RULE AND THE PROPOSED TEXT OF FEE DOCKET NO. 27-0101-1402
(Only those Sections being amended are shown.)

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. Outsourcing Drug Outlet. A drug outlet that is registered by the United States Food and Drug Administration pursuant to 21 U.S.C. Section 353b and either registered or endorsed by the Board. (9-1-14)T

~~09~~10. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

1~~0~~1. **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)

1~~1~~2. Pharmacist Extern. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)

1~~2~~3. 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)

1~~3~~4. Pharmacy Operations. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

1~~4~~5. 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)

1~~5~~16. PIC. Pharmacist-in-charge. (3-21-12)

1~~6~~17. PMP. Prescription Monitoring Program. (3-21-12)

1~~7~~18. 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. (3-21-12)

1~~8~~19. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

~~19~~20. 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)

2~~0~~1. 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)

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

~~22~~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)

~~23~~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)

~~24~~5. **Retail Non-Pharmacy Drug Outlet**. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

~~25~~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)

~~26~~7. **R.N**. Registered nurse. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

021. FEE SCHEDULE.

01. Licenses -- Professionals. (3-21-12)

a. Original pharmacist license: one hundred dollars ($100). (3-21-12)

b. Licensure by reciprocity: two hundred fifty dollars ($250). (3-21-12)

c. Pharmacist license annual renewal. (3-21-12)

i. Active: ninety dollars ($90). (3-21-12)

ii. Inactive: fifty dollars ($50). (3-21-12)

d. Late payment processing: fifty dollars ($50). (3-21-12)

e. License reinstatement fee: seventy-five dollars ($75). (3-21-12)

02. Certificates of Registration -- Professionals. (3-21-12)

a. Pharmacist registration or annual renewal: two hundred fifty dollars ($250). (7-1-13)

b. Pharmacist intern - registration or annual renewal: fifty dollars ($50). (3-21-12)

c. Pharmacist extern registration and annual renewal: fifty dollars ($50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. (3-21-12)

d. Technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

e. Veterinary drug technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

f. Registration reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

03. Certificates of Registration and Licensure - Facilities. (3-21-12)

a. Retail pharmacy - registration or annual renewal: one hundred dollars ($100). (3-21-12)

b. Institutional facility - registration or annual renewal. (3-21-12)

i. Hospital pharmacy: one hundred dollars ($100). (3-21-12)

ii. Nursing home: thirty-five dollars ($35). (3-21-12)

c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars ($100). (3-21-12)

d. Wholesaler. (3-21-12)

i. License or annual renewal: one hundred thirty dollars ($130); or (3-21-12)

ii. Registration or annual renewal: one hundred dollars ($100). (3-21-12)

e. Veterinary drug outlet - registration or annual renewal: one hundred dollars ($100). (3-21-12)

f. Nonresident central drug outlet. (7-1-13)

i. Initial license: five hundred dollars ($500). (7-1-13)

ii. License annual renewal: two hundred fifty dollars ($250). (7-1-13)

g. Mail service pharmacy. (3-21-12)

i. Initial license: five hundred dollars ($500). (3-21-12)

ii. License annual renewal: two hundred fifty dollars ($250). (3-21-12)

h. Limited service outlet - registration or annual renewal. (3-21-12)

i. Limited service outlet, if not listed: one hundred dollars ($100). (3-21-12)

ii. Sterile product pharmacy: one hundred dollars ($100). (4-4-13)

iii. Remote dispensing pharmacy: one hundred dollars ($100). (3-21-12)

iv. Facility operating a narcotic treatment program: one hundred dollars ($100). (3-21-12)

v. Durable medical equipment outlet: fifty dollars ($50). (3-21-12)

vi. Prescriber drug outlet: thirty five dollars ($35). (3-21-12)

vii. Outsourcing facilities: (9-1-14)T

(1) Initial nonresident registration: five hundred dollars ($500). (9-1-14)T

(2) Initial resident registration: two hundred fifty dollars ($250). (9-1-14)T

(3) Registration annual renewal: two hundred fifty dollars ($250). (9-1-14)T

i. Analytical or research lab -- registration or annual renewal: forty dollars ($40). (3-21-12)

j. Retail non-pharmacy outlets - registration or annual renewal. (3-21-12)

i. "A" (Stocks more than fifty (50) drug items): sixty dollars ($60). (3-21-12)

ii. "B" (Stocks fifty (50) or fewer drug items): twenty-five dollars ($25). (3-21-12)

iii. "V" (Vending machines): ten dollars ($10) per machine. (3-21-12)

k. Supplemental facility registrations or annual renewals. (3-21-12)

i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration required for one (1) or more hoods: no charge. (3-21-12)

ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)

l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

04. Controlled Substance Registration. (3-21-12)

a. Controlled substance - registration or annual renewal: sixty dollars ($60). (3-21-12)

b. Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars ($100). (3-21-12)

c. Controlled substance registration reinstatement: seventy-five dollars ($75). (3-21-12)

05. Administrative Services and Publications. (3-21-12)

a. Experiential hours certification: twenty-five dollars ($25). (3-21-12)

b. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). (3-21-12)

c. Duplicate registration or license card: ten dollars ($10). (3-21-12)

d. Commercial lists. (3-21-12)

i. Pharmacy list: fifty dollars ($50). (3-21-12)

ii. Pharmacist list: fifty dollars ($50). (3-21-12)

iii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). (3-21-12)

e. Official Idaho Register: fifteen dollars ($15). (3-21-12)

f. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). (3-21-12)

g. Hearing transcript: five dollars ($5) per page. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

074. OUTSOURCING FACILITY REGISTRATION.
An outsourcing facility must be registered with the Board in order to distribute compounded drug product in or into Idaho. (9-1-14)T

01. Application. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: (9-1-14)T

a. A copy of a valid FDA registration as an outsourcing facility as required by 21 U.S.C. Section 353b; (9-1-14)T

b. Identity of a pharmacist licensed or registered in Idaho who is designated the PIC of the outsourcing facility; and (9-1-14)T

c. An inspection report indicating compliance with applicable state and federal law. (9-1-14)T

02. Coincidental Activity. An outsourcing facility applicant currently registered by the Board as a pharmacy or mail service pharmacy will be considered for an outsourcing facility registration with a supplemental pharmacy or mail service pharmacy registration at no additional fee. Exemption from registration fees does not excuse compliance with all laws and rules pertaining to pharmacies and mail service pharmacies. (9-1-14)T

074~~4~~5. -- 079. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

731. -- 7~~4~~39. (RESERVED)

740. OUTSOURCING FACILITY.

01. Federal Act Compliance. An outsourcing facility must ensure compliance with 21 U.S.C. Section 353b of the Federal Food, Drug and Cosmetic Act. (9-1-14)T

02. Policies and Procedures. An outsourcing facility must adopt policies and procedures for maintaining records pertaining to compounding, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (9-1-14)T

741. -- 749. (RESERVED)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1403

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:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

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:

Note, the overwhelming majority of this docket contains pending language from 2014 that the Board asked the Legislature to reject via concurrent resolution, while the Board studied the new federal Compounding Quality Act. Such study is complete and edits have been made. In addition to such 2014 pending compounding rules, this docket of rules contains an additional hazardous drug compounding rule pursuant to the recently released draft United State Pharmacopeia Chapter 800. This docket is necessary to protect public safety post New England Compounding Center tragedy whereby over seventy (70) Americans have died so far from tainted, injectable, compounded drug product. This docket creates a labeling rule for distributed compounded drug product, establishes general compounding standards, limits pharmacy distribution of non-sterile compounded drug product, and expands a sterile compounding rule and a hazardous drug sub-rule.

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 received fourteen thousand dollars ($14,000) in appropriation for FY2015 to train its inspectors.

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 under Docket No. 27-0101-1401 in the July 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

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: NA

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, Executive Director, (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 22, 2014.

DATED this 29th Day of August, 2014.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1403
(Only those Sections being amended are shown.)

144. ~~(RESERVED)~~ LABELING OF DISTRIBUTED COMPOUNDED DRUG PRODUCT.
Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription drug order, solely as permitted for outsourcing facilities and pharmacies herein, must be labeled with the following information: ( )

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

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

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

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

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

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

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

08. Resale. The statement "not for resale;" and ( )

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

(BREAK IN CONTINUITY OF SECTIONS)

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

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

01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: ( )

a. Compound positron emission tomography drugs; ( )

b. Radiopharmaceutics; ( )

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

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

02. General Compounding Standards. ( )

a. Bulk Substances. All bulk drug substances must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. ( )

b. Certificate of Analysis. Unless the bulk drug substance complies with the standards of an applicable USP-NF monograph, a COA issued by a firm located in the United States must be obtained for all bulk drug substances procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied. The following minimum information is required on the COA: ( )

i. Product name; ( )

ii. Lot number; ( )

iii. Expiration date; and ( )

iv. Assay. ( )

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

d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction. ( )

03. Prohibited Compounding. Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited. ( )

04. Limited Compounding. ( )

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

b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if: ( )

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or ( )

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

c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product. ( )

05. Drug Compounding Controls. ( )

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

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

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

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

iv. Labeling accuracy and completeness; ( )

v. Beyond use dating; ( )

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

vii. Maintaining environmental quality control; and ( )

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

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

c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: ( )

i. Production date; ( )

ii. Beyond use date; ( )

iii. List and quantity of each ingredient; ( )

iv. Internal control or serial number; and ( )

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

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 in or into Idaho. ( )

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

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

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

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

c. Irrigations for wounds and body cavities; ( )

d. Ophthalmic drops and ointments; and ( )

e. 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, and sterile (or the ability to sterilize) non-vinyl gloves, 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; and ~~(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)~~

~~**03. Cytotoxic Drugs.** *A drug outlet in which cytotoxic drugs are prepared must also:* (3-21-12)~~

~~**a.** *Be equipped with and prepare the drugs in a vented 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)~~

04~~**6**~~. **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, evidencing that personnel are trained on a routine basis and 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. Periodic hand hygiene and garbing competency; ( )

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

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

(1) Total particle counts; ( )

(2) Viable air sampling; ( )

(3) Gloved fingertip sampling; ( )

(4) Surface sampling; ( )

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

d. Temperature, logged daily; ( )

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

~~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~~7. 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. Selecting and appropriately donning protective garb; ( )

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

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

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

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

241. HAZARDOUS DRUGS PREPARATION.
In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products and Sterile Product Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: ( )

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

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

a. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a

barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; ( )

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

c. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless the hazardous drugs in use will not volatilize while they are being handled. ( )

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

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

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

06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit does or unit-of-use packaging; ( )

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

08. Training. Ensure that personnel working with hazardous drugs are trained in: ( )

a. Hygiene; ( )

b. Garbing; ( )

c. Receipt; ( )

d. Storage; ( )

e. Handling; ( )

f. Transporting; ( )

g. Compounding; ( )

h. Spill control; ( )

i. Clean up; ( )

j. Disposal; ( )

k. Dispensing; ( )

l. Medical surveillance; and ( )

m. Environmental quality and control. ( )

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

242. OFFICE USE.

Compounded drug product may be distributed in or into Idaho in the absence of a patient specific prescription drug order to licensed practitioners in the usual course of professional practice by: ( )

01. Outsourcing Facility. An outsourcing facility or a pharmacy distributing compound positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; or ( )

02. Pharmacy. A pharmacy if: ( )

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

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

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

24~~1~~3. -- 259. (RESERVED)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1404

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:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

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 of rules provides various forms of clarification, and harmony with 2014 statute changes. This docket also addresses the situation whereby a patient cannot use their dispensed drugs when being admitted to an institutional facility because the drugs are not unit dosed packaged. This docket of rules clarifies that a pharmacist foreign graduate is required to obtain 1,500 student pharmacist hours; clarifies that a technician-in-training may only renew two times; harmonizes the standard drug labeling rule with 2014 statutory changes; creates a new limited pharmacy repackaging rule; clarifies when a controlled substance inventory is to be taken; allows pharmacist immunizers to utilize all forms of injectible epinephrine; clarifies that statutory requirements of nonresident registered pharmacists also pertain to nonresident licensed pharmacists; clarifies pharmacy security requirements; combines various pharmacy authorized entry rules into one rule; and updates remote dispensing site security and training requirements, also requiring a continuous quality improvement program.

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: NA

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 under Docket No. 27-0101-1401 in the July 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

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: NA

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, Executive Director, (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 22, 2014.

DATED this 29th Day of August, 2014.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1404
(Only those Sections being amended are shown.)

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

01. Licensure Submission Requirements. To be considered for licensure, a graduate of a school or college of pharmacy located outside of the United States must submit an application for licensure by examination, ~~*certification by the FPGEC, and*~~ certification of completion of a minimum of fifteen hundred (1500) experiential hours~~.~~, and; ~~*(4-4-13)*~~( )

a. Certification by the FPGEC; or ( )

b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. ( )

02. Affidavit. 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. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

041. TECHNICIAN-IN-TRAINING REGISTRATION.
A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a technician and obtains and maintains employment as a technician-in-training. (4-4-13)

01. Duties. Upon registration, a technician-in-training may perform any of the duties allowed by statute or rule to be delegated to a registered technician under the supervision of a pharmacist. (3-21-12)

02. Renewal. The registration of a technician-in-training must be renewed by June 30 annually, ~~*but is*~~ however a technician-in-training may only renew~~*able two (2) times*~~ a technician-in-training registration twice.
~~*(4-4-13)*~~( )

03. Registration Expiration. Upon the final expiration of a technician-in-training registration, a person must satisfy the technician certification and registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (3-21-12)

04. Cancellation of Registration. Failure to maintain employment will result in the cancellation of the registration. (4-4-13)

(BREAK IN CONTINUITY OF SECTIONS)

140. STANDARD PRESCRIPTION DRUG LABELING.
Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (3-21-12)

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business); (3-21-12)

02. Serial Number. The serial number; (4-4-13)

03. Date. The date the prescription is filled; (3-21-12)

04. Prescriber. The name of the prescriber; (3-21-12)

05. ~~*Patient*~~ Name. ~~*The name of the patient, and if the patient is an animal, the species;*~~ ~~*(3-21-12)*~~( )

a. If a person, the name of the patient; ( )

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

c. If a school for epinephrine auto-injectors pursuant to Section 33-520A, Idaho Code, the name of the school. ( )

06. Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name); (3-21-12)

07. Quantity. The quantity of item dispensed; (3-21-12)

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

09. Cautionary Information. Cautionary information as required or deemed appropriate for proper use and patient safety; (3-21-12)

10. Expiration. An expiration date that is the lesser of: (3-21-12)

a. One (1) year from the date of dispensing; (3-21-12)

b. The manufacturer's original expiration date; (3-21-12)

c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)

d. A shorter period if warranted; (3-21-12)

11. Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable; and (3-21-12)

12. Warning. The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed." (3-21-12)

13. ~~*Pharmacist*~~ Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. ~~*(4-4-13)*~~( )

(BREAK IN CONTINUITY OF SECTIONS)

146. REPACKAGING.
A pharmacy may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: ( )

01. Unit Dose. The drugs are repackaged into unit dose packaging; ( )

02. Pharmacist Verification. The repackaging pharmacist verifies: ( )

a. The identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within; and ( )

b. The validity and accuracy of the original prescription drug order; ( )

03. Adulterated Drugs. In the repackaging pharmacist's best professional judgment, the drug has not been adulterated; ( )

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

05. Time for Repackaging. The pharmacy repackages the entire amount that was delivered to it for repackaging no later than three (3) days after receipt; ( )

06. Date of Repackaging. The date of repackaging is less than one (1) year from the original date of dispensing and the original expiration date is also used on the repackaged drug's label; ( )

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

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

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

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

08. Record. The repackaging pharmacy makes a record of: ( )

a. All required components of the standard prescription drug labeling rule; ( )

b. The original dispensing pharmacy's name, address, and phone number; ( )

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

d. The name of the pharmacist responsible for compliance with this rule. ( )

09. Policy and Procedures. The repackaging pharmacy develops policy and procedures to ensure compliance with this rule. ( )

1467. -- 199. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

206. CONTROLLED SUBSTANCES: INVENTORIES.

01. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually ~~within~~ no later than seven (7) days ~~of~~ after the date of the prior year's inventory in a form and manner that satisfies the inventory requirements of federal law. ~~(4-4-13)~~( )

02. Separate Inventories for Each Location. A separate controlled substances inventory must be taken and retained at each registered location. (3-21-12)

03. Inventory on PIC or Director Change. A complete controlled substance inventory must be conducted in the event of a change of PIC or director on or by the first day of employment of the incoming PIC or director. (4-4-13)

04. Inventory After Discovery of Theft or Loss. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. (3-21-12)

05. 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. (3-21-12)

06. Annual Inventory Compliance. Complete inventories otherwise conducted ~~as otherwise required by these rules~~ may also be considered in complying with the annual inventory requirement. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

~~**304. PHARMACIST: AUTHORIZED PHARMACY ENTRANCE.**~~
~~*A pharmacist must not permit a person other than a pharmacist, student pharmacist, or technician to enter or work in the secured pharmacy, except that a pharmacist may authorize other persons to be present temporarily in the pharmacy for legitimate business purposes if under the direct supervision of a pharmacist at all times.* (3-21-12)~~

305~~3~~4. -- 309. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

330. PHARMACIST: ADMINISTERED IMMUNIZATIONS.

01. Patient Eligibility. A pharmacist may administer an immunization to a healthy patient without immunization contraindications pursuant to the latest recommendations by the CDC or other qualified government authority or to any patient pursuant to a prescription drug order issued by another prescriber. (3-21-12)

02. Pharmacist Qualifications. To qualify to administer immunizations, a pharmacist must first: (3-21-12)

a. Successfully complete an ACPE-accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the CDC's Advisory Committee on Immunization Practices and includes at least the following: (3-21-12)

i. Basic immunology, vaccine, and immunization protection; (3-21-12)

ii. Diseases that may be prevented by vaccination or immunization; (3-21-12)

iii. Current recommended immunization schedules; (3-21-12)

iv. Vaccine and immunization storage and management; (3-21-12)

v. Informed consent; (3-21-12)

vi. Physiology and techniques for administration of immunizations; (3-21-12)

vii. Pre-immunization and post-immunization assessment and counseling; (3-21-12)

viii. Immunization reporting and records management; and (3-21-12)

ix. Identification response, documentation, and reporting of adverse events. (3-21-12)

b. Hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program that includes cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training and requires a hands-on skills assessment by an authorized instructor. (3-21-12)

03. Maintaining Qualification. To maintain qualification to administer immunizations, a pharmacist must annually complete a minimum of one (1) CPE hour of ACPE-approved CPE related to vaccines, immunizations, or their administration, which may also be applied to the general CPE requirements of these rules. (4-4-13)

04. Student Pharmacist Administration. A pharmacist may not delegate authority to administer immunizations; however, a student pharmacist who has satisfied the qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. (3-21-12)

05. Waste Disposal. An immunizing pharmacist must properly dispose of used or contaminated supplies. (3-21-12)

06. Required Reports. An immunizing pharmacist must report: (3-21-12)

a. Adverse events to the healthcare provider identified by the patient, if any, and to the Vaccine Adverse Event Reporting System (VAERS); and (3-21-12)

b. Administration of immunizations to the Idaho Immunization Reminder Information System (IRIS), as required. (3-21-12)

07. Required Resources. A pharmacist must have a current copy of, or on-site access to, the CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases. (3-21-12)

08. Vaccine Information Statements. A corresponding, current CDC-issued VIS must be provided to the patient or the patient's representative for each administered immunization. (3-21-12)

09. Recordkeeping. For each administered immunization, the following information must be collected and maintained in the patient profile: (3-21-12)

a. The patient's name, address, date of birth, and known allergies; (3-21-12)

b. The date of administration; (3-21-12)

c. The product name, manufacturer, dose, lot number, and expiration date of the vaccine; (3-21-12)

d. Documentation identifying the VIS provided; (3-21-12)

e. The site and route of administration and, if applicable, the dose in a series (e.g. one (1) of three (3)); (3-21-12)

f. The name of the patient's healthcare provider, if any; (3-21-12)

g. The name of the immunizing pharmacist and of the student pharmacist, if any; (3-21-12)

h. Adverse events observed or reported, if any, and documentation including at least the dates of any subsequent required reporting; and (3-21-12)

i. Completed informed consent forms. (3-21-12)

10. Emergencies. (3-21-12)

a. An immunizing pharmacist must maintain an immediately retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. At a minimum, the kit must include: ~~(3-21-12)~~( )

i. Intramuscular diphenhydramine; ( )

ii. Oral diphenhydramine; ( )

iii. Appropriate needles and syringes for injection; ( )

iv. Alcohol; and ( )

v. At least one (1) of the following: ( )

(1) Auto-inject epinephrine; ( )

(2) A vial of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14); or ( )

(3) An ampule of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14) and filter needles. ( )

b. An immunizing pharmacist may initiate and administer ~~*auto-inject*~~ epinephrine, intramuscular diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association. ~~(3-21-12)~~( )

331. -- 3~~5~~39. (RESERVED)

340. NONRESIDENT PHARMACIST PRACTICE STANDARDS.
An Idaho licensed or registered nonresident pharmacist practicing pharmacy into Idaho must comply with the Board's laws and rules of this state unless compliance would violate the laws or rules in the state in which the registrant is located, except as follows: ( )

01. Pharmacy Technician. A pharmacist must not allow a technician to exceed the practice limitations for a technician in Idaho; ( )

02. Drug Product Substitution. A pharmacist must only substitute drug products in accordance with Idaho law; ( )

03. Drug Product Selection. A pharmacist must only select drug products in accordance with Idaho law; and ( )

04. Staffing Ratio. A pharmacist must not exceed the pharmacy staffing ratio, as defined in rule. ( )

341. -- 359. (RESERVED)

(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: (3-20-14)

01. Emergency Drug Access and Pharmacist Absence. As allowed by these rules for emergency access to an institutional pharmacy; (3-20-14)

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; (3-20-14)

03. Storage for Delivery. Filled prescriptions may be picked up for delivery from a pharmacy when the pharmacy is closed for business if: (3-20-14)

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 diversion; (3-20-14)

b. The secured delivery area has walls that extend to the roof and solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner so that the hinge hardware is ~~*accessible only from inside the secured delivery area*~~ tamper-proof when closed; ~~*(3-20-14)*~~( )

c. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements; (3-20-14)

d. The secured delivery area is attached or located adjacent to the pharmacy that filled the prescriptions; (3-20-14)

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: (3-20-14)

i. Something ~~*you*~~ known (a knowledge factor); ~~*(3-20-14)*~~( )

ii. Something ~~*you have*~~ possessed (a hard token stored separately from the computer being accessed); and ~~*(3-20-14)*~~( )

iii. Something ~~*you are*~~ biometric (~~*biometric information*~~ fingerprint, retinal scan, etc.);~~*(3-20-14)*~~( )

f. The pharmacy has a means of recording the time of entry and the identity of all persons who access the secured delivery area; (3-20-14)

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; (3-20-14)

h. The pharmacy maintains written policies and procedures for secured delivery area storage and removal of prescriptions; and (3-20-14)

i. The PIC of a pharmacy that ships drugs by common carrier must require the common carrier to conduct criminal background checks on its employees who have access to the secured delivery area. (3-20-14)

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: (3-20-14)

a. Emergency kits; (3-20-14)

b. Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and (3-20-14)

c. Those deemed qualified for return pursuant to the Restricted Return of Drugs or Devices rule. (3-20-14)

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.*~~ New construction or a remodeled pharmacy must meet the following minimum security requirements: ~~*(3-21-12)*~~( )

0~~2~~1. ~~***Non-Institutional Pharmacy Security During Pharmacist Absence***~~ **Alarm**. ~~*A non-institutional pharmacy must be*~~ At least while closed ~~*for business and secured during all times a pharmacist is not present except:*~~ an alarm or other comparable monitoring system is required. ~~*(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)*~~

0~~3~~2. ~~***Structural Security Requirements***~~ **Walls**. ~~*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:* *(3-20-14)*~~

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

~~***b***~~**03. Doors**. Solid core or metal doors are required ~~*for new or remodeled pharmacies after the effective date of this rule*~~. ~~*(4-4-13)*~~( )

~~***c***~~**04. Hinges and Locks**. 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*~~ tamper-proof when closed. ~~*(3-21-12)*~~( )

05. Differential Hours. When closed for business, a pharmacy must be: ( )

a. Completely enclosed in a manner sufficient to provide adequate security; or ( )

b. Located within a larger business establishment that is also closed. In such cases, the establishment must meet these minimum security requirements, and no person is allowed entry to the establishment unless a pharmacist is present. ( )

~~***d***~~**06. Drop Box**. 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)~~

(BREAK IN CONTINUITY OF SECTIONS)

611. PHARMACY AUTHORIZED ENTRY.

01. Open Pharmacy. A person other than a pharmacist, student pharmacist, or technician must not enter or work in the secured pharmacy, except that a pharmacist may authorize other persons to be present temporarily in the pharmacy for legitimate business purposes if under the direct supervision of a pharmacist at all times. ( )

02. Closed Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist. ( )

03. Non-Institutional Temporary Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except: ( )

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

b. When a pharmacist performs professional services in the peripheral areas immediately outside of the pharmacy. ( )

04. Institutional Pharmacy Temporary Pharmacist Absence. To accommodate periods of temporary absence of a pharmacist from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions: ( )

a. No other person may be allowed access or entrance to the pharmacy; ( )

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and ( )

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. ( )

61~~1~~2. -- 619. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

631. INSTITUTIONAL FACILITY: EMERGENCY DRUG ACCESS ~~*AND PHARMACIST ABSENCE*~~.
The director must make advance arrangements necessary to facilitate continuity of patient care and for the provision of drugs to the medical staff and other authorized personnel of the institutional facility in emergencies and during the absences of a pharmacist in compliance with this rule. ~~(3-21-12)~~( )

01. Emergency Pharmacy Access. If a drug is unavailable from any other authorized emergency source in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug and in the absence of a pharmacist from the premises of the institutional facility, it may be retrieved from an institutional pharmacy by an R.N. as follows: (3-21-12)

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; (3-21-12)

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access; and (3-21-12)

c. Only a non-controlled substance may be removed and only in an amount necessary to treat a patient's immediate need until the pharmacy is again attended by a pharmacist. (3-21-12)

02. Emergency Cabinets. A cabinet or similar enclosure located outside an institutional pharmacy may be used for emergency access of drugs by an R.N. as follows: (3-21-12)

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; and (3-21-12)

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. (3-21-12)

03. Emergency Drug Access ~~***Conditions and Documentation***~~. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows:
~~*(3-21-12)*~~( )

a. Removal of a drug must be pursuant to a valid drug order; (3-21-12)

b. Removal of a drug must be documented in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The initials or other unique identifier of the designated nurse. (4-4-13)

c. The removal record and a copy of the drug order must be left conspicuously in the pharmacy, emergency cabinet, or alternative location to facilitate prompt accuracy verification and initialing by a pharmacist. (3-21-12)

~~***04. Temporary Pharmacist Absence.*** *To accommodate periods of temporary absence of a pharmacist from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions:* *(3-21-12)*~~

~~***a.*** *No other person may be allowed access or entrance to the pharmacy;* *(3-21-12)*~~

~~***b.*** *Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and* *(3-21-12)*~~

~~***c.*** *Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility.* *(3-21-12)*~~

(BREAK IN CONTINUITY OF SECTIONS)

710. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES.
Pharmacies and pharmacists commencing retail telepharmacy operations with a remote dispensing site after

August 23, 2011, must comply with the following requirements: (3-21-12)

01. Telepharmacy Practice Sites and Settings. Prior to engaging in the practice of telepharmacy with a remote dispensing site, the supervising pharmacy must demonstrate that there is limited access to pharmacy services in the community in which the remote site is located. (3-21-12)

a. Information justifying the need for the remote dispensing site must be submitted with the initial registration application. (3-21-12)

b. The Board will consider the availability of pharmacists in the community, the population of the community to be served by the remote dispensing site, and the need for the service. (3-21-12)

c. The remote dispensing site must be located in a medical care facility operating in areas otherwise unable to obtain pharmaceutical care services on a timely basis. (3-21-12)

d. The Board will not approve a remote dispensing site if a retail pharmacy that dispenses prescriptions to outpatients is located within the same community as the proposed remote dispensing site. (3-21-12)

02. Independent Entity Contract. Unless jointly owned, a supervising pharmacy and a remote dispensing site must enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract. (3-21-12)

a. A copy of the contract must be submitted to the Board with the initial registration application and at any time there is a substantial change in a contract term. (3-21-12)

b. The contract must be retained by the supervising pharmacy. (3-21-12)

03. PIC Responsibility. Unless an alternative PIC from the supervising pharmacy is specifically designated in writing, the PIC of the supervising pharmacy is also considered the responsible PIC for the remote dispensing site. (3-21-12)

04. Remote Dispensing Site Limitations. The Board may limit the number of remote dispensing sites under the supervision and management of a single pharmacy. (3-21-12)

05. Technician Staffing. Unless staffed by a pharmacist, ~~A~~a remote dispensing site must be staffed by at least one (1) ~~*or more*~~ certified technician~~s~~ with two thousand (2,000) hours pharmacy technician experience in Idaho and under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is open. Supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist must supervise telepharmacy operations electronically from the supervising pharmacy. ~~(3-21-12)~~( )

06. Common Electronic Recordkeeping System. The remote dispensing site and the supervising pharmacy must utilize a common electronic recordkeeping system that must be capable of the following: (3-21-12)

a. Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site; and (3-21-12)

b. Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy. (3-21-12)

07. Records Maintenance. Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, federal law. (3-21-12)

08. Video and Audio Communication Systems. A supervising pharmacy of an ADS system used in a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other

matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of such video and audio surveillance for a minimum of ninety (90) days. ~~(3-21-12)~~( )

a. Adequate supervision by the pharmacist in this setting is maintaining constant visual supervision and auditory communication with the site and full supervisory control of the automated system that must not be delegated to another person or entity. (3-21-12)

b. Video monitors used for the proper identification and communication with persons receiving prescription drugs must be a minimum of twelve inches (12") wide and provided at both the pharmacy and the remote location for direct visual contact between the pharmacist and the patient or the patient's agent. (3-21-12)

c. Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed if any component of the communication system is malfunctioning until system corrections or repairs are completed. (3-21-12)

09. Access and Operating Limitations. Unless a pharmacist is present, a remote dispensing site must not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing site, and the PIC must periodically review the record of entries. (3-21-12)

10. Delivery and Storage of Drugs. If controlled substances are maintained or dispensed from the remote dispensing site, transfers of controlled substances from the supervising pharmacy to the remote dispensing site must comply with applicable state and federal requirements. (3-21-12)

a. Drugs must only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, drug strength, and quantities included in the container. Drugs must not be delivered to the remote dispensing site unless a technician or pharmacist is present to accept delivery and verify that the drugs sent were actually received. The technician or pharmacist who receives and checks the order must verify receipt by signing and dating the list of drugs delivered. (3-21-12)

b. If performed by a technician, a pharmacist at the supervising pharmacy must ensure, through use of the electronic audio and video communications systems or bar code technology, that a technician has accurately and correctly restocked drugs into the ADS system or cabinet. (3-21-12)

c. Drugs at the remote dispensing site must be stored in a manner to protect their identity, safety, security, and integrity and comply with the drug product storage requirements of these rules. (3-21-12)

d. Drugs, including previously filled prescriptions, not contained within an ADS system must be stored in a locked cabinet within a secured area of a remote dispensing site and access must be limited to pharmacists from the supervising pharmacy and the technicians authorized in writing by the PIC. (3-21-12)

11. Wasting or Discarding of Drugs Prohibited. Wasting or discarding of drugs resulting from the use of an ADS system in a remote dispensing site is prohibited. (3-21-12)

12. Returns Prohibited. The technician at a remote dispensing site must not accept drugs returned by a patient or patient's agent. (3-21-12)

13. Security. A remote dispensing site must be equipped with adequate security. ( )

a. At least while closed, a remote dispensing site must 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. The site must have a means of recording the time of entry and the identity of all persons who access the site, which must be retained for ninety (90) days. Two (2) factoring credentialing is required for entry, which must include two (2) of the following: ( )

i. Something known (a knowledge factor); ( )

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

iii. Something biometric (finger print, retinal scan, etc.); ( )

b. A remote dispensing site 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 remote dispensing sites must meet the following security requirements: ( )

i. Walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. ( )

ii. Solid core or metal doors are required. ( )

iii. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. ( )

c. Access to the area of the remote dispensing site where prescription drugs are prepared, distributed, dispensed or stored must be limited to technicians and pharmacists. Any other persons requiring access to the remote dispensing site for legitimate business reasons may only be present in the secured area with the permission and under the supervision of a pharmacist, which may be satisfied via audio/video communication. ( )

d. A remote dispensing site must be closed for business and secured during all times a pharmacist or technician is not present. ( )

1~~3~~4. Patient Counseling. A remote dispensing site must include an appropriate area for patient counseling. (3-21-12)

a. The area must be readily accessible to patients and must be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. (3-21-12)

b. Unless onsite, a pharmacist must use the video and audio communication system to counsel each patient or the patient's caregiver on new medications. (3-21-12)

1~~4~~5. Remote Dispensing Site Sign. A remote dispensing site must display a sign, easily visible to the public, that informs patients that: (3-21-12)

a. The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy; (3-21-12)

b. Identifies the city or township where the supervising pharmacy is located; and (3-21-12)

c. Informs patients that a pharmacist is required to speak with the patient using audio and video communication systems each time a new medication is delivered or if counseling is accepted at a remote dispensing site. (3-21-12)

1~~5~~6. Pharmacist Inspection of Remote Dispensing Site. A pharmacist must complete and document a monthly in-person inspection of a remote dispensing site and inspection reports must be retained. (3-21-12)

17. Continuous Quality Improvement Program. The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. ( )

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1405

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:

Wednesday, October 22, 2014, 1:00 p.m.

Idaho Capitol Building
700 W. Jefferson St., Room WW53
Boise, Idaho 83702

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:

Congress passed the Drug Quality and Security Act in November of 2013, which mandates that states regulate wholesale distribution consistently with this new federal law. This docket of rules will fulfill our federal responsibility by striking the affected, existing rules promulgated for the Idaho Wholesale Drug Distribution Act and inserting language consistent with this new federal requirement.

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:

This docket of rules is expected to increase the number of Board registrants slightly, at one hundred thirty dollars ($130) per.

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 under Docket No. 27-0101-1401 in the July 2, 2014 Idaho Administrative Bulletin, **Vol. 14-7, page 125**, and in the August 6, 2014 Idaho Administrative Bulletin, **Vol. 14-8, page 84**.

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: NA

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, Executive Director, (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 22, 2014.

DATED this 29th Day of August, 2014.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1405
(Only those Sections being amended are shown.)

270. ~~EMERGENCY~~ DRUG DISTRIBUTION BY A DISPENSER.
~~For an emergency medical reason, pursuant to Section 54-1752(16), Idaho Code,~~ The distribution of a drug by a dispenser ~~may distribute (without obtaining a wholesale distribution registration) a drug to another dispenser,~~ is permitted only as follows: ~~(3-21-12)~~( )

01. Authorized Recipients. A dispenser may distribute prescription drugs only to a person licensed or registered by the appropriate state licensing agency to dispense or prescribe such prescription drugs. A dispenser may distribute controlled substances only to a person who holds a valid federal and Idaho state controlled substance registration, unless exempted by federal or state law. ( )

02. Authorized Dispensing. ( )

~~01~~a. Emergency Medical Reasons. ~~For purposes of this rule, an emergency medical reason is a situation where a quantity of a~~ A prescription drug ~~is needed by a dispenser without an~~ may be distributed by a dispenser to an authorized recipient if a legitimate alternative source for the drug is not reasonably available ~~and the drug is unavailable through a normal distribution channel~~ in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug. ~~(3-21-12)~~

~~02.~~ ~~Allowable Amount.~~ The amount of the drug distributed ~~must~~ in an emergency may not reasonably exceed the amount required for immediate ~~dispensing~~ use. ~~(3-21-12)~~( )

b. Office Use. Minimal quantities of prescription drugs may be distributed by a pharmacy to a prescriber for in office administration (and not for subsequent dispensing or distribution). ( )

03. Delivery Requirements. Prescription drugs distributed by a dispenser may be delivered only to the premises listed on the authorized recipient's license or registration. ( )

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

0~~3~~5. ~~Controlled Substance Distribution~~ Invoice. Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: ~~(3-21-12)~~( )

a. The date of the transaction; (3-21-12)

b. The name, address, and DEA registration number of the distributing dispenser; (3-21-12)

c. The name, address, and DEA registration number of the receiving dispenser; (3-21-12)

d. The drug name, strength, and quantity for each product distributed; and (3-21-12)

e. The signature of the person receiving the drugs. (3-21-12)

06. Reporting. Specified data on controlled substances distributed by dispensers must be reported at least monthly to the Board in a form and manner prescribed by the Board. ( )

(BREAK IN CONTINUITY OF SECTIONS)

~~***809. PRESCRIPTION DRUG PEDIGREES.***~~

~~*Each person, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, engaged in wholesale distribution of prescription drugs that leave or have left the normal distribution channel must tender a pedigree to the person receiving the drug upon delivery. A retail pharmacy or chain pharmacy warehouse must comply with these pedigree requirements only if engaging in wholesale distribution.* (3-21-12)~~

~~***01. Pedigree Contents**. A pedigree for each prescription drug must contain the following information:* (3-21-12)~~

~~***a.** The proprietary and established name of the drug;* (3-21-12)~~

~~***b.** The container size;* (3-21-12)~~

~~***c.** The number of containers;* (3-21-12)~~

~~***d.** The dosage form;* (3-21-12)~~

~~***e.** The dosage strength;* (3-21-12)~~

~~***f.** The lot number with expiration dates and the NDC;* (3-21-12)~~

~~***g.** The name of the manufacturer and repackager, if applicable, of the finished product;* (3-21-12)~~

~~***h.** The name, address, telephone number, and, if available, the e-mail address, of each owner and each wholesale distributor of the drug;* (3-21-12)~~

~~***i.** The name and address of each location from which the drug was shipped, if different from the owner's;* (3-21-12)~~

~~***j.** The dates of each transaction;* (3-21-12)~~

~~***k.** A certification that each recipient has authenticated the pedigree; and* (3-21-12)~~

~~***l.** The name and address of each recipient.* (3-21-12)~~

~~***02. Authentication**. Each person engaged in wholesale distribution who is provided a pedigree must affirmatively verify each listed transaction before further wholesale distribution may occur.* (3-21-12)~~

~~***03. Availability of Records for Inspection**. Pedigrees must be retained and made available to the Board upon request.* (3-21-12)~~

8~~1~~09. -- 849. (RESERVED)