Dear Senators HEIDER, Nuxoll, Schmidt, and
Representatives WOOD, Packer, Rusche:

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

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Fee Rule, Proposed Rule (Docket No. 27-0101-1501);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1502);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1503);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1504);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1505).

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 10/23/2015. 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 11/20/2015.

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

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

Eric Milstead
Director

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

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

FROM: Legislative Research Analyst - Elizabeth Bowen

DATE: October 5, 2015

SUBJECT: Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Fee Rule, Proposed Rule (Docket No. 27-0101-1501)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1502)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1503)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1504)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1505)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01.

The **first proposed rule** sets a flat registration or renewal fee of $35 for the sale of over-the-counter products. This simplifies the present system, under which there are two different registrations and two different fees depending on the number of over-the-counter products in stock. The fee change is expected to be budget-neutral.

The rule also:

- Modifies certain licensure requirements for foreign pharmacy school graduates to match those of in-state graduates;
- Modifies registration requirements for certified pharmacy technicians;
- Clarifies the number of experiential hours that a certified pharmacy technician must have worked to staff a remote dispensing site without an on-site pharmacist; and
- Modifies storage requirements for controlled substances in order to prevent theft.

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

The **second proposed rule** clarifies the circumstances under which drugs and devices may be dispensed to inpatients and outpatients of an institutional facility. Inpatients may be prescribed drugs or devices only:

- Upon orders from a licensed facility prescriber;
- Under emergency protocol in life-or-death situations; or

- For self-administration or use if specifically authorized by the treating or ordering prescriber.

Outpatients may be prescribed drugs or devices for self-administration or use outside of the facility if:

- Standard prescription labeling requirements are complied with; and
- The drug or device is dispensed for a limited and reasonable time to continue or supplement treatment that was administered at the facility.

In order for dispensing to outpatients to be permissible, the outpatient must have received emergency or other care or consultation from the facility, be an employee, a member of the medical staff, or a student at the facility, or be a dependent of an employee, a staff member, or a student. A facility may not dispense refills for former patients or dispense drugs or devices to walk-up customers who have no connection to the facility.

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

The **third proposed rule** defines certain terms, including "hazardous drugs," "USP 795," and "USP 797," for purposes of clarification. The rule also revises language relating to prescriber information and compounding drug products.

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

The **fourth proposed rule** establishes that the Board may:

- Suspend licensing and registration requirements during a national, state, or local emergency for individuals engaged in the scope of practice for which they're licensed in another state;
- Transfer drug outlet licenses and registrations in the event of a national, state, or local emergency; and
- Approve temporary pharmacy facilities and mobile pharmacies and arrange for monitoring and inspection of such facilities.

Additionally, the proposed rule allows existing pharmacies to relocate to a temporary pharmacy or mobile pharmacy in the event of an emergency, provided that the temporary pharmacy or mobile pharmacy is located within the affected area, notifies the Board of its proposed location, is properly secured to prevent the theft of drugs, maintains its records in accordance with the laws and rules of this state, and ceases services when the emergency is over or as otherwise authorized by the Board.

Finally, the proposed rule includes provisions relating to prescription refills during an emergency and to statewide protocol agreements.

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

The **fifth proposed rule** adds the definition of "reconstitution" for purposes of clarification. It also adds language to the existing definition of "pharmaceutical care services," again for purposes of clarification.

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

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

PROPOSED RULE COST/BENEFIT ANALYSIS

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

Department or Agency: Board of Pharmacy

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

Date: September 4, 2015

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

Fee Rule Status: _x__ Proposed ___ Temporary

Rulemaking Docket Number: 27-0101-1501

STATEMENT OF ECONOMIC IMPACT:

Currently, there are two different non-pharmacy registrations depending on how many over-the-counter products are sold by the outlet. Class A retail non-pharmacy outlets stock more than 50 drug items and pay a registration or renewal fee of $60. Class B retail non-pharmacy outlets stock fewer than 50 drug items and pay a registration or renewal fee of $25.

The proposed changes streamline this to just one registration with a $35 registration or renewal fee, allowing the sale of over-the-counter products. This change was designed to be budget neutral, and will make it easier for Idaho retailers as well as Board staff to complete registrations.

Currently, there are 299 active Class A retail non-pharmacy outlets, and 814 Class B retail non-pharmacy outlets. At current fees, this projects to $38,290 in revenue. Under the proposal, revenue is projected to be $38,955. Thus, the proposal is expected to have minimal economic impact.

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1501 (FEE RULE)

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

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

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

Currently, there are two different non-pharmacy registrations depending on how many over the counter products are sold. The changes streamline to one registration allowing the sale of over the counter products. Currently, there are different commercial lists, but the same fee. The changes simplify language to charge the same fee for all similar commercial lists. Currently, rules do not allow the cancellation of Certified Technician registration if a registrant does not maintain the required National Certification registration. The changes enable the cancelling of technician certification registration upon notification for the lapsing of National Certification. In addition, new language requires a set amount of hours required for a certified technician to be supervised in a remote dispensing location. Present language requires less experiential hours for a foreign pharmacist than it does for a U.S. citizen. New language equalizes experiential hours for both. Finally, the changes add language setting storage requirements for controlled substances to further prevent theft or diversion.

This rulemaking docket: 1) modifies the retail storage registration or annual renewal fee to a flat fee of $35 regardless of the number of drug items in stock; 2) modifies licensure requirements for foreign pharmacy graduates to increase experiential hours to match those hours required of in state students; 3) modifies registration requirements for certified pharmacy technicians to replace Institute for Certification of Pharmacy Technicians (ICPT) with National Healthcare Association certification and sets forth that failure to maintain necessary certification may result in cancellation of registration; 4) clarifies the amount of experiential hours required by a certified pharmacy technician to work in a remote dispensing site; and 5) modifies the storage requirements for controlled substances to further prevent theft or diversion.

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

The rule change modifies the retail storage registration or annual renewal fee to a flat fee of $35 regardless of the number of drug items in stock. Section 54-1720, Idaho Code, authorizes the imposition of this fee.

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: None.

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 1, 2015 Idaho Administrative Bulletin, **Vol. 15-7, page 71** and in the August 5, 2015 Idaho Administrative Bulletin, **Vol. 15-8, page 106**.

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

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

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2015.

DATED this 4th Day of September 2015.

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

THE FOLLOWING IS THE PROPOSED TEXT OF FEE DOCKET NO. 27-0101-1501
(Only Those Sections With Amendments Are Shown.)

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: (4-6-15)

(1) Initial nonresident registration: five hundred dollars ($500). (4-6-15)

(2) Initial resident registration: two hundred fifty dollars ($250). (4-6-15)

(3) Registration annual renewal: two hundred fifty dollars ($250). (4-6-15)

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

j. Retail non-pharmacy outlets. ( )

i. ~~- r~~Retail store registration or annual renewal: thirty-five dollars ($35). ~~(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)~~

ii~~i~~. "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~~ Subject to Subparagraph 021.05.d.ii. below, any registrant or licensee lists: fifty dollars ($50). ~~(3-21-12)~~( )

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

ii~~i~~. 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)

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 of completion of a minimum of ~~fifteen~~ seventeen hundred forty (1~~50~~740) experiential hours, and; ~~(4-11-15)~~( )

a. Certification by the FPGEC; or (4-11-15)

b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. (4-11-15)

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)

040. CERTIFIED PHARMACY TECHNICIAN REGISTRATION.
To be approved for registration as a certified pharmacy technician, a person must satisfy the following requirements: (3-21-12)

01. Age. Be at least eighteen (18) years of age unless a waiver is granted by the Board's executive director; (3-21-12)

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma unless a waiver is granted by the Board's executive director; (3-21-12)

03. Personal Characteristics. Be of good moral character and temperate habits; and (3-21-12)

04. Certification. Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the ~~Institute for Certification of Pharmacy Technicians (ICPT)~~ National Healthcare Association, or their successors unless qualified for a continuous employment exemption. ~~(3-21-12)~~( )

05. Cancellation of Registration. Failure to maintain the certification requirements for certified pharmacy technician registration may result in cancellation of the registration. ( )

(BREAK IN CONTINUITY OF SECTIONS)

210. CONTROLLED SUBSTANCE STORAGE.
Controlled substances must be stored as follows: ( )

01. Schedule I. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. ( )

02. Schedules II, III, IV and, V. Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and prescribers may disperse such substances, in whole or in part, throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. ( )

21~~0~~1. -- 219. (RESERVED)

(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 remote dispensing site must be staffed by at least one (1) certified technician with at least 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. ~~(4-11-15)~~( )

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. (4-11-15)

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. (4-11-15)

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: (4-11-15)

i. Something known (a knowledge factor); (4-11-15)

ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)

iii. Something biometric (finger print, retinal scan, etc.); (4-11-15)

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: (4-11-15)

i. Walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

ii. Solid core or metal doors are required. (4-11-15)

iii. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

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. (4-11-15)

d. A remote dispensing site must be closed for business and secured during all times a pharmacist or technician is not present. (4-11-15)

14. 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)

15. 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)

16. 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. (4-11-15)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1502

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

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

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

This rulemaking is necessary to clarify the dispensing of drugs and devices within an institutional facility. This rulemaking provides new language to clarify and list to whom an institutional facility may dispense drugs and devices.

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. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, **Vol. 15-7, page 71** and in the August 5, 2015 Idaho Administrative Bulletin, **Vol. 15-8, page 106**.

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

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

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2015.

DATED this 4th Day of September 2015.

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Board of Pharmacy
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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1502
(Only Those Sections With Amendments Are Shown.)

620. INSTITUTIONAL FACILITY: PRACTICE OF PHARMACY AND ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
These institutional facility rules are applicable to the practice of pharmacy and the administration and control of drugs and devices ~~within~~ by institutional facilities or by persons employed by them. ~~(3-21-12)~~( )

(BREAK IN CONTINUITY OF SECTIONS)

630. INSTITUTIONAL FACILITY: GENERAL STANDARDS FOR ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
~~01. Drugs and Devices Dispensed for Administration or Use Within an Institutional Facility.~~ Within an institutional facility, drugs and devices may be dispensed for administration to, or for self-administration or use by, a patient ~~while in the institutional facility~~ only as permitted by applicable law and these rules consistent with usual and customary standards of good medical practice~~, as follows~~: ~~(3-21-12)~~( )

01. Drugs and Devices Dispensed for Administration Within an Institutional Facility. Drugs and devices must only be dispensed to inpatients of an institutional facility: ( )

a. Upon the drug orders of licensed facility prescribers; (3-21-12)

b. Pursuant to an emergency protocol for the administration of drugs without an order in life or death situations; ~~and~~ or ~~(3-21-12)~~( )

c. ~~By~~ For self-administration or use if specifically authorized by the treating or ordering prescriber, the patient has been appropriately educated and trained to perform self-administration, and there is no risk of harm. ~~(3-21-12)~~( )

02. Drugs and Devices Dispensed for Administration or Use Outside an Institutional Facility. A drug or device prepared for self-administration or use by a patient while outside the confines of the institutional facility must comply with the standard prescription drug labeling requirements~~.~~, only be dispensed for a limited and reasonable time as a continuation of or supplemental to treatment that was administered at the hospital and subject to the following: ~~(3-21-12)~~( )

a. Permissible dispensing; ( )

i. To emergency room patients pursuant to these rules; ( )

ii. To other outpatients who receive treatment or consultation on the premises; and ( )

iii. To hospital employees, medical staff, and students at the hospital and their dependents, for their own personal use only and not for resale. ( )

b. Impermissible activities include dispensing refills for former patients and dispensing to walk up customers who have no connection to the hospital. ( )

03. Controlled Substances Reporting and Documentation. Distribution, dispensing, delivery, or administration of controlled substances within an institutional facility or by facility personnel must be properly and adequately documented and reported in the time and manner required by the appropriate committee of the institutional facility and the director. (3-21-12)

04. Patient's Personal Drug Supplies. If an admitted patient brings a drug into the institutional facility, the drug must not be administered or used except pursuant to a drug order and only if it can be precisely identified and the quantity and quality of the drug visually evaluated by a pharmacist. (3-21-12)

a. If a patient's drug will not be administered or used, the pharmacy must package, seal, and return the

drug to an adult member of the patient's immediate family or store and return it to the patient upon discharge. (3-21-12)

b. Drugs not returned to the patient or the patient's family may be disposed of after a reasonable number of days following discharge or death. (3-21-12)

05. Suspected Adverse Drug Reaction Reporting. Suspected adverse drug reactions must be communicated in a timely manner to the pharmacy. (3-21-12)

06. Required Pharmacy Returns. Discontinued, expired, and damaged drugs and containers with worn, illegible, or missing labels must be returned to the pharmacy for proper handling. (3-21-12)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1503

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

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

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

This rulemaking docket streamlines, clarifies and adds missing or incomplete language. Current language is missing in the definitions associated with compounding of drugs. These changes clarify the language to add a hazardous drug definition, and definitions of USP 795 and USP 797. The changes clarify the components of a prescription drug order to include the prescriber phone number. These changes add language to allow certain product preparations to not be considered compounded if combined according to the manufacturer's labeling.

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. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, **Vol. 15-7, page 71** and in the August 5, 2015 Idaho Administrative Bulletin, **Vol. 15-8, page 106**.

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 Alex Adams, Executive Director, at (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2015.

DATED this 4th Day of September 2015.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1503
(Only Those Sections With Amendments 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 and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (4-11-15)

06. Biosimilar. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (4-11-15)

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

08. 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)

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

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

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)

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

13. 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)

14. 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)

15. **CME**. Continuing medical education. (3-21-12)

16. **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)

17. **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)

18. **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)

19. **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)

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)

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

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

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

24. **DME**. Durable medical equipment. (3-21-12)

25. **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)

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

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

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

29. **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)

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

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

32. **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)

33. **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)

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

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

a. Carcinogenicity; ( )

b. Teratogenicity or developmental toxicity; ( )

c. Reproductive toxicity in humans; ( )

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

e. Genotoxicity; or ( )

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

3~~5~~6. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

3~~6~~7. **Hospital System**. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

3~~7~~8. **Idaho State Board of Pharmacy or Idaho Board of Pharmacy**. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (3-21-12)

3~~8~~9. **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)

~~39~~40. **Institutional Pharmacy**. A pharmacy located in an institutional facility. (3-21-12)

4~~0~~1. **Interchangeable Biosimilar**. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (4-11-15)

(BREAK IN CONTINUITY OF SECTIONS)

012. DEFINITIONS AND ABBREVIATIONS (S -- Z).

01. **Sample**. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (3-21-12)

02. Secured Pharmacy. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-21-12)

03. Skilled Nursing Facility. An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (3-21-12)

04. Student Pharmacist. A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. (3-21-12)

05. Technician. Unless specifically differentiated, a term inclusive of pharmacy technician, certified pharmacy technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (3-21-12)

06. Telepharmacy. The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (3-21-12)

07. Therapeutic Equivalent Drugs. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). (4-4-13)

08. Unit Dose. Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (3-21-12)

09. USP. United States Pharmacopeia. (3-21-12)

10. USP-NF. United State Pharmacopeia-National Formulary. (3-21-12)

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

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

1~~1~~3. VAWD -- Verified Accredited Wholesale Distributor. An accreditation program for wholesale distributors offered through NABP. (3-21-12)

1~~2~~4. VDO -- Veterinary Drug Outlet. A registered establishment that employs a qualified VDT to distribute prescription veterinary drugs pursuant to lawful orders of a veterinarian. (3-21-12)

1~~3~~5. VDT -- Veterinary Drug Technician. A non-pharmacist qualified by registration with the Board to distribute prescription veterinary drugs in a VDO. (3-21-12)

1~~4~~6. Veterinary Drug Order. A lawful order by a veterinarian issued pursuant to the establishment of a veterinarian-patient-client relationship as recognized by the American Veterinary Medical Association. (3-21-12)

1~~5~~7. VIS. Vaccine Information Statement. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

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

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

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

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

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

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

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

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

06. Signature. If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, or if statutorily allowed, the prescriber's agent's signature, and if electronic, the prescriber's electronic signature. (3-20-14)

(BREAK IN CONTINUITY OF SECTIONS)

239. COMPOUNDING DRUG PRODUCTS.
Any compounding that is not permitted herein is considered manufacturing. (4-11-15)

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: (4-11-15)

a. Compound positron emission tomography drugs; (4-11-15)

b. Radiopharmaceutics; (4-11-15)

c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; ~~and~~ ~~(4-11-15)~~( )

d. The addition of a flavoring agent to a drug product~~.~~; and ~~(4-11-15)~~( )

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

02. General Compounding Standards. (4-11-15)

a. Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. (4-11-15)

b. Certificate of Analysis. Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a CO must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is required on the COA: (4-11-15)

i. Product name; (4-11-15)

ii. Lot number; (4-11-15)

iii. Expiration date; and (4-11-15)

iv. Assay. (4-11-15)

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (4-11-15)

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. (4-11-15)

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. (4-11-15)

04. Limited Compounding. (4-11-15)

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. (4-11-15)

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: (4-11-15)

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (4-11-15)

ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (4-11-15)

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. (4-11-15)

05. Drug Compounding Controls. (4-11-15)

a. Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: (4-11-15)

i. Appropriate packaging, handling, transport, and storage requirements; (4-11-15)

ii. Accuracy and precision of calculations, measurements, and weighing; (4-11-15)

iii. Determining ingredient identity, quality, and purity; (4-11-15)

iv. Labeling accuracy and completeness; (4-11-15)

v. Beyond use dating; (4-11-15)

vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (4-11-15)

vii. Maintaining environmental quality control; and (4-11-15)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (4-11-15)

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. (4-11-15)

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: (4-11-15)

i. Production date; (4-11-15)

ii. Beyond use date; (4-11-15)

iii. List and quantity of each ingredient; (4-11-15)

iv. Internal control or serial number; and (4-11-15)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (4-11-15)

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1504

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

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

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

This rulemaking docket adds missing or incomplete language allowing for statewide protocols. In the event of a federal or state declared emergency, new language would allow a pharmacist to perform drug therapy management as well as other patient care services according to statewide protocol in conjunction with the Board of Pharmacy and the Idaho Department of Health and Welfare. In addition, changes would allow for the suspension of requirements for those engaged in the scope of practice for which they are licensed in another state. New language would also allow for temporary pharmacies as well as mobile pharmacies and requirements therefor. Changes also provide that a pharmacist be allowed to refill prescriptions essential to the patients' health or continuation of therapy.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, **Vol. 15-7, page 71** and in the August 5, 2015 Idaho Administrative Bulletin, **Vol. 15-8, page 106**.

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 Alex Adams, Executive Director, at (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2015.

DATED this 4th Day of September 2015.

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THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1504
(Only Those Sections With Amendments Are Shown.)

016. BOARD OF PHARMACY LICENSURE AND REGISTRATION.
The Board is responsible for the control and regulation of the practice of pharmacy in or into the state of Idaho, which includes the licensure or registration of professional, supportive, and ancillary personnel who engage in or support the practice. The Board is also responsible for the control, regulation, and registration of persons or drug outlets that manufacture, distribute, or dispense controlled substances within or into the state. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions, except that the Board may suspend such requirements for the duration of a national, state or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, for individuals engaged in the scope of practice for which they are licensed in another state. ~~(3-21-12)~~( )

01. Pharmacy Practice Act Licenses and Registrations. The Board will issue or renew a license or a certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act and any additional criteria specified by these rules for the license or registration classification. Licenses and certificates of registration issued pursuant to Title 54, Chapter 17, Idaho Code, expire annually on June 30 unless an alternate expiration term or date is specifically stated in these rules. (3-21-12)

02. Idaho Controlled Substances Act Registrations. The Board will issue or renew controlled substance registrations upon application and determination that the applicant has satisfied the requirements of the Idaho Controlled Substances Act and any additional criteria specified by state or federal law applicable to applicants that manufacture, distribute, or dispense, or conduct research with, controlled substances. Registrations issued pursuant to Title 37, Chapter 27, Idaho Code, must be renewed annually by June 30 for pharmacists and by December 31 for all other registrants. (4-4-13)

a. Unless a wholesaler, an applicant for an Idaho controlled substance registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances and, unless a pharmacist or certified euthanasia technician, a valid federal DEA registration. If a required license or registration is cancelled or otherwise invalidated by the issuing agency, the Idaho controlled substance registration will be correspondingly cancelled. (3-21-12)

b. A registrant engaging in more than one (1) group of independent activities, as defined by federal law, must obtain a separate Idaho controlled substance registration for each group of activities if not exempted from separate DEA registration by federal law. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

060. DRUG OUTLET LICENSURE AND REGISTRATION.
A license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. (3-21-12)

01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location and the drug outlet may not open for business prior to satisfactory completion of the opening inspection, if required. (3-21-12)

02. Licenses and Registrations ~~*Nontransferable*~~ Transferability. ( )

a. Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place, except in the event of a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. ~~(3-21-12)~~( )

b. Temporary Pharmacy Facilities and Mobile Pharmacies. The Board may approve or disapprove temporary pharmacy facilities and mobile pharmacies and shall make arrangements for appropriate monitoring and inspection of such facilities on a case-by-case basis. To provide pharmacy services during a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy: ( )

i. Is under the control and management of the pharmacist-in-charge or designated supervising pharmacist; ( )

ii. Is located within the declared disaster area or affected areas; ( )

iii. Notifies the Board of its proposed location; ( )

iv. Is properly secured to prevent theft and diversion of drugs; ( )

v. Maintains records in accordance with laws and rules of the state; and ( )

vi. Ceases the provision of services with the termination of the declared emergency, or as otherwise authorized by the Board. ( )

03. Nonresident Drug Outlet. The Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. (7-1-13)

(BREAK IN CONTINUITY OF SECTIONS)

116. PRESCRIPTION DRUG ORDER: REFILLS.

01. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal laws and only as specifically authorized by the prescriber. (3-21-12)

a. A pharmacist, utilizing his best professional judgment, may dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills. (3-21-12)

b. Refills exceeding those authorized by the prescriber on the original prescription drug order may only be authorized through issuance of a new and separate prescription drug order. (3-21-12)

02. Emergency Prescription Refills. A pharmacist may refill a prescription for a patient when: ( )

a. ~~t~~The prescriber is not available for authorization if, in the professional judgment of the pharmacist, a situation exists that threatens the health or safety of the patient should the prescription not be refilled. Only sufficient medication may be provided, consistent with the dosage instructions, to maintain the prescribed treatment until, at the earliest possible opportunity, the issuing or an alternative prescriber is contacted for further renewal instructions. ~~(3-21-12)~~( )

b. Upon the declaration of a national, state, or local emergency by the President of the United States,

the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, and subject to the provisions of Subsection 310.02 of these rules, a pharmacist may dispense a refill of a prescription drug, not to exceed a thirty (30)-day supply if, in the pharmacist's professional judgment, the prescription drug is essential to the patient's health or continuation of therapy. ( )

(BREAK IN CONTINUITY OF SECTIONS)

310. PHARMACIST: COLLABORATIVE PHARMACY PRACTICE AND STATEWIDE PROTOCOL AGREEMENTS.

01. Collaborative Agreement. Pharmacists and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. ~~(3-21-12)~~( )

~~01~~a. Agreement Elements. The collaborative pharmacy practice agreement must include: (3-21-12)

~~a~~i. Identification of the parties to the agreement; (3-21-12)

~~bi~~i. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; (3-21-12)

~~c~~iii. The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; (3-21-12)

~~d~~iv. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; (3-21-12)

~~e~~v. A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; (3-21-12)

~~f~~vi. A provision allowing any party to cancel the agreement by written notification; (3-21-12)

~~g~~vii. An effective date; and (3-21-12)

~~h~~viii. Signatures of the parties to the agreement and dates of signing. (3-21-12)

ix. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (3-21-12)

~~02~~b. Board Review. The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. (3-21-12)

~~03~~c. Agreement Review. The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. (3-21-12)

~~04~~d. Documentation of Pharmacist Activities. The patient care provided pursuant to the agreement must be documented in the patient's permanent record in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. (3-21-12)

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

a. An effective date; ( )

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

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

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1505

NOTICE OF RULEMAKING - PROPOSED RULE

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

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be scheduled if requested in writing by twenty-five (25) persons, a political subdivision, or an agency, not later than October 21, 2015.

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

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

This rulemaking clarifies and adds missing language in definitions. The changes provide needed updating and additional language to definitions. Pharmaceutical Care Services is updated by adding the ability to order and interpret laboratory tests. Reconstitution definition is also added to provide clarification as to what is considered compounding as opposed to reconstitution of a drug.

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

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

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published under Docket No. 27-0101-1501 in the July 1, 2015 Idaho Administrative Bulletin, **Vol. 15-7, page 71** and in the August 5, 2015 Idaho Administrative Bulletin, **Vol. 15-8, page 106**.

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

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

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 28, 2015.

DATED this 4th Day of September 2015.

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

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1505
(Only Those Sections With Amendments 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. (4-6-15)

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

11. 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. Ordering and interpreting laboratory tests; and ( )

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

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

13. 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)

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

15. 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)

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

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

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)

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

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)

21. Purple Book. The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. (4-11-15)

22. 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)

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

2324. Relative Contraindication. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

2425. 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)

2526. 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)

2627. Retail Non-Pharmacy Drug Outlet. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

2728. Retail Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

2829. R.N. Registered nurse. (3-21-12)