

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 - Proposed Rule (Docket No.  
27-0101-1601);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No.  
27-0101-1602);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No.  
27-0101-1603);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No.  
27-0101-1604).

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 10/21/2016. 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 11/18/2016.

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:** Senior Legislative Research Analyst - Elizabeth Bowen

**DATE:** October 03, 2016

**SUBJECT:** Board of Pharmacy

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1601)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1602)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1603)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy - Proposed Rule (Docket No. 27-0101-1604)

The Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01. There are four proposed rules. Negotiated rulemaking was conducted for each one, and none of the rules has a negative fiscal impact on the state general fund. The Board states that the rulemaking is authorized pursuant to Section 54-1717, Idaho Code, which grants the Board rulemaking authority.

The first rule, Docket No. 27-0101-1601, revises existing rules to conform to several bills passed by the Legislature in the 2016 session, including House Bills 338, 373, 374, and 481, and Senate Bill 1322. The rule:

- Allows emergency medication kits to be housed at specialty infusion clinics;
- Allows regional behavioral health clinics to donate and receive donated medications to distribute to medically indigent patients;
- Allows the delegate of a licensed prescriber or pharmacist to access the Prescription Monitoring Program;
- Provides that investigational drugs, by themselves, are not products that would require registration by an entity as a prescriber drug outlet; and
- Allows prescription medications to be labeled in the name of an entity, such as a school, authorized to receive them.

The second rule, Docket No. 27-0101-1602, revises rules relating to telepharmacy in order to update them and reflect modern practice. Revisions include a streamlined registration process for remote dispensing sites, staffing requirements for remote dispensing sites, requirements for video and audio communication systems, and inventory requirements. Language that is duplicative of other rules has also been removed.

Mike Nugent, Manager  
Research & Legislation

Cathy Holland-Smith, Manager  
Budget & Policy Analysis

April Renfro, Manager  
Legislative Audits

Glenn Harris, Manager  
Information Technology

The third rule, Docket No. 27-0101-1603, revises pharmacy technician rules. The revisions allow pharmacists to delegate certain tasks to pharmacy technicians who meet training, registration, and certification requirements and allow qualified technicians to perform remote data entry.

The fourth rule, Docket No. 27-0101-1604, clarifies and updates existing rules based on recent inspections and Board hearings. The revisions include:

- Updated security requirements for pharmacies;
- Greater authority for emergency rooms to dispense medications;
- Greater authority for pharmacists to coordinate medication refills;
- Required notice to the Board, within two business days, of medication errors that result in fatalities; and
- Updated requirements for licensure applicants, including for reciprocal licenses.

cc: Board of Pharmacy  
Alex Adams, PharmD, MPH

## **IDAPA 27 - BOARD OF PHARMACY**

### **27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY**

**DOCKET NO. 27-0101-1601**

#### **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 Sections 37-2715, 37-2726(5) and 54-1717, Idaho Code.

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

**Wednesday, October 26, 2016 – 1:00 pm (MDT)**

**Idaho State Capitol Building  
Room WW53  
514 West Jefferson  
Boise, ID**

For those planning to attend the open, public hearing, written and verbal comments will be accepted by and/or presented before the Board. For all others not planning to attend the meeting, written comments will be accepted by the Executive Director on or before October 25, 2016 as follows:

- Written comments received by October 12, 2016 will be included in the Board's distributed meeting materials for consideration in advance of the meeting;
- Written comments received between October 13, 2016 and October 25, 2016 will be printed and provided to the Board at the open, public hearing.

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

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

The 2016 Idaho Legislature passed several bills that necessitate conforming changes in Board rules. The specific bills are HB 338, HB 373, HB 374, HB 481, and SB 1322a. The rulemaking aims to update existing Board rules to conform to the newly passed legislation. Specifically, the rule updates will:

- Expand the venues at which emergency medication kits can be housed to include specialty infusion clinics.
- Allow Idaho's Regional Behavioral Health Clinics to donate and receive donated medications to dispense to medically indigent patients.
- Enable delegate access to the Prescription Monitoring Program.
- Exempt investigational drugs from the products that necessitate registration as a prescriber drug outlet.
- Allow prescription medications to be labeled in the name of an authorized entity.

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

**FISCAL IMPACT:** The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year 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 in the June 1, 2016 Idaho Administrative Bulletin, [Vol. 16-6, pages 49-50](#).

**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 or at [alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov).

DATED this 5th Day of August, 2016

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

**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1601**  
**(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; (3-25-16)
  - m.**     Ordering and interpreting laboratory tests; and (3-25-16)
  - 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 or investigational drugs as permitted in Title 39, Chapter 93, Idaho Code. ~~(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. (3-25-16)
- 24. Relative Contraindication.** A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

**25. 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)

**26. 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)

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

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

**29. R.N.** Registered nurse. (3-21-12)

**(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. Name.** (4-11-15)

**a.** If a person, the name of the patient or other person authorized to possess a legend drug in accordance with Idaho Code; (4-11-15)( )

**b.** If an animal, the name and species of the patient; or (4-11-15)

**c.** If a ~~school for epinephrine auto-injectors pursuant to Section 33-520A;~~ facility or other entity is authorized to possess a legend drug in accordance with Idaho Code, the name of the ~~school~~ facility or entity; (4-11-15)( )

**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. (4-11-15)
- 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," except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. (4-11-15)
- 13. **Identification.** The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. (4-11-15)

**(BREAK IN CONTINUITY OF SECTIONS)**

**204. CONTROLLED SUBSTANCES: PMP.**

Specified data on controlled substances must be reported ~~weekly, or more often as required~~ by the ~~Board~~, end of the next business day by all ~~pharmacies holding a DEA retail pharmacy registration entities~~ that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. ~~(4-4-13)~~( )

**01. Online Access to PMP.** Online access to the Board's PMP is limited to licensed prescribers and pharmacists, or their delegates, for treatment purposes. To obtain online access, a prescriber or pharmacist, or their delegate must: ~~(3-21-12)~~( )

- a. Complete and submit a registration application and a written agreement to adhere to the access restrictions and limitations established by law; (3-21-12)
- b. Obtain Board approval for access; and (3-21-12)
- c. Be issued a user account, login name, and password. (3-21-12)

**02. Use Outside Scope of Practice Prohibited.** Information obtained from the PMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. A delegate may not access the PMP outside of their supervisor's scope of professional practice. ~~(3-21-12)~~( )

**03. Profile Requests.** Authorized persons without online access may obtain a profile by completing the required form and submitting it to the Board office with proof of identification and other credentials required to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. (3-21-12)

**04. Suspension, Revocation, or Restriction of PMP Access.** Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's, ~~or~~ pharmacist's, or delegate's authorization for online access to the PMP. ~~(3-21-12)~~( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**265. LEGEND DRUG DONATION -- STANDARDS AND PROCEDURES.**

**01. Drug Donation Criteria.** A drug considered for donation to a qualifying charitable clinic or center must meet the following eligibility criteria or it must not be accepted for donation. (3-21-12)

- a. The drug name, strength, lot number, and expiration date must appear on the package or label. (3-21-12)
- b. The drug must be FDA-approved and: (3-21-12)
  - i. Be in the original unit dose packaging; or (3-21-12)
  - ii. Be an oral or parenteral drug in a sealed, single dose container approved by the FDA; or (3-21-12)
  - iii. Be a topical or inhalant drug in a sealed, unit-of-use container approved by the FDA; or (3-21-12)
  - iv. Be a parenteral drug in a sealed, multiple dose container approved by the FDA from which no doses have been withdrawn. (3-21-12)

v. Be a patient assistant program drug, which must be originally received by the qualified donor, and remain under the control and storage of the donor. ( )

c. The drug must not be the subject of a mandatory recall by a state or federal agency or of a voluntary recall by a drug wholesaler or manufacturer. (3-21-12)

d. The drug must not require storage temperatures other than normal room temperature as specified by the manufacturer or the USP. (3-21-12)

e. The drug must not be subject to an FDA-restricted drug distribution program such as and including, but not limited to, thalidomide and lenalidomide. (3-21-12)

**02. Donation Standards.** (3-21-12)

a. A pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority at the qualifying charitable clinic or center must be designated as responsible for defining the drugs included in the qualifying charitable clinic or center's formulary. (3-21-12)

b. ~~Donating nursing homes~~ A qualified donor may only donate drugs that appear on the formulary. ~~(3-21-12)~~( )

c. Prior to the delivery of donated drugs to the qualifying charitable clinic or center, a pharmacist, nurse, physician, or physician assistant from the ~~donating nursing home~~ qualified donor must sign and date a manifest that: ~~(3-21-12)~~( )

i. Attests that the donated drugs have been maintained in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and the USP standards; (3-21-12)

ii. Attests that the drugs have been continuously under the control of a healthcare professional and have never been in the custody of a patient or other individual; (3-21-12)

iii. Attests that the donated drugs are those qualified for donation by their inclusion in the qualifying charitable clinic or center's formulary; (3-21-12)

iv. Attests that the donation is fully compliant with these rules; (3-21-12)

v. Attests that all PHI has been removed or redacted from the package; (3-21-12)

vi. Lists the name of the ~~donating nursing home~~ qualified donor and the name of the receiving

qualifying charitable clinic or center; and ~~(3-21-12)~~( )

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug donated. (3-21-12)

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. (3-21-12)

**03. Receipt and Handling of Donated Drugs.** Donated drugs may be received and handled at a qualifying charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or other authorized clinic or center personnel. (3-21-12)

**04. Verification of Received Drugs.** Qualified recipients must meet the following requirements, except in the instance in which a qualified recipient and a qualified donor are the same entity as permitted in Idaho Code: ~~(3-21-12)~~( )

a. Each donated drug must be verified against the donation manifest by an individual authorized to receive the drugs. (3-21-12)

b. If all PHI has not been removed by the donating entity, the information must be removed or redacted prior to dispensing. (3-21-12)

c. Before donated drugs are placed with a qualifying charitable clinic or center's regular stock, a pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must: (3-21-12)

i. Using a current drug identification book, a computer program, or an online service, verify that each donated drug unit meets the criteria specified by these rules; (3-21-12)

ii. Verify that the name and strength indicated on the label of each donated drug unit is correct; and (3-21-12)

iii. Determine for each donated drug that it is not adulterated or misbranded and is safe to dispense. (3-21-12)

d. Donated drugs that do not meet the criteria of these rules must be destroyed and documentation of the destruction retained. (3-21-12)

**05. Storage of Donated Drugs.** (3-21-12)

a. Donated drug storage must have proper environmental controls to ensure the integrity of the drug in accordance with the manufacturer's recommendations and USP standards. (3-21-12)

b. Donated drugs may be commingled with the qualifying charitable clinic or center's regular stock of drugs only if the packaging on the donated drug has been labeled to indicate that the drug was obtained from a nursing home qualified donor and otherwise must be segregated. ~~(3-21-12)~~( )

c. The drug storage area must be secured at all times and accessible only to persons authorized to handle donated drugs. (3-21-12)

**06. Dispensing Donated Drugs.** (3-21-12)

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not stored in appropriate conditions must not be re-dispensed, must be destroyed, and their destruction must be appropriately documented. (3-21-12)

b. A pharmacist, physician, physician assistant, dentist, optometrist, or an advanced practice

professional nurse with prescriptive authority at a qualifying charitable clinic or center who re-dispenses donated drugs to a patient must: (3-21-12)

- i. Use an appropriate container; (3-21-12)
- ii. Label the container as required by these rules except that the expiration date must be the same as on the original container; and (3-21-12)
- iii. Initial the prescription label. (3-21-12)
- c. A qualifying charitable clinic or center must retain records for each donated drug dispensed. (3-21-12)
- d. Pharmacists, physicians, physician assistants, dentists, optometrists, and advanced practice professional nurses with prescriptive authority dispensing donated drugs must perform prospective drug review and provide patient counseling. (3-21-12)

**07. Miscellaneous.** (3-21-12)

- a. The qualifying charitable clinic or center must maintain a list of the names of authorized clinic or center personnel, their individual duties, and a summary of their qualifications. (3-21-12)
- b. A qualifying charitable clinic or center that receives donated drugs must adopt policies and procedures requiring and with sufficient detail to ensure that authorized clinic or center personnel will comply with applicable local, state, and federal laws. (3-21-12)
- c. Drugs donated pursuant to these rules must not be sold, resold, offered for sale, traded, or transferred to another qualifying charitable clinic or center. (3-21-12)
- d. Nothing in these rules precludes a qualifying charitable clinic or center from charging a dispensing fee. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**635. INFUSION CLINIC, HOME HEALTH OR HOSPICE EMERGENCY KITS.**

A pharmacy may supply emergency kits ~~for~~ to an infusion clinic, or to state licensed or Medicare certified home health or hospice agencies, ~~or both~~, as follows: (3-21-12)( )

**01. Storage and Security.** Emergency kits used by infusion clinics or home health or hospice agencies must be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs, except that nurses licensed by the Idaho Board of Nursing and employed by affiliated with the supplying pharmacy, an infusion clinic, or a state-licensed or Medicare-certified home health or hospice agency, may carry emergency kits on their person while on duty and in the course and scope of their employment for affiliation with the pharmacy, clinic, or agency. While not on duty or working within the course and scope of their employment affiliation, the nurses must return the emergency kits to a locked storage area or supplying pharmacy. (3-21-12)( )

**02. Prescription Drugs.** Prescription drugs included in a home health or hospice agency emergency kit must remain the property of, and under the responsibility of, the Idaho-registered supplying pharmacy. (3-21-12)

**03. Controlled Substances.** Emergency kits supplied to infusion clinics or home health or hospice agencies must not include controlled substances. (3-21-12)( )

## **IDAPA 27 - BOARD OF PHARMACY**

### **27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY**

**DOCKET NO. 27-0101-1602**

#### **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 26, 2016 – 1:00 pm (MDT)**

**Idaho State Capitol Building  
Room WW53  
514 West Jefferson  
Boise, ID**

For those planning to attend the open, public hearing, written and verbal comments will be accepted by and/or presented before the Board. For all others not planning to attend the meeting, written comments will be accepted by the Executive Director on or before October 25, 2016 as follows:

- Written comments received by October 12, 2016 will be included in the Board's distributed meeting materials for consideration in advance of the meeting;
- Written comments received between October 13, 2016 and October 25, 2016 will be printed and provided to the Board at the open, public hearing.

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

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

The Board needs to update and modernize its telepharmacy rules given advancements in technology. The proposed updates will also incorporate several waivers the Board has already granted to telepharmacy petitioners. The proposed updates will do the following:

- Allow streamlined registration of remote dispensing sites to applicants who meet certain criteria.
- Broaden the technology that may be used at a remote dispensing site beyond just an Automated Dispensing System.
- Remove the requirement that a remote dispensing site be co-located with a medical care facility.
- Remove the requirement that business contracts be filed with the Board.
- Update limits on the oversight of multiple remote dispensing sites.
- Remove duplicative language from the telepharmacy rules that are already specified in other existing Board rules.

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

**FISCAL IMPACT:** The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year 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 in the June 1, 2016

Idaho Administrative Bulletin, **Vol. 16-6, pages 49-50**, under Docket No. 27-0101-1601.

**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 or at [alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov).

DATED this 5th Day of August, 2016

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**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1602**  
**(Only Those Sections With Amendments Are Shown.)**

**071. REMOTE DISPENSING SITE REGISTRATION.**

**01. Remote Dispensing Site Registration.** A limited service outlet registration must be obtained by a remote dispensing site prior to participating in the practice of telepharmacy. (3-21-12)

**02. Supplemental Registration Application Requirements.** Prior to construction, an applicant for registration of a remote dispensing site must submit ~~and obtain Board approval of~~ a registration application. The application must include: (3-21-12)( )

**a.** An attached description of the telepharmacy communication, electronic recordkeeping, and ~~ADS~~ electronic verification systems; (3-21-12)( )

**b.** The operating specifications including location, ownership, current levels of pharmacist and technician staffing, and current number of supervised remote dispensing sites; ~~and~~ (3-21-12)( )

**c.** An accurate scale drawing of the facility that illustrates: (3-21-12)

**i.** The layout and location of the systems; (3-21-12)

**ii.** The location of a patient counseling area; and (3-21-12)

**iii.** All access points to the electronic recordkeeping system and the ~~ADS~~ electronic verification system. (3-21-12)( )

**iv.** A description of the proposed supervising pharmacy located in Idaho. ( )

**03. Approval of Registration.** Prior to approval of an initial registration, an applicant with a proposed

remote dispensing site located within fifteen (15) road miles of an existing retail pharmacy must appear before the Board and demonstrate to the Board how the proposed remote dispensing site will promote public health and safety in the community. ( )

(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)

**021. 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 and made available to the Board upon request.~~ (3-21-12)( )

**032. 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)

**043. Remote Dispensing Site Staffing and Limitations.** The ~~Board may limit the number of PIC and pharmacist-on-duty are responsible for ensuring that the supervising pharmacy and~~ remote dispensing sites ~~under the are sufficiently staffed to allow for appropriate supervision and management of a single pharmacy that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.~~ (3-21-12)( )

~~a. A pharmacist may neither be designated nor function as the PIC of more than two (2) total locations at one time;~~ ( )

~~b. The ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) students and technicians in total at the supervising pharmacy and remote dispensing sites; and~~ ( )

~~c. A designated pharmacist must be capable of being on site at the remote dispensing site within twelve (12) hours if an emergency arises.~~ ( )

**054. 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 All technicians must remain under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is open operational. 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. (3-24-16)(\_\_\_\_)

**065. 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)

**076. 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)

**087. 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* facility surveillance, excluding patient communications, 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~~ if applicable, and 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, be of high definition 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. The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and HIPAA-compliant. (\_\_\_\_)

d. 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 to the public if any component of the communication system is malfunctioning until system corrections or repairs are completed. (3-21-12)(\_\_\_\_)

**098. 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)

~~109.~~ **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, unless placed in a secure delivery area in accordance with state and federal law. 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, as applicable. (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~~ manner 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)~~

**130. 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)~~

~~**e.** 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)~~

**141. 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 HIPAA-compliant the video and audio communication system to counsel each patient or the patient's caregiver on new medications. (3-21-12)( )~~

**152. 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~~ and if counseling is accepted on a refill at a remote dispensing site. (3-21-12)( )

**163. Pharmacist Inspection and Inventories of Remote Dispensing Site.** A pharmacist must complete and document: ( )

~~a. A monthly in-person self-inspection of a remote dispensing site using a form designated by the Board and such inspection reports must be retained: (3-21-12)( )~~

~~b. A perpetual inventory must be kept for all Schedule II controlled substances; and ( )~~

~~c. Three (3) controlled substances must be audited and documented quarterly by the pharmacist. ( )~~

**174. Continuous Quality Improvement Program.** The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. This program must be made available to the Board upon request. (4-11-15)( )

**711. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: PRESCRIPTION DRUG ORDERS.**

~~*Prescription drug orders dispensed from a remote dispensing site must be previously filled by the supervising pharmacy or, unless a pharmacist is present, must only be filled on the premises of a remote dispensing site through the use of an ADS system and as follows:* (3-21-12)~~

**01. Pharmacist Verification of New Prescription Drug Order Information.** If a technician at the remote dispensing site enters original or new prescription drug order information into the automated pharmacy system, the pharmacist at the supervising pharmacy must, prior to approving, verify the information entered against a faxed, electronic, or video image of the original prescription. (3-21-12)

a. The technician may transmit the prescription drug order to the pharmacist by scanning it into the electronic recordkeeping system if the means of scanning, transmitting, or storing the image does not obscure the prescription information or render the prescription information illegible. (3-21-12)

b. Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription via video communication systems between the remote dispensing site and the supervising pharmacy. Using the video communication, the pharmacist must verify the accuracy of the drug dispensed and must check the prescription label for accuracy, unless checked in compliance with the accuracy checking technician procedures. (3-21-12)( )

c. Except when prohibited by law for controlled substances, the technician may also transmit the prescription drug order to the supervising pharmacist by fax. (3-21-12)

~~d. A technician at a remote dispensing site must not receive oral prescription drug orders from a prescriber or a prescriber's agent. Oral prescription drug orders must be communicated directly to a pharmacist. (3-21-12)~~

**02. Pharmacist and Technician Identification.** The initials or other unique identifiers of the pharmacist and technician involved in the dispensing must appear in the prescription record. (3-21-12)

**03. Pharmacist Verification of Drug Product and Label.** A pharmacist must compare, via video or image-based communication, the drug stock, the drug dispensed, and the label including the beyond use date. (3-21-12)( )

**04. Electronic Verification System.** The remote dispensing site must use an electronic verification system that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. The technician must electronically verify each prescription prepared for dispensing. (3-21-12)

## **712. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: POLICIES AND PROCEDURES.**

A supervising pharmacy commencing telepharmacy operations with a remote dispensing site must adopt policies and procedures that address each of the following areas prior to engaging in the practice of telepharmacy. (3-21-12)

**01. Minimum Standards.** The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality, including at least: (3-21-12)

**a.** Identification of personnel authorized to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site; (3-21-12)

**b.** Procedures for the procurement of drugs and devices to the remote site and into any ADS systems used, as applicable; and (3-21-12)( )

**c.** The criteria for monthly in-person pharmacist inspections of the remote dispensing site and appropriate documentation. (3-21-12)

**02. Training Standards.** The adoption of standards and training required for remote dispensing site technicians and pharmacists to ensure the competence and ability of each person that operates the ADS electronic verification system, electronic recordkeeping, and communication systems and a requirement for retention of training documentation. (3-21-12)( )

**03. Written Recovery Plan.** A written plan for recovery from an event that interrupts or prevents pharmacist supervision of, or otherwise compromises, the dispensing of drugs from the remote dispensing site that includes at least the following: (3-21-12)

**a.** Procedures for response while the communication or electronic recordkeeping systems are experiencing downtime or for an ADS electronic verification system malfunction; and (3-21-12)( )

**b.** Procedures for the maintenance and testing of the written plan for recovery. (3-21-12)

**IDAPA 27 - BOARD OF PHARMACY**  
**27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY**  
**DOCKET NO. 27-0101-1603**  
**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 26, 2016 – 1:00 pm (MDT)**

**Idaho State Capitol Building  
Room WW53  
514 West Jefferson  
Boise, ID**

For those planning to attend the open, public hearing, written and verbal comments will be accepted by and/or presented before the Board. For all others not planning to attend the meeting, written comments will be accepted by the Executive Director on or before October 25, 2016 as follows:

- Written comments received by October 12, 2016 will be included in the Board's distributed meeting materials for consideration in advance of the meeting;
- Written comments received between October 13, 2016 and October 25, 2016 will be printed and provided to the Board at the open, public hearing.

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

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

The Board needs to update and modernize its pharmacy technician rules given advancements in the education and training of technicians as well as advancements in the technology environment. The proposed updates seek to achieve the following, many of which are commonplace in other states:

- Allow pharmacists to delegate certain non-judgmental tasks to properly-trained, registered and certified pharmacy technicians under their supervision. Such delegated tasks include the ability to clarify missing elements on prescriptions, transfer prescriptions, administer medications, and take verbal prescriptions in certain circumstances.
- Expand verification technician programs beyond acute care hospitals.
- Enable remote data entry by certain pharmacy technicians.

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

**FISCAL IMPACT:** The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year 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 in the June 1, 2016 Idaho Administrative Bulletin, [Vol. 16-6, pages 49-50](#), under Docket No. 27-0101-1601.

**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 or at [alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov).

DATED this 5th Day of August, 2016

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**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1603**  
**(Only Those Sections With Amendments Are Shown.)**

**115. PRESCRIPTION DRUG ORDER: TRANSFERS.**

**01. Communicating Prescription Drug Order Transfers.** ~~Except prescription drug orders for Schedule II controlled substances, a~~ **A pharmacist, student pharmacist, or a certified technician** may transfer prescription drug order information for the purpose of filling or refilling if the information is communicated ~~from pharmacist to pharmacist~~ verbally, electronically, or via fax. (3-21-12)(    )

~~a. Prescription drug order information may also be communicated verbally by a student pharmacist, under the supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist.~~ (3-21-12)

~~b. If transferring by fax transmission, the transfer document used must be signed by the transferring pharmacist.~~ (3-21-12)

**02. Documentation Required of the Transferring Pharmacy.** The ~~pharmacist~~ **qualified individual** transferring prescription drug order information must void or otherwise indicate that the original prescription drug order has been transferred and record the following information: (3-21-12)(    )

- a. The name of the transferring ~~pharmacist~~ **individual**; (3-21-12)(    )
- b. The name of the ~~pharmacist~~ **individual**; (3-21-12)(    )
- c. The name of the receiving pharmacy; (3-21-12)
- d. The date of the transfer; (3-21-12)
- e. The number of authorized refills available; and (3-21-12)
- f. If written for a controlled substance, the address and DEA registration number of the receiving

pharmacy. (3-21-12)

**03. Documentation Required of the Receiving Pharmacy.** The *pharmacist* qualified individual receiving a transferred prescription drug order must document that the prescription drug order is a “transfer” and record the following information: (3-21-12)(    )

- a. The name of the receiving *pharmacist* individual; (3-21-12)(    )
- b. The name of the transferring *pharmacist* individual; (3-21-12)(    )
- c. The name of the transferring pharmacy; (3-21-12)
- d. The date of issuance of the original prescription drug order; (3-21-12)
- e. The number of refills authorized by the original prescription drug order; (3-21-12)
- f. The number of authorized refills available; and (3-21-12)
- g. If written for a controlled substance: (3-21-12)
  - i. The dates and locations of the original dispensing and previous refills; and (3-21-12)
  - ii. The name, address, DEA registration number, and the serial number assigned to the prescription by the transferring pharmacy and any additional pharmacy that filled the prescription, if applicable. (4-4-13)

**04. Electronic Prescription Drug Order Transfers.** For electronic prescription drug orders that are transferred electronically, the transferring pharmacist must provide all of the information required to be recorded by the receiving pharmacist in addition to the original electronic prescription data. The receiving pharmacist must create an electronic record for the prescription drug order that includes the receiving pharmacist’s name and all of the information transferred with the prescription. (3-21-12)

**05. Pharmacies Using Common Electronic Files.** Pharmacies may establish and use a common electronic file to maintain required dispensing information. (3-21-12)

- a. Pharmacies using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other pharmacies sharing the common electronic file. (3-21-12)
- b. Common electronic files must contain complete and accurate records of each prescription and refill dispensed. (3-21-12)

**06. Transferring Prescription Drug Orders for Controlled Substances.** A prescription drug order for a controlled substance listed in Schedules III, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber’s authorization. (3-21-12)

**07. Transferring Prescription Drug Order Refills.** Prescription drug orders for non-controlled substances may be transferred more than one (1) time if there are refills remaining and other legal requirements are satisfied. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**321. TECHNICIAN: REMOTE DATA ENTRY SITES.**

A pharmacy located in Idaho may employ one (1) or more certified technicians under the authority of the PIC for the

purpose of data entry in remote practice sites located in Idaho. ( )

**01. Technician Qualification.** All pharmacy technicians employed to work at a remote data entry practice site must be a certified technician. ( )

**02. Prohibition on Inventory.** No drug inventory may be kept at any remote pharmacy technician data entry site and no dispensing may take place from a remote pharmacy technician data entry site. ( )

**03. Audit Trail Documentation.** All remote pharmacy technician data entry sites must have a procedure for identifying the certified technician and all other persons responsible for each aspect of the prescription preparation. ( )

**04. Remote Site Operations.** ( )

**a.** If the remote pharmacy data entry site is located within a home, there must be a designated area in which all of the technician's work will be performed. ( )

**b.** All computer equipment used at the remote technician data entry site must be able to establish a secure connection. Remote equipment must be configured so that patient information is not stored at the remote site electronically or in printed form. ( )

**c.** Computer equipment may be used for remote technician data entry. No other use of the equipment is allowed. ( )

**d.** Computer equipment must be locked or shut down whenever the technician is absent. ( )

**05. Security Requirements.** Remote pharmacy technician data entry sites must have adequate security to maintain patient confidentiality, and utilize equipment that prevents unauthorized storage or transfer of patient information. ( )

**06. PIC Responsibilities.** The PIC must: ( )

**a.** Provide a written policy and procedure document outlining the operation and security of each remote pharmacy technician data entry site location. The document must be available at each practice site; ( )

**b.** Keep a continuously updated list of all remote technician data entry sites to include address and phone number for each site. The record must be retained as part of the records of the licensed pharmacy; ( )

**c.** Ensure that the Idaho licensed pharmacy and each remote data entry technician has entered into a written agreement outlining all conditions and policies governing the operation of the remote site; ( )

**d.** Ensure that all computer equipment used at the remote site is in good working order, provides data protection, and complies with all security and HIPAA requirements; ( )

**e.** Establish a quality monitoring and improvement program for each remote data entry site; and ( )

**f.** Ensure adequate supervision of all remote technicians. The PIC is expected to ensure that the overall level of staffing does not result in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, or welfare. ( )

**07. Ratio.** A remote data entry technician does not count against the ratio of pharmacists to student pharmacists and technicians set forth in these rules. ( )

**08. Inspections.** All remote data entry sites are subject to unannounced inspection by a representative of the Board during established hours of operation. ( )

~~32+2.~~ -- 329. (RESERVED)

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 a course by an ACPE-accredited provider or a 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)~~

~~043. **Student Pharmacist Delegation of Administration.** An immunizing pharmacist may not delegate authority to the technical task of administering an immunizations; however, to a student pharmacist or a certified technician under their supervision who has satisfied the qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. ~~(3-21-12)~~( )~~

~~a. Holds 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; and ( )~~

~~b. Has successfully completed a course on intramuscular, subcutaneous, and intranasal technique by an ACPE-accredited provider or a comparable course; or ( )~~

~~c. Has successfully completed the pharmacist qualifications specified under this rule. ( )~~

- 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: (4-11-15)
- i.** Intramuscular diphenhydramine; (4-11-15)
- ii.** Oral diphenhydramine; (4-11-15)
- iii.** Appropriate needles and syringes for injection; (4-11-15)
- iv.** Alcohol; and (4-11-15)
- v.** At least one (1) of the following: (4-11-15)
- (1)** Auto-inject epinephrine; (4-11-15)

(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 (4-11-15)

(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. (4-11-15)

**b.** An immunizing pharmacist may initiate and administer epinephrine, intramuscular diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association. (4-11-15)

**(BREAK IN CONTINUITY OF SECTIONS)**

**360. STUDENT PHARMACIST: UTILIZATION AND PRACTICE LIMITATIONS.**

**01. Activities.** A student pharmacist may engage in the practice activities of a pharmacist if: (3-21-12)

**a.** The activity is not specifically required to be performed only by a pharmacist; (3-21-12)

**b.** The activity is commensurate with the education and skill of the student pharmacist and performed under the supervision of a pharmacist; (3-21-12)

**c.** Any activity of a compounding, dispensing, or interpretive nature is checked by a pharmacist; and (3-21-12)

**d.** Any recording activity that requires the initial or signature of a pharmacist is countersigned by a pharmacist, unless performing activities in compliance with the accuracy checking technician procedures. (3-21-12)( )

**02. Unlawful Acceptance of Assignment.** A student pharmacist must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the student pharmacist is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

**03. Identification of Student Pharmacists.** (3-21-12)

**a.** Each student pharmacist must be identified by a clearly visible name badge designating the individual as a student pharmacist. The name badge must contain the individual's printed first name and the title of student pharmacist, pharmacist intern, pharmacist extern, or another title that conveys the same meaning. (3-21-12)

**b.** Student pharmacists must identify themselves as a student pharmacist, pharmacist intern, or pharmacist extern on any phone calls initiated or received while on duty. (3-21-12)

**361. -- 399. (RESERVED)**

**400. TECHNICIAN -- UTILIZATION AND PRACTICE LIMITATIONS.**

**01. Unlawful Acceptance of Assignment.** A technician must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the technician is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

**02. Unlawful Performance.** A technician must not perform tasks or functions connected with pharmacy operations that: (3-21-12)

**a.** Are not routine; (3-21-12)

**b.** The technician is not adequately trained to perform; (3-21-12)

- c. The technician has inadequate pharmacist supervision to perform; or (3-21-12)
- d. Requires the use of a pharmacist's professional judgment. (3-21-12)

**03. Prohibited Tasks or Functions by a Technician.** Unless excepted, A technician must not do any of the following which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a pharmacist's professional judgment: ~~(3-21-12)~~( )

a. Receive a new verbal prescription drug order from a prescriber or other person authorized by law and, either manually or electronically, reduce the order to writing. except if performed by a certified technician; ~~(3-21-12)~~( )

b. Consult with the prescriber prior to filling if clarification of information is needed regarding a patient or the prescription drug order. except if performed by a certified technician at the direction of a supervising pharmacist; ~~(3-21-12)~~( )

c. Perform prospective drug review or interpret clinical data in a patient's medication record (e.g., contraindications, drug interactions, etc.); (3-21-12)

d. Perform professional consultation with a prescriber, nurse, or other healthcare professional; (3-21-12)

e. Supervise the packaging of drugs and check the completed procedure and product, unless checked in compliance with the ~~verification~~ accuracy checking technician procedures ~~allowed in institutional facilities;~~ ~~(3-21-12)~~( )

f. Provide patient consultation on a new or refilled prescription or on over-the-counter drugs or supplements; and (3-21-12)

g. Supervise the pharmacy operations activities of student pharmacists and technicians. (3-21-12)

**04. Technician Identification.** (3-21-12)

a. Each technician must be identified by a clearly visible name badge designating the individual as a technician. The name badge must contain the individual's printed first name and the title of technician. (3-21-12)

b. Technicians must identify themselves as a technician on any phone calls initiated or received while on duty. (3-21-12)

**401. -- 409. (RESERVED)**

**410. ~~VERIFICATION~~ ACCURACY CHECKING TECHNICIAN PROGRAM.**

~~Only institutional p~~Pharmacies ~~located within acute care hospitals~~ may utilize ~~a verification~~ an accuracy checking technician program according to these rules.

**01. Program Scope.** ~~A verification~~ An accuracy checking technician program allows qualified technicians to ~~verify~~ perform accuracy checking the work of other technicians and student pharmacists, or products filled by an ADS and other technology-assisted filling equipment, in the filling of ~~floor and ward stock and unit dose distribution systems for patients whose;~~ ( )

a. Drug orders or prescription drug orders that have previously ~~been~~ undergone prospective drug reviewed ~~ed and approved~~ by a pharmacist; or ~~(3-21-12)~~( )

b. If in an institutional setting, floor and ward stock, and drugs that a practitioner controls the order, preparation, and administration of in accordance with state and federal law. ( )

**012. Written Program ~~Filing~~ Description.** Prior to initiating ~~a verification~~ an accuracy checking technician program, ~~an institutional~~ pharmacy must prepare a written program description that includes at least the following: (3-21-12)(    )

a. The name of the pharmacist assigned as the coordinator of the ~~verification~~ accuracy checking technician program; (3-21-12)(    )

b. A description of the duties of the coordinator sufficient to ensure and demonstrate compliance by the ~~institutional~~ pharmacy with these ~~verification~~ accuracy checking technician program rules; (3-21-12)(    )

c. A description of the duties of technicians designated to perform the functions of verifying the work of other technicians; (3-21-12)

d. Identification of the types of drugs ~~verification~~ accuracy checking technicians are authorized to verify; (3-21-12)(    )

e. A description of the specialized and advanced training that must be provided to each ~~verification~~ accuracy checking technician; and (3-21-12)(    )

f. A description of the monitoring and evaluation processes used by the ~~institutional~~ pharmacy to ensure the ongoing competency of each ~~verification~~ accuracy checking technician. (3-21-12)(    )

**023. Program Requirements.** Each ~~institutional~~ pharmacy utilizing ~~a verification~~ an accuracy checking technician program must comply with the following requirements: (3-21-12)(    )

a. A technician must neither be designated to perform, nor may the technician perform, ~~verification~~ accuracy checking functions without competently completing the required training. (3-21-12)(    )

b. ~~A verification~~ An accuracy checking technician may not verify ~~only manufacturer prepared or robotically prepared unit dose drugs identified in the written program description for floor or ward stock or unit dose distribution systems of pharmacist reviewed and approved~~ a compounded drug orders for hospital patients. ~~If either the alteration of a unit dose or the combination of unit doses is required, a pharmacist must verify the resulting unit dose alteration or combination of unit doses~~ any other drug excluded in the written program description. (3-21-12)(    )

c. The ~~institutional~~ pharmacy must conduct ~~ongoing~~ unannounced monitoring and evaluation of each ~~verification~~ accuracy checking technician at least quarterly for the first year and then annually thereafter to ensure the ongoing competency of the technician, and must remediate or remove from accuracy checking duty a technician who does not meet defined performance standards. (3-21-12)(    )

d. For each ~~verification~~ accuracy checking technician, ~~an institutional~~ pharmacy utilizing ~~a verification~~ an accuracy checking technician program must maintain records containing: (3-21-12)(    )

i. The date the accuracy checking technician was designated; (3-21-12)(    )

ii. The date the accuracy checking technician completed the required training; (3-21-12)(    )

iii. The dates and results of each competency evaluation; and (3-21-12)

iv. The dates of, and reasons for, any suspension or revocation of the technician's designation or other disciplinary action against the ~~verification~~ accuracy checking technician connected with the performance of the technician's duties in the ~~verification~~ accuracy checking technician program. (3-21-12)(    )

e. While on duty, each ~~verification~~ accuracy checking technician must wear identification that includes the title, "~~verification~~ Accuracy Checking Technician." (3-21-12)(    )

f. The duties of the ~~verification~~ accuracy checking technician program coordinator must include the

supervision of ~~verification~~ accuracy checking technicians to ensure their duties are performed competently in a manner that protects patient safety. ~~(3-21-12)~~( )

g. Retail pharmacies implementing an accuracy checking technician program must use an electronic verification system that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. Each prescription prepared for dispensing under an accuracy checking program must be electronically verified and electronically documented. ( )

04. Student Pharmacist Participation. Student pharmacists may participate fully in an accuracy checking technician program with the same limitations and requirements as accuracy checking technicians. ( )

05. Board Review. The written program description and records required under this section must be made available to the Board upon request. ( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**607. PHARMACY STAFFING AND RATIO.**

**01. Staffing.** A pharmacy must be staffed sufficiently to allow for appropriate supervision, to otherwise operate in compliance with the law, and if applicable, to remain open during the hours posted as open to the public for business. (3-21-12)

**02. Ratio.** Unless otherwise provided by these rules, ~~7~~the ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) student pharmacists and technicians in total in any practice setting. A pharmacist must not operate a pharmacy, allow the operation of a pharmacy, or be required to operate a pharmacy with a ratio that results in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, or welfare. ~~(3-21-12)~~( )

## **IDAPA 27 - BOARD OF PHARMACY**

### **27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY**

**DOCKET NO. 27-0101-1604**

#### **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 26, 2016 – 1:00 pm (MDT)**

**Idaho State Capitol Building  
Room WW53  
514 W. Jefferson  
Boise, ID**

For those planning to attend the open, public hearing, written and verbal comments will be accepted by and/or presented before the Board. For all others not planning to attend the meeting, written comments will be accepted by the Executive Director on or before October 25, 2016 as follows:

- Written comments received by October 12, 2016 will be included in the Board's distributed meeting materials for consideration in advance of the meeting;
- Written comments received between October 13, 2016 and October 25, 2016 will be printed and provided to the Board at the open, public hearing.

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

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

The Board needs to update several rules given advancements in technology and changes in pharmacy practice. In addition, the Board intends to clarify several rules based on recent inspections and Board administrative hearings. The proposed updates will do the following:

- Update the security requirements that pharmacies must follow.
- Clarify the provisions for legal medication returns for institutional pharmacies and to authorize collection for destruction.
- Enable broader emergency room dispensing in conformance with a U.S. Supreme Court decision.
- Enable pharmacists to better coordinate refills of medications in order to improve patient medication adherence.
- Require the timely notification of medication errors that result in fatal outcomes.
- Update requirements for licensure applicants.
- Clarify prepackaged product labeling requirements.
- Update the list of required pharmacy references.
- Update pharmacy delivery restrictions.

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

**FISCAL IMPACT:** The following is a specific description, if applicable, of any negative fiscal impact on the state

general fund greater than ten thousand dollars (\$10,000) during the fiscal year 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 in the June 1, 2016 Idaho Administrative Bulletin, **Vol. 16-6, pages 49-50**, under Docket No. 27-0101-1601.

**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 or at [alex.adams@bop.idaho.gov](mailto:alex.adams@bop.idaho.gov).

DATED this 5th Day of August, 2016

Alex Adams, Pharm D, MPH  
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**THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 27-0101-1604**  
**(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. Maintenance Drug.** A drug intended for the treatment of a health condition or disease that is persistent or otherwise expected to be long lasting in its effects. ( )

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

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

**046. 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)
- ~~057.~~ **NABP.** National Association of Boards of Pharmacy. (3-21-12)
- ~~068.~~ **NAPLEX.** North American Pharmacists Licensure Examination. (3-21-12)
- ~~079.~~ **NDC.** National Drug Code. (3-21-12)
- ~~0810.~~ **Non-Institutional Pharmacy.** A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)
- ~~0911.~~ **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)
- ~~102.~~ **Parenteral Admixture.** The preparation and labeling of sterile products intended for administration by injection. (3-21-12)
- ~~143.~~ **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; (3-25-16)
  - m.** Ordering and interpreting laboratory tests; and (3-25-16)
  - n.** Other services as allowed by law. (3-21-12)
- 124.** **Pharmacist Extern.** A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy. (4-4-13)
- 135.** **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)
- 146.** **Pharmacy Operations.** Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)
- 157.** **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)
- 168.** **PIC.** Pharmacist-in-charge. (3-21-12)
- 179.** **PMP.** Prescription Monitoring Program. (3-21-12)
- 1820.** **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)
- 1921.** **Prescriber.** An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)
- 202.** **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)

~~213.~~ **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)

~~224.~~ **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)

~~235.~~ **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. (3-25-16)

~~246.~~ **Relative Contraindication.** A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

~~257.~~ **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)

~~268.~~ **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)

~~279.~~ **Retail Non-Pharmacy Drug Outlet.** A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

~~2830.~~ **Retail Pharmacy.** A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

~~2931.~~ **R.N.** Registered nurse. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**032. PHARMACIST LICENSURE EXAMINATIONS.**

Qualified applicants may sit for and to obtain licensure must pass the NAPLEX and the MPJE in accordance with NABP standards. A candidate who fails the NAPLEX three (3) times must complete at least thirty (30) hours of continuing education accredited by ACPE-accredited provider prior to being eligible to sit for each subsequent reexamination. (~~3-21-12~~)(      )

**033. PHARMACIST LICENSURE BY RECIPROCITY.**

An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and this rule to obtain an Idaho license. ~~The Board will issue a reciprocal license only to a~~ An applicant whose pharmacist licensed in good standing is currently restricted by a licensing entity in another state at the time of application and issuance of the Idaho license must appear before the Board to petition for licensure by reciprocity. (~~3-21-12~~)(      )

**01. Transfer Application.** The applicant must submit a preliminary application for licensure transfer through NABP. (3-21-12)

**02. MPJE.** The applicant must pass the Idaho-based MPJE. (3-21-12)

**03. Intern Hours.** An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may also be required to complete up to forty (40) intern hours for each year away from the practice of pharmacy. (3-21-12)

**(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, except that upon patient request, a pharmacist may extend a maintenance drug, other than a controlled drug, compounded drug, or biological product, for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. ~~(3-21-12)~~( )

**02. Emergency Prescription Refills.** A pharmacist may refill a prescription for a patient when: (3-25-16)

**a.** 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. (3-25-16)

**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, a pharmacist may dispense a refill of a prescription drug to an affected patient, 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. (3-25-16)

**(BREAK IN CONTINUITY OF SECTIONS)**

**142. PARENTERAL ADMIXTURE LABELING.**

If one or more drugs are added to a parenteral admixture the admixture's container must include a distinctive, supplementary label with at least the following information: (3-21-12)

**01. Ingredient Information.** The name, amount, strength, and if applicable, the concentration of the drug additive and the base solution or diluent; (3-21-12)

**02. Date and Time.** The date and time of the addition, or alternatively, the beyond use date and time; ~~(3-21-12)~~( )

**03. Identification.** The initials or other unique identifier of the pharmacist or preparing prescriber responsible for its accuracy; (4-4-13)

**04. Prescribed Administration Regimen.** The rate or appropriate route of administration or both, as applicable; and (3-21-12)

**05. Special Instructions.** Any special handling, storage, or device-specific instructions. (3-21-12)

**143. PREPACKAGED PRODUCT LABELING.**

The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label with at least the following information: (3-21-12)

**01. Drug Name and Strength.** The name and strength of the drug; (3-21-12)

- 02. Expiration Date.** An expiration date that is the lesser of: (3-21-12)
- a.** The manufacturer's original expiration date; (3-21-12)
  - b.** One (1) year from the date the drug is prepackaged; or (3-21-12)
  - c.** A shorter period if warranted (A prepackaged drug returned unopened from an institutional facility and again prepackaged must be labeled with the expiration date used for the initial prepackaging.); (3-21-12)
- 03. Conditional Information.** If not maintained in ~~the a separate records of the pharmacy~~, the manufacturer's name and lot number and the identity of the pharmacist or provider responsible for the prepackaging. ~~(3-21-12)~~( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**200. CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.**

A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. (3-21-12)

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

- a.** The controlled substance will be paid for, in whole or in part, by an insurer; or (3-21-12)
- b.** The patient is being treated at an institutional facility or is housed in a correctional facility. (4-4-13)
- c.** The filled prescription is delivered to the patient's ~~residence~~ or patient's provider either by mail, common carrier, or an employee of the pharmacy. ~~(4-4-13)~~( )

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

- a.** The recipient's name (if other than the patient); (3-21-12)
- b.** A notation indicating that the recipient was known to the staff member; and (3-21-12)
- c.** The identity of the staff member making the personal identification. (3-21-12)

**03. Acceptable Identification.** The identification presented must include an unaltered photograph and signature and acceptable forms include: (3-20-14)

- a.** A valid U.S. state or U.S. military driver's license or identification card; (3-20-14)
- b.** A Western Hemisphere Travel Initiative (WHTI) compliant document (i.e., Enhanced Driver's License (EDL) or Nexus Air Card); (3-20-14)
- c.** A valid passport; and (3-20-14)
- d.** A U.S. passport card (PASS Card). (3-20-14)

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

- a. A copy of the identification presented; or (3-21-12)
- b. A record that includes: (3-21-12)
  - i. The recipient's name; (3-21-12)
  - ii. A notation of the type of identification presented; (3-21-12)
  - iii. The government entity that issued the identification; and (3-20-14)
  - iv. The unique identification number. (3-20-14)

**(BREAK IN CONTINUITY OF SECTIONS)**

**262. RESTRICTED RETURN OF DRUGS OR DEVICES.**

Once removed from the premises from which it was dispensed, a drug or prescription device must only be accepted for return or destruction under the conditions permitted by this rule or pursuant to the Legend Drug Donation Act and rules. ~~(3-21-12)~~( )

**01. Qualifying Returns.** ~~Unless dispensed in any manner inconsistent with the prescriber's instructions and returned for quarantine for destruction purposes only, a drug or prescription device that has been received from or delivered to the patient or the patient's representative is ineligible for return.~~ Drugs or devices that may qualify for return include: ~~(3-21-12)~~( )

a. Those that were dispensed in a manner inconsistent with the prescriber's instructions may be returned for quarantine and destruction purposes only. ( )

~~b.~~ Those intended for inpatients of an institutional facility that have been maintained in the custody and control of the institutional facility or dispensing pharmacy; and (3-21-12)

~~b.c.~~ That are liquid or in unit dose or unit-of-use packaging and, if a controlled substance, returned from a hospital daily delivery system. A hospital daily delivery system means a system under which a pharmacy dispenses no more than a twenty-four (24) hour supply for a drug order, or up to a seventy-two (72) hour supply for a drug order if warranted for good patient care; and ~~(3-21-12)~~( )

~~d.~~ Those for which the following conditions are satisfied: (3-21-12)

i. The drug was delivered by the dispensing pharmacy directly to the institutional facility or its authorized agent and subsequently stored in a suitable drug storage area that is inaccessible to patients; (3-21-12)

ii. The drug is returned in an unopened manufacturer-sealed container or with other tamper-evident packaging intact; (3-21-12)

iii. In the professional judgment of the pharmacist, the safety and efficacy of the drug has not been compromised; and (3-21-12)

iv. A system is in place to track the restocked drug for purposes of a recall. (3-21-12)

**02. Marking Ineligible Returns.** Drugs or devices otherwise eligible for return that are or will become ineligible for any reason must be clearly marked "Not Eligible for Return" prior to leaving the institutional facility or upon discovery and before storing in an area with other eligible returns. (3-21-12)

**03. Consulting Pharmacy and PIC Responsibilities.** The pharmacy and its PIC are responsible for: (4-4-13)

- a. Consulting with an institutional facility from which returns will be accepted; (4-4-13)
- b. Ensuring that the institutional facility has an employee trained and knowledgeable in the proper storage, use, and administration of drugs and devices; (4-4-13)
- c. Reviewing, approving, and enforcing written protocols that will ensure compliance with the conditions necessary to allow returns; and (4-4-13)
- d. Storing a copy of the protocols, as well as the written approval thereof, in an immediately retrievable fashion. (4-4-13)

04. Collection for Destruction. A pharmacy registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. ( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**300. PIC: QUALIFICATIONS.**

A pharmacist may neither be designated nor function as the PIC of ~~a more than two (2) pharmacies unless the designee spends a substantial part of the designee's working time each month at the pharmacy in which designated as the PIC.~~ (3-21-12)( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**500. UNPROFESSIONAL CONDUCT.**

The following acts or practices by a pharmacist, student pharmacist, or technician are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (3-21-12)

**01. Unethical Conduct.** Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (3-21-12)

**02. Lack of Fitness.** A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (3-21-12)

**03. On-Duty Intoxication or Impairment.** Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (3-21-12)

**04. Diversion of Drug Products and Devices.** Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (3-21-12)

**05. Unlawful Possession or Use of Drugs.** Possessing or using a controlled substance without a lawful prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (3-21-12)

**06. Prescription Drug Order Noncompliance.** Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. (4-4-13)

**07. Failure to Confer.** Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (3-21-12)

**08. Excessive Provision of Controlled Substances.** Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (3-21-12)

**09. Failure to Counsel or Offer Counseling.** Failing to counsel or offer counseling, unless specifically exempted or refused. The failure to retain appropriate documentation evidencing compliance with patient counseling requirements creates a rebuttable presumption of a violation of this rule. (3-21-12)

**10. Substandard, Misbranded, or Adulterated Products.** Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. (3-21-12)

**11. Prescriber Incentives.** Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (3-21-12)

**12. Exclusive Arrangements.** Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (3-21-12)

**13. Failure to Report.** Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (3-21-12)

**14. Failure to Report Medication Errors With Fatal Outcomes.** Within two (2) business days of discovery, the PIC, pharmacy director, or pharmacist on duty must provide a brief notification to the Board of a fatality that is reasonably expected to have resulted from a medication error. ( )

**a. Reportable Events.** A fatality is reportable if it is suspected to be related to an error in medication use process, including product labeling, packaging, compounding, dispensing, or direct administration of a medication. ( )

**b. Follow-up Reporting Requirements.** The pharmacy director must provide a copy of the official incident report filed with an accrediting body or government agency to the Board within two (2) business days of submission to the other entity. ( )

**145. Failure to Follow Board Order.** Failure to follow an order of the Board. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**503. PRESCRIPTION DELIVERY RESTRICTIONS.**

A pharmacist must not participate in any arrangement or agreement whereby filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not registered as a pharmacy except that a pharmacist or a pharmacy, by means of its agent, may deliver filled prescriptions to the following: ( )

**01. Patient.** To the patient, or the patient's residence, the hospital or other institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed, or if a non-controlled substance, or ( )

**02. Provider.** To the patient's licensed or registered healthcare provider, except if a controlled substance not intended for direct administration. (4-4-13)( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**603. PHARMACY REFERENCES.**

Required pharmacy references include the latest hard copy or electronic editions and supplements of the following: (3-21-12)

**01. Pharmacy Laws and Rules.** Idaho Pharmacy Laws and Rules. (3-21-12)

~~02. DEA Manual.~~ DEA Pharmacist's Manual. ( )

~~03. Current Pharmacy References.~~ One (1) of the following current pharmacy references: (3-21-12)

~~a. Facts and Comparisons;~~ (3-21-12)

~~b. Clinical Pharmacology;~~ (3-21-12)

~~c. Micromedex; or~~ (3-21-12)

~~d. Lexicomp.~~ (3-21-12)

~~03. Additional Current Pharmacy Reference.~~ One (1) additional At least two (2) current pharmacy references relevant to the practice setting. (3-21-12)( )

**(BREAK IN CONTINUITY OF SECTIONS)**

**605. PHARMACY SECURITY.**

A pharmacy must be constructed and equipped with adequate security to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. Failure to provide effective controls to prevent unauthorized access, acquisition, or use constitutes grounds for discipline to the PIC and the facility. New construction or a remodeled pharmacy must meet the following minimum security requirements: (4-11-15)( )

**01. Alarm.** At least while closed an alarm or other comparable monitoring system is required. (4-11-15)

~~02. Walls.~~ Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

~~03. Doors.~~ Solid core or metal doors are required. (4-11-15)

~~04. Hinges and Locks.~~ Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

~~05. Differential Hours.~~ When ~~closed for~~ located in a larger business establishment, a pharmacy that is closed must be: (4-11-15)

~~a. Completely enclosed in a manner sufficient to provide adequate security; or.~~ (4-11-15)

~~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.~~ (4-11-15)

**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.

(4-11-15)

**(BREAK IN CONTINUITY OF SECTIONS)**

**637. INSTITUTIONAL FACILITY: EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.**

Drugs may be delivered by an RN to outpatients being treated in a hospital emergency room as follows: (4-4-13)

**01. Prerequisites:** (4-4-13)

**a.** In the presence of a prescriber, acting as an agent of that prescriber, or outside the presence of a prescriber, when there is no prescriber present in the hospital in accordance with applicable state and federal law; (4-4-13)

**b.** Pursuant to a valid drug order issued by a prescriber; and ~~(4-4-13)~~( )

**e.** ~~When no pharmacist is on duty in the community; and~~ ~~(4-4-13)~~

**d.** When drugs are stored and accessed in accordance with applicable laws and rules. (4-4-13)

**02. Limitations.** ~~No more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided~~ Dispensing must be in limited quantities and for a reasonable time duration as a continuation of or supplemental to treatment that is administered in the emergency room. ~~(3-21-12)~~( )

**03. Documentation.** Delivery must be documented as required by these rules for institutional facility emergency drug access. (4-4-13)

**04. Labeling.** The institutional pharmacy must prepackage and affix a label to the container with the information required by the standard prescription drug labeling rules, except that blank spaces may be left for the names of the patient and prescriber and directions for use. (4-4-13)

**(BREAK IN CONTINUITY OF SECTIONS)**

**650. INSTITUTIONAL FACILITY: CENTRALIZED PHARMACY SERVICES.**

In addition to the rules for centralized pharmacy services, an institutional facility that centralizes pharmacy services must be in compliance with the following rules: (7-1-13)

**01. Limited Purpose.** Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis Centralized product distribution is permissible if performed by a centralized pharmacy under common ownership with the institutional facility, and if such distribution is within the limits of other applicable state and federal laws; ~~(7-1-13)~~( )

**02. Policies and Procedures.** An institutional pharmacy and its contracted central drug outlet or central pharmacist that provides centralized pharmacy services must adopt policies and procedures and retain documentation that evidences at least the following, as applicable: ~~(7-1-13)~~( )

**a.** A copy of the contract if required by these rules; (7-1-13)

**b.** Identification of the directors or PICs; (7-1-13)

**c.** The protocol for ensuring that the central drug outlet maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; (7-1-13)

**d.** The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central drug outlet or central pharmacist and for maintaining the security of the drugs; (7-1-13)

**e.** Essential information utilized by the institutional facility, such as its formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to the information; and (7-1-13)

**f.** The protocol for the central drug outlet or central pharmacist to perform a review of the patient's profile, including but not limited to performing a prospective drug review. (7-1-13)