

IDAPA 27 – BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO BOARD OF PHARMACY

DOCKET NO. 27-0101-1404

NOTICE OF RULEMAKING - ADOPTION OF PENDING RULE

EFFECTIVE DATE: This rule has been adopted by the agency and is now pending review by the 2015 Idaho State Legislature for final approval. The pending rule becomes final and effective at the conclusion of the legislative session, unless the rule is approved or rejected in part by concurrent resolution in accordance with Section 67-5224 and 67-5291, Idaho Code. If the pending rule is approved or rejected in part by concurrent resolution, the rule becomes final and effective upon adoption of the concurrent resolution or upon the date specified in the concurrent resolution.

AUTHORITY: In compliance with Section 67-5224, Idaho Code, notice is hereby given that this agency has adopted a pending rule. The action is authorized pursuant to Section 54-1717, Idaho Code.

DESCRIPTIVE SUMMARY: The following is a concise explanatory statement of the reasons for adopting the pending rule and a statement of any change between the text of the proposed rule and the text of the pending rule with an explanation of the reasons for the change.

This pending rule is necessary to harmonize labeling requirements with 2014 statutory changes. Changes from proposed to pending language create an exception for veterinarians.

The text of the pending rule has been amended in accordance with Section 67-5227, Idaho Code. Only those sections that have changes that differ from the proposed text are printed in this bulletin. The complete text of the proposed rule was published in the October 1, 2014 Idaho Administrative Bulletin, Vol. 14-10, pages 347 through 360.

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: N/A

ASSISTANCE ON TECHNICAL QUESTIONS: For assistance on technical questions concerning this pending rule, contact Mark Johnston, Executive Director, (208) 334-2356.

DATED this 28th day of November, 2014.

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

IDAPA 27
TITLE 01
CHAPTER 01

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

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

a. Certification by the FPGEC; or (_____)

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

02. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

(BREAK IN CONTINUITY OF SECTIONS)

041. TECHNICIAN-IN-TRAINING REGISTRATION.

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

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

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

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

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

(BREAK IN CONTINUITY OF SECTIONS)

140. STANDARD PRESCRIPTION DRUG LABELING.

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

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

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

03. **Date.** The date the prescription is filled; (3-21-12)
04. **Prescriber.** The name of the prescriber; (3-21-12)
05. **Patient Name.** The name of the patient, and if the patient is an animal, the species; ~~(3-21-12)~~(____)
- a. If a person, the name of the patient; (____)
- b. If an animal, the name and species of the patient; or (____)
- c. If a school for epinephrine auto-injectors pursuant to Section 33-520A, Idaho Code, the name of the school. (____)
06. **Drug Name and Strength.** Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name); (3-21-12)
07. **Quantity.** The quantity of item dispensed; (3-21-12)
08. **Directions.** The directions for use; (3-21-12)
09. **Cautionary Information.** Cautionary information as required or deemed appropriate for proper use and patient safety; (3-21-12)
10. **Expiration.** An expiration date that is the lesser of: (3-21-12)
- a. One (1) year from the date of dispensing; (3-21-12)
- b. The manufacturer's original expiration date; (3-21-12)
- c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)
- d. A shorter period if warranted; (3-21-12)
11. **Refills.** The number of refills remaining, if any, or the last date through which the prescription is refillable; ~~and~~ (3-21-12)
12. **Warning.** The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."; except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. (3-21-12)
13. **Pharmacist Identification.** The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. ~~(4-4-13)~~(____)

(BREAK IN CONTINUITY OF SECTIONS)

146. REPACKAGING.

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

01. **Unit Dose,** The drugs are repackaged into unit dose packaging; (____)
02. **Pharmacist Verification.** The repackaging pharmacist verifies; (____)

- a.** The identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within; and ()
- b.** The validity and accuracy of the original prescription drug order; ()
- 03.** **Adulterated Drugs.** In the repackaging pharmacist's best professional judgment, the drug has not been adulterated; ()
- 04.** **Intermingled Drugs.** The drugs are never intermingled with the repackaging pharmacy's regular stock; ()
- 05.** **Time for Repackaging.** The pharmacy repackages the entire amount that was delivered to it for repackaging no later than three (3) days after receipt; ()
- 06.** **Date of Repackaging.** The date of repackaging is less than one (1) year from the original date of dispensing and the original expiration date is also used on the repackaged drug's label; ()
- 07.** **Labeling.** The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes: ()
- a.** The original dispensed prescription's serial number; ()
- b.** The name, address, and phone number of the original dispensing pharmacy; and ()
- c.** A statement that indicates that the drug has been repackaged, such as the words "repackaged by" followed by the name of the repackaging pharmacy. ()
- 08.** **Record.** The repackaging pharmacy makes a record of: ()
- a.** All required components of the standard prescription drug labeling rule; ()
- b.** The original dispensing pharmacy's name, address, and phone number; ()
- c.** The original dispensed prescription's serial number; and ()
- d.** The name of the pharmacist responsible for compliance with this rule. ()
- 09.** **Policy and Procedures.** The repackaging pharmacy develops policy and procedures to ensure compliance with this rule. ()

1467. -- 199. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

206. CONTROLLED SUBSTANCES: INVENTORIES.

- 01. Annual Inventory of Stocks of Controlled Substances.** Each registrant must conduct an inventory of controlled substances on hand annually within no later than seven (7) days ~~of~~ after the date of the prior year's inventory in a form and manner that satisfies the inventory requirements of federal law. (4-4-13)()
- 02. Separate Inventories for Each Location.** A separate controlled substances inventory must be taken and retained at each registered location. (3-21-12)
- 03. Inventory on PIC or Director Change.** A complete controlled substance inventory must be conducted in the event of a change of PIC or director on or by the first day of employment of the incoming PIC or director. (4-4-13)

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

05. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory. (3-21-12)

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

(BREAK IN CONTINUITY OF SECTIONS)

~~304. PHARMACIST: AUTHORIZED PHARMACY ENTRANCE.~~

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

3054. -- 309. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

330. PHARMACIST: ADMINISTERED IMMUNIZATIONS.

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

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

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

- i. Basic immunology, vaccine, and immunization protection; (3-21-12)
- ii. Diseases that may be prevented by vaccination or immunization; (3-21-12)
- iii. Current recommended immunization schedules; (3-21-12)
- iv. Vaccine and immunization storage and management; (3-21-12)
- v. Informed consent; (3-21-12)
- vi. Physiology and techniques for administration of immunizations; (3-21-12)
- vii. Pre-immunization and post-immunization assessment and counseling; (3-21-12)
- viii. Immunization reporting and records management; and (3-21-12)
- ix. Identification response, documentation, and reporting of adverse events. (3-21-12)

b. Hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program that includes cardiopulmonary

resuscitation (CPR) and automated electronic defibrillator (AED) training and requires a hands-on skills assessment by an authorized instructor. (3-21-12)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10. Emergencies. (3-21-12)

a. An immunizing pharmacist must maintain an immediately retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. At a minimum, the kit must include:

~~(3-21-12)~~(_____)

- i. Intramuscular diphenhydramine: ()
- ii. Oral diphenhydramine: ()
- iii. Appropriate needles and syringes for injection: ()
- iv. Alcohol; and ()
- v. At least one (1) of the following: ()
 - (1) Auto-inject epinephrine: ()
 - (2) A vial of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14); or ()
 - (3) An ampule of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14) and filter needles. ()

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

331. -- 3539. (RESERVED)

340. NONRESIDENT PHARMACIST PRACTICE STANDARDS.

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

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

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

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

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

341. -- 359. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

604. PHARMACY PRODUCT STORAGE AND REMOVAL.

Prescription drugs, devices, and other products restricted to sale or dispensing by, or under the supervision of, a pharmacist must be stored in the pharmacy and must not be sold, delivered, or otherwise removed from a pharmacy unless a pharmacist is present, except: (3-20-14)

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

02. Institutional Facility Alternative Storage. In an institutional facility these restricted products may

also be stored in an alternative designated area that is appropriately equipped to ensure compliance with drug product storage requirements, to provide adequate security and protection from diversion, and that otherwise complies with applicable requirements of these rules; (3-20-14)

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

a. The prescriptions are placed in a secured delivery area equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion; (3-20-14)

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

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

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

e. The PIC, or a pharmacist designated by the PIC, and the approved transport agent solely have access to the secure delivery area. Two (2) factor credentialing is required for entry, which must include two (2) of the following: (3-20-14)

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

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

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

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

g. The pharmacy maintains immediately retrievable records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery; (3-20-14)

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

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

04. Qualified Returns to the Secured Delivery Area. A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area: (3-20-14)

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

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

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

605. PHARMACY SECURITY.

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

~~021. **Non-Institutional Pharmacy Security During Pharmacist Absence Alarm.** A non-institutional pharmacy must be At least while closed for business and secured during all times a pharmacist is not present except an alarm or other comparable monitoring system is required.~~ (4-4-13)()

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

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

~~032. **Structural Security Requirements Walls.** If a pharmacy is located within an establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All pharmacies must meet the following security requirements:~~ (3-20-14)

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

~~b03. **Doors.** Solid core or metal doors are required for new or remodeled pharmacies after the effective date of this rule.~~ (4-4-13)()

~~e04. **Hinges and Locks.** Doors and other access points must be constructed in a manner that the hinge hardware is accessible only from inside of the pharmacy and must be equipped with locking devices tamper-proof when closed.~~ (3-21-12)()

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

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

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

~~06. **Drop Box.** If used, a “drop box” or “mail slot” allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment.~~ (3-21-12)()

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

(BREAK IN CONTINUITY OF SECTIONS)

611. PHARMACY AUTHORIZED ENTRY.

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

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

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

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

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

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

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

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

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

6142. -- 619. (RESERVED)

(BREAK IN CONTINUITY OF SECTIONS)

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

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

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

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

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

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

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

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

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

~~(3-21-12)~~(_____)

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

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

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

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

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

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

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

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

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

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

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

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

(BREAK IN CONTINUITY OF SECTIONS)

710. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES.

Pharmacies and pharmacists commencing retail telepharmacy operations with a remote dispensing site after August 23, 2011, must comply with the following requirements: (3-21-12)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

08. Video and Audio Communication Systems. A supervising pharmacy of an ADS system used in a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision, and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of such video and audio surveillance for a minimum of ninety (90) days. (~~3-21-12~~)()

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

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

c. Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed if any component of the communication system

is malfunctioning until system corrections or repairs are completed. (3-21-12)

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

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

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

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

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

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

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

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

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

a. At least while closed, a remote dispensing site must utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. The site must have a means of recording the time of entry and the identity of all persons who access the site, which must be retained for ninety(90) days. Two (2) factoring credentialing is required for entry, which must include two (2) of the following: ()

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

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

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

b. A remote dispensing site must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All remote dispensing sites must meet the following security requirements: ()

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

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

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

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

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

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

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

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

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

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

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

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

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

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