

## IDAPA 27 - BOARD OF PHARMACY

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

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

#### NOTICE OF RULEMAKING - PROPOSED RULE

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

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

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

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

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

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

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

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

**FISCAL IMPACT:** The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year resulting from this rulemaking: None.

**NEGOTIATED RULEMAKING:** Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notice of Intent to Promulgate Rules - Negotiated Rulemaking was published in the July 1, 2015 Idaho Administrative Bulletin, [Vol. 15-7, page 71](#) and in the August 5, 2015 Idaho Administrative Bulletin, [Vol. 15-8, page 106](#).

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

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

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

DATED this 4th Day of September 2015.

Alex Adams  
Executive Director  
Board of Pharmacy  
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**THE FOLLOWING IS THE PROPOSED TEXT OF FEE DOCKET NO. 27-0101-1501**  
**(Only Those Sections With Amendments Are Shown.)**

**021. FEE SCHEDULE.**

- |   |           |
|---|-----------|
| <b>01. Licenses -- Professionals.</b>   | (3-21-12) |
| <b>a.</b> Original pharmacist license: one hundred dollars (\$100).   | (3-21-12) |
| <b>b.</b> Licensure by reciprocity: two hundred fifty dollars (\$250).  | (3-21-12) |
| <b>c.</b> Pharmacist license annual renewal.  | (3-21-12) |
| <b>i.</b> Active: ninety dollars (\$90).  | (3-21-12) |
| <b>ii.</b> Inactive: fifty dollars (\$50).  | (3-21-12) |
| <b>d.</b> Late payment processing: fifty dollars (\$50).  | (3-21-12) |
| <b>e.</b> License reinstatement fee: seventy-five dollars (\$75).   | (3-21-12) |
| <b>02. Certificates of Registration -- Professionals.</b>   | (3-21-12) |
| <b>a.</b> Pharmacist registration or annual renewal: two hundred fifty dollars (\$250).   | (7-1-13)  |
| <b>b.</b> Pharmacist intern - registration or annual renewal: fifty dollars (\$50).   | (3-21-12) |
| <b>c.</b> Pharmacist extern registration and annual renewal: fifty dollars (\$50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. | (3-21-12) |
| <b>d.</b> Technician - registration or annual renewal: thirty-five dollars (\$35).  | (3-21-12) |
| <b>e.</b> Veterinary drug technician - registration or annual renewal: thirty-five dollars (\$35).  | (3-21-12) |
| <b>f.</b> Registration reinstatement: one-half (1/2) the amount of the annual fee.  | (3-21-12) |
| <b>03. Certificates of Registration and Licensure - Facilities.</b>   | (3-21-12) |

- a. Retail pharmacy - registration or annual renewal: one hundred dollars (\$100). (3-21-12)
- b. Institutional facility - registration or annual renewal. (3-21-12)
  - i. Hospital pharmacy: one hundred dollars (\$100). (3-21-12)
  - ii. Nursing home: thirty-five dollars (\$35). (3-21-12)
- c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars (\$100). (3-21-12)
- d. Wholesaler. (3-21-12)
  - i. License or annual renewal: one hundred thirty dollars (\$130); or (3-21-12)
  - ii. Registration or annual renewal: one hundred dollars (\$100). (3-21-12)
- e. Veterinary drug outlet - registration or annual renewal: one hundred dollars (\$100). (3-21-12)
- f. Nonresident central drug outlet. (7-1-13)
  - i. Initial license: five hundred dollars (\$500). (7-1-13)
  - ii. License annual renewal: two hundred fifty dollars (\$250). (7-1-13)
- g. Mail service pharmacy. (3-21-12)
  - i. Initial license: five hundred dollars (\$500). (3-21-12)
  - ii. License annual renewal: two hundred fifty dollars (\$250). (3-21-12)
- h. Limited service outlet - registration or annual renewal. (3-21-12)
  - i. Limited service outlet, if not listed: one hundred dollars (\$100). (3-21-12)
  - ii. Sterile product pharmacy: one hundred dollars (\$100). (4-4-13)
  - iii. Remote dispensing pharmacy: one hundred dollars (\$100). (3-21-12)
  - iv. Facility operating a narcotic treatment program: one hundred dollars (\$100). (3-21-12)
  - v. Durable medical equipment outlet: fifty dollars (\$50). (3-21-12)
  - vi. Prescriber drug outlet: thirty five dollars (\$35). (3-21-12)
  - vii. Outsourcing facilities: (4-6-15)
    - (1) Initial nonresident registration: five hundred dollars (\$500). (4-6-15)
    - (2) Initial resident registration: two hundred fifty dollars (\$250). (4-6-15)
    - (3) Registration annual renewal: two hundred fifty dollars (\$250). (4-6-15)
- i. Analytical or research lab -- registration or annual renewal: forty dollars (\$40). (3-21-12)
- j. Retail non-pharmacy outlets. ( )

- ~~i.~~ - ~~Retail store~~ registration or annual renewal: ~~thirty-five dollars (\$35).~~ ~~(3-21-12)~~(    )
- ~~ii.~~ ~~“A” (Stocks more than fifty (50) drug items): sixty dollars (\$60).~~ ~~(3-21-12)~~
- ~~iii.~~ ~~“B” (Stocks fifty (50) or fewer drug items): twenty-five dollars (\$25).~~ ~~(3-21-12)~~
- iii. “V” (Vending machines): ten dollars (\$10) per machine. (3-21-12)
- k. Supplemental facility registrations or annual renewals. (3-21-12)
  - i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration required for one (1) or more hoods: no charge. (3-21-12)
  - ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)
- l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)
- 04. Controlled Substance Registration.** (3-21-12)
  - a. Controlled substance - registration or annual renewal: sixty dollars (\$60). (3-21-12)
  - b. Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars (\$100). (3-21-12)
  - c. Controlled substance registration reinstatement: seventy-five dollars (\$75). (3-21-12)
- 05. Administrative Services and Publications.** (3-21-12)
  - a. Experiential hours certification: twenty-five dollars (\$25). (3-21-12)
  - b. Duplicate pharmacist certificate of licensure: thirty-five dollars (\$35). (3-21-12)
  - c. Duplicate registration or license card: ten dollars (\$10). (3-21-12)
  - d. Commercial lists. (3-21-12)
  - i. ~~Pharmacy list~~ Subject to Subparagraph 021.05.d.ii. below, any registrant or licensee lists: fifty dollars (\$50). ~~(3-21-12)~~(    )
  - ~~ii.~~ ~~Pharmacist list: fifty dollars (\$50).~~ ~~(3-21-12)~~
  - ~~iii.~~ Controlled Substances Act (“CSA”) registrant list: one hundred fifty dollars (\$150). (3-21-12)
  - e. Official Idaho Register: fifteen dollars (\$15). (3-21-12)
  - f. Idaho Pharmacy Laws and Rules book: thirty-five dollars (\$35). (3-21-12)
  - g. Hearing transcript: five dollars (\$5) per page. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.**

- 01. Licensure Submission Requirements.** To be considered for licensure, a graduate of a school or

college of pharmacy located outside of the United States must submit an application for licensure by examination, certification of completion of a minimum of ~~fifteen~~ seventeen hundred ~~forty~~ (150740) experiential hours, and; ~~(4-11-15)~~ ( )

- a. Certification by the FPGEC; or (4-11-15)
  - b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. (4-11-15)
- 02. Affidavit.** An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

**(BREAK IN CONTINUITY OF SECTIONS)**

**040. CERTIFIED PHARMACY TECHNICIAN REGISTRATION.**

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

- 01. Age.** Be at least eighteen (18) years of age unless a waiver is granted by the Board's executive director; (3-21-12)
- 02. Education.** Be a high school graduate or the recipient of a high school equivalency diploma unless a waiver is granted by the Board's executive director; (3-21-12)
- 03. Personal Characteristics.** Be of good moral character and temperate habits; and (3-21-12)
- 04. Certification.** Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the ~~Institute for Certification of Pharmacy Technicians (ICPT)~~ National Healthcare Association, or their successors unless qualified for a continuous employment exemption. ~~(3-21-12)~~ ( )

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

**(BREAK IN CONTINUITY OF SECTIONS)**

**210. CONTROLLED SUBSTANCE STORAGE.**

Controlled substances must be stored as follows: ( )

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

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

~~2101.~~ -- 219. (RESERVED)

**(BREAK IN CONTINUITY OF SECTIONS)**

**710. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES.**

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

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

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

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

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

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

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

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

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

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

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

**05. Technician Staffing.** Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified technician with at least two thousand (2,000) hours pharmacy technician experience in Idaho and under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is open. Supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist must supervise telepharmacy operations electronically from the supervising pharmacy. (~~4-11-15~~) ( )

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

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

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

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

**08. Video and Audio Communication Systems.** A supervising pharmacy of an ADS system used in a remote dispensing site must maintain a video and audio communication system that provides for effective

communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of such video and audio surveillance for a minimum of ninety (90) days. (4-11-15)

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

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

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

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

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

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

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

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

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

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

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

**13. Security.** A remote dispensing site must be equipped with adequate security. (4-11-15)

**a.** At least while closed, a remote dispensing site must utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. The site must have a means of recording the time of entry and the identity of all persons who access the site, which must be retained for ninety (90) days. Two (2) factoring credentialing is required for entry, which must include two (2) of the following: (4-11-15)

- i. Something known (a knowledge factor); (4-11-15)
- ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)
- iii. Something biometric (finger print, retinal scan, etc.); (4-11-15)
- b.** A remote dispensing site must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All remote dispensing sites must meet the following security requirements: (4-11-15)
  - i. Walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)
  - ii. Solid core or metal doors are required. (4-11-15)
  - iii. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)
- c.** Access to the area of the remote dispensing site where prescription drugs are prepared, distributed, dispensed or stored must be limited to technicians and pharmacists. Any other persons requiring access to the remote dispensing site for legitimate business reasons may only be present in the secured area with the permission and under the supervision of a pharmacist, which may be satisfied via audio/video communication. (4-11-15)
- d.** A remote dispensing site must be closed for business and secured during all times a pharmacist or technician is not present. (4-11-15)
- 14. Patient Counseling.** A remote dispensing site must include an appropriate area for patient counseling. (3-21-12)
  - a.** The area must be readily accessible to patients and must be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. (3-21-12)
  - b.** Unless onsite, a pharmacist must use the video and audio communication system to counsel each patient or the patient's caregiver on new medications. (3-21-12)
- 15. Remote Dispensing Site Sign.** A remote dispensing site must display a sign, easily visible to the public, that informs patients that: (3-21-12)
  - a.** The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy; (3-21-12)
  - b.** Identifies the city or township where the supervising pharmacy is located; and (3-21-12)
  - c.** Informs patients that a pharmacist is required to speak with the patient using audio and video communication systems each time a new medication is delivered or if counseling is accepted at a remote dispensing site. (3-21-12)
- 16. Pharmacist Inspection of Remote Dispensing Site.** A pharmacist must complete and document a monthly in-person inspection of a remote dispensing site and inspection reports must be retained. (3-21-12)
- 17. Continuous Quality Improvement Program.** The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. (4-11-15)