

IDAPA 27
TITLE 01
CHAPTER 01

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

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)~~

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 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 of 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'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~~**a.** Something known (a knowledge factor); (4-11-15)

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

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

~~152.~~ **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.~~ **163. Pharmacist Inspection and Inventories of Remote Dispensing Site.** A pharmacist must complete and document; (3-21-12)()

~~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)