

**TITLE 16            OCCUPATIONAL AND PROFESSIONAL LICENSING**  
**CHAPTER 19        PHARMACISTS**  
**PART 33            TELE-PHARMACY AND REMOTE DISPENSING**

**16.19.33.1            ISSUING AGENCY:** Regulation and Licensing Department - Board of Pharmacy.  
[16.19.33.1 NMAC - N, 05-14-10]

**16.19.33.2            SCOPE:** This section applies to hub pharmacies and remote tele-pharmacies. Both the hub pharmacy and all remote tele-pharmacies must be located within **licensed by the New Mexico Board of Pharmacy**. The remote tele-pharmacy must be greater than ~~25~~ **20 (twenty)** miles from an existing ~~community~~ **retail** pharmacy to qualify under these rules **unless one of the following exceptions apply:**

- A.            The tele-pharmacy is located in a hospital or clinic setting; or**
  - B.            The mileage restriction does not apply to a pharmacy that will use tele-pharmacy to expand its current hours or days of operation at its existing location.**
- [16.19.33.2 NMAC - N, 05-14-10]

**16.19.33.3            STATUTORY AUTHORITY:** Section 61-11-6.A.(6) NMSA 1978 requires that the board of pharmacy provide for the licensing of retail pharmacies and nonresident pharmacies and for the inspection of their facilities and activities. Section 61-11-6.A.(1) NMSA 1978 requires the board of pharmacy to adopt, regularly review and revise or repeal rules and regulations necessary to carry out the provisions of the Pharmacy Act.  
[16.19.33.3 NMAC - N, 05-14-10]

**16.19.33.4            DURATION:** Permanent.  
[16.19.33.4 NMAC - N, 05-14-10]

**16.19.33.5            EFFECTIVE DATE:** May 14, 2010, unless a different date is cited at the end of a section.  
[16.19.33.5 NMAC - N, 05-14-10]

**16.19.33.6            OBJECTIVE:** The objective of Part 33 of Chapter 19 is to ensure the safe and competent delivery of quality pharmaceutical products and the provision of pharmaceutical care to the public by establishing standards for the operation of remote dispensing sites and tele-pharmacy, including but not limited to minimum space requirements and standards for equipment, accessories, personnel, dispensing and labeling.  
[16.19.33.6 NMAC - N, 05-14-10]

**16.19.33.7            DEFINITIONS:**

~~A.            “Average number of prescriptions filled per day (ANPFD)” means the total number of prescriptions filled during a calendar month divided by the total number of days open that month.~~

~~A.            “Board” means the New Mexico Board of Pharmacy~~

**B.            “Electronic link” means a real time, continuous on-demand, HIPAA-compliant computer video and audio link between the hub pharmacy and the remote tele-pharmacy during all hours of the remote tele-pharmacy’s operation and in compliance with Paragraph (4) of Subsection A of 16.19.33.9 NMAC.**

**C.            “Indirect continuous supervision” means indirect-continuous supervision through a constant live video link with not less than four camera views which allow for real time live monitoring by the hub pharmacy of the remote tele-pharmacy remote dispensing site which is recorded for a minimum of ninety one hundred eighty (18090) days. This indirect supervision must be in compliance with subsection B in 16.19.22.7 NMAC.**

~~**D.            “Hub pharmacist” means a board registered pharmacist who oversees-provides the-the day to-day operations indirect supervision of a remote tele-pharmacy via an-HIPAA-compliant electronic link that**~~

includes provisions for visual observations and inspection of the inside of the remote tele-pharmacy and all prescription orders prior to dispensing and is in compliance with subsection B of 16.19.22.7 NMAC.. This oversight is to include visual inspection of and patient consultation for any prescription order dispensed from the remote tele-pharmacy.

**EE.** “Hub pharmacy” means a board licensed pharmacy operating under the direct control of a board registered pharmacist from which computer-aided pharmacist supervision of a remote tele-pharmacy occurs.

**DF.** “Patient-pharmacist audio visual link” means a real time HIPAA-compliant audio visual link from the private patient counseling area of the remote tele-pharmacy to the pharmacist at the hub pharmacy.

**ED.** “Hub pharmacy” means a New Mexico licensed pharmacy operating under the direct control of a New Mexico licensed pharmacist from which computer-aided pharmacist supervision of a remote tele-pharmacy occurs.

**FC.** “Hub pharmacist” means a New Mexico registered pharmacist who oversees provides the the day to day operations indirect supervision of a remote tele pharmacy via an HIPAA-compliant electronic link that includes provisions for visual observations and inspection of the inside of the remote tele pharmacy and all prescription orders prior to dispensing and is in compliance with subsection B of 16.19.22.7 NMAC.. This oversight is to include visual inspection of and patient consultation for any prescription order dispensed from the remote tele pharmacy.

**G.** “Pharmacist-in-charge” means the pharmacist for the hub pharmacy from which the hub pharmacist oversees the day to day operation of a remote tele-pharmacy and who shall comply with 16.19.6.9 NMAC.

**H.** “Pharmacist site visits” means the visitation and inspection of the tele-pharmacy by the hub pharmacist by which the hub pharmacist is physically present to assess the remote tele-pharmacy’s compliance with all laws and regulations. defines how often a pharmacist must physically visit the remote tele-pharmacy.

- (1) at least once a month when the ANPFD is 1 to 50;
- (2) at least once every two weeks when the ANPFD is 51 to 100 per day;
- (3) at least once per week when the ANPFD is 101 to 150;
- (4) at least twice per week when the ANPFD is 151 to 200;
- (5) A pharmacist is required on-site full time during normal operating hours if the ANPFD exceeds 200.

**I**

**HI.** “Practice of tele-pharmacy” means the provision of pharmacist care by registered pharmacies and pharmacists New Mexico board licensed pharmacies and board registered New Mexico pharmacists through the use of telecommunications or other technologies to patients or their agents at a remote tele-pharmacy site.

**IJ.** “Remote dispensing site” means a pharmacy location primarily staffed by technicians and remote dispensing technology “electronic link” and continuous indirect video supervision with required pharmacist supervision and pharmacist site visits and in-person visits from the hub pharmacy pharmacist.

**JK.** “Remote tele-pharmacy” means a board licensed pharmacy located in the state of New Mexico staffed by a remote tele-pharmacy technician who practices under the direct, computer aided and supervision of a hub pharmacist working from the hub pharmacy by electronic link during all hours of operation.

**KL.** “Remote tele-pharmacy technician” means a New Mexico board registered pharmacy technician employed by the hub pharmacy, with a minimum of two-thousand hours of experience working as a certified registered pharmacy technician who under the computer aided supervision of an off-site pharmacist, handles the day to day operation of a remote tele-pharmacy, including the preparation and dispensing of prescription drugs.

[16.19.33.7 NMAC - N, 05-14-10]

**16.19.33.8 PURPOSE:** The board of pharmacy is responsible for maintaining, continuing and enhancing the development of the education and professional role of the pharmacist for the protection of the health, welfare and

safety of the citizens of New Mexico. New Mexico is facing a pharmacy services accessibility problem due to the closing of pharmacies ~~and the lack of registered pharmacists~~. In order to maintain, **augment**, or **expand the availability of pharmacist** ~~make pharmacy services available~~ in communities that have **pharmacy access issues** ~~no licensed pharmacy or are in jeopardy of losing their licensed pharmacy~~, rules are necessary to permit remote tele-pharmacy services and remote dispensing.

[16.19.33.8 NMAC - N, 05-14-10]

#### **16.19.33.9 OPERATIONS:**

**A.** A remote tele-pharmacy shall comply with all standards of 16.19.6.8 NMAC governing the procedure for obtaining a license to operate a pharmacy in New Mexico:

(1) The license holder of the hub pharmacy must apply for a license to operate a remote tele-pharmacy. A remote tele-pharmacy license is established for the purpose of conducting a remote tele-pharmacy. The license is issued to a remote tele-pharmacy connected to a hub pharmacy via an electronic link. The initial licensure fee and subsequent license renewal fee are the same as those for retail pharmacies, as required by Subsection E of 16.19.12.13 NMAC.

(2) A remote tele-pharmacy that operates under different ownership than the hub pharmacy to which it is attached; shall have a written contractual agreement outlining the responsibilities of each pharmacy. This written agreement shall be submitted with the initial licensure application for a remote tele-pharmacy. Any subsequent changes to that contractual agreement shall be submitted to the board's executive director for approval. The applicant must provide sufficient evidence that **the addition of a tele-pharmacy will augment or expand the availability of pharmacist services and pharmacy access within the proposed area of location**. ~~the proposed location is in an area of the state lacking access to a retail pharmacy; the board will utilize the evidence supplied by the applicant and from other sources when making a determination that sufficient evidence exists to approve an application for a remote tele-pharmacy.~~

(3) A remote tele-pharmacy shall comply with all the applicable requirements for a pharmacy as contained in 16.19.6 NMAC, **including the requirement that all medications be stored under proper conditions**.

(4) A remote tele-pharmacy shall be connected to a hub pharmacy via an **HIPAA-compliant** electronic link. All links must be fully operational during all hours of operation of the remote tele-pharmacy. If the link malfunctions, the remote tele-pharmacy must be closed unless a hub pharmacist is physically present at the remote tele-pharmacy site.

(a) Video equipment must be capable of providing an adequate number of simultaneous views of the pharmacy operation at the remote tele-pharmacy.

(b) The video equipment at the remote tele-pharmacy site must be capable of resolution sufficient to allow for pharmacist identification of medication dosage forms and the reading of bottle labels via video camera.

(c) The video equipment at the remote tele-pharmacy site must be capable of recording and maintaining at least **ninety one hundred eighty (180 90)** days of video surveillance of the remote tele-pharmacy site and operations for future review.

(d) Only a remote tele-pharmacy technician designated for that site or a pharmacist who is physically present at the remote tele-pharmacy may access a remote tele-pharmacy site, linked to a hub pharmacy via an electronic link.

(e) The remote tele-pharmacy may only remain open as long as the designated pharmacy technician is present in the remote tele-pharmacy and the hub pharmacist is **providing indirect supervision from the hub pharmacy** ~~present at the hub pharmacy~~ or **the hub pharmacist is physically present** at the remote site.

(5) The name of each certified pharmacy technician that works at a remote tele-pharmacy shall be recorded with the ~~New Mexico~~ board of pharmacy.

(6) **The remote tele-pharmacy shall utilize bar coding or similar technology that effectively recognizes the drug or device stock selected to fill the prescription is the same as indicated on the prescription label.**

**(7) The hub pharmacy, and pharmacist providing indirect supervision hub pharmacist are responsible for ensuring fulfillment of all pharmacist responsibilities in accordance with NMAC-16.19.4.16 NMAC**

**(58) The pharmacist in charge of the hub pharmacy shall produce a policy and procedure manual. Written policies and procedures must be submitted to the board prior to the issuance of any license. The pharmacist in charge is responsible for the development, implementation, maintenance and review of written policies and procedures for the safe and effective operation of the remote tele-pharmacy and the oversight by the hub pharmacy. These policies and procedures shall comply with New Mexico board of pharmacy regulations and laws. This manual and shall be available for board inspection in both the remote tele-pharmacy and the hub pharmacy. The policy and procedure manual shall be reviewed by the pharmacist-in-charge **at least** annually and revised if necessary to promote improvements in safety and service at the remote tele-pharmacy. The annual review and any changes to the manual shall be documented. The policy and procedure manual must address each of the following, at a minimum, prior to the remote tele-pharmacy engaging in the practice of pharmacy:**

**(a) The establishment of standards and practices necessary to ensure safety, accuracy, security and patient confidentiality;**

**(b) The establishment of standards and practices necessary to ensure drugs and devices are procured, handled, stored, and dispensed or otherwise dispositioned in compliance accordance with New Mexico board of pharmacy laws and regulations;**

**(c) Identification of pharmacy personnel authorized to access drug storage and dispensing areas at the remote tele-pharmacy and to receive drugs delivered to the remote tele-pharmacy;**

**(d) The establishment of standards and practices necessary to ensure all records are kept maintained in compliance with New Mexico board of pharmacy laws and regulations;**

**(e) The establishment of processes to assure the integrity, legitimacy, and authenticity of prescriptions;**

**(f) The criteria for monthly inspections conducted during pharmacist site visits of the remote tele-pharmacy and appropriate site visit documentation;**

**(g) medication error prevention;**

**(gh) The establishment of training standards and practices to ensure facility personnel are properly trained and comply with all applicable policies and procedures. Training required for the remote tele-pharmacy technicians and pharmacists shall ensure the competence and ability of each person that operates the electronic verification system, electronic recordkeeping, and communication systems. Technician training documentation shall be retained maintained in accordance to 16.19.22 NMAC.**

**(69) The pharmacist-in-charge is responsible for an ongoing review of incident reports and outcomes, with appropriate corrective action taken and documented.**

**(10) The pharmacist-in-charge must ensure each remote tele-pharmacy location records, for each prescription dispensed, the identification of each pharmacist who performed:**

**(a) order interpretation;**

**(b) order entry verification;**

**(c) prospective drug utilization review;**

**(d) final order verification;**

**(e) any intervention required; and**

**(f) patient counseling, when there are no other means of definitively determining the identity of the pharmacist who provided counseling.**

**(11) A hub pharmacist shall not provide direct or indirect supervision for more than four pharmacies.**

**(712) The hub pharmacist employed by the hub pharmacy must conduct pharmacist site visits and visit and complete inspections of the remote tele-pharmacy at least once monthly according to the visitation requirements of Subsection H of 16.19.33.8 NMAC. The pharmacist shall increase frequency of the monthly site visits if issues are identified, and additional pharmacist intervention will shall be taken until the issue is resolved. A list of inspection criteria shall be included in the policy and procedure manual for the remote tele-**

pharmacy. The pharmacist's inspection shall include a determination of the average number of prescriptions filled per day. A copy of the inspection report shall be reviewed and signed by the pharmacist-in-charge of the hub pharmacy and a copy of the inspection report shall be maintained ~~for a period of three (3) years~~ at both the remote tele-pharmacy and at the hub pharmacy for the board of pharmacy inspection.

~~(813)~~ The number of pharmacy technicians that a hub pharmacist shall oversee shall be limited according to 16.19.22.10 NMAC. Any pharmacy technicians on duty at the hub pharmacy site shall be taken into account along with any remote tele-pharmacy technicians working at remote tele-pharmacy sites, when computing the ratio of pharmacists to pharmacy technicians. ~~Application for an increase in the ratio of pharmacy technicians to pharmacists may be made in accordance with Subsection B of 16.19.22.10 NMAC.~~

~~(914)~~ A remote tele-pharmacy may have a dangerous drug inventory. Any controlled substances shall be kept at the remote site in accordance with 16.19.20 NMAC.

(a) If controlled substances are kept, the remote tele-pharmacy shall be registered with the drug enforcement administration and obtain a DEA number.

(b) If controlled substances are kept, the remote tele-pharmacy shall have a valid New Mexico controlled substance registration as required in 16.19.20 NMAC.

(c) All controlled substances kept in inventory by the remote tele-pharmacy shall be listed on a perpetual inventory log, which shall be updated upon the dispensing of each controlled substance prescription or other disposition.

(d) The pharmacist shall perform monthly audits of all controlled substances during ~~regular inspection~~ **pharmacist site** visits to the remote tele-pharmacy. **If a perpetual reconciliation is not achieved through the use of technology, the pharmacist shall perform and document a complete monthly reconciliation.**

~~(1015)~~ Prescriptions may be received, entered and filled or re-filled by the hub pharmacy and sent to the remote tele-pharmacy for distribution to the patient during hours when the technician is present in the remote tele-pharmacy. A pharmacist at the hub pharmacy must **complete a final check of** ~~approve~~ each prescription before it leaves the remote tele-pharmacy site, **in accordance with subsection B of NMAC 16.19.4.16(b) NMAC.**

(a) The pharmacist's initials and the technician's initials shall be recorded.

(b) The pharmacist shall compare the stock bottle, drug dispensed and drug strength. The entire prescription label must be checked for accuracy. All prescriptions distributed by the remote- tele-pharmacy must have the label affixed to the prescription container prior to being inspected by the pharmacist via electronic link.

~~(1116)~~ Patient counseling shall be done by a **hub** pharmacist via an **"Patient-pharmacist audio visual link"** ~~electronic link~~. The pharmacist shall counsel the patient or the patient's agent on all new prescriptions and refills **in compliance with subsection F in 16.19.4.16 NMAC**. All counseling, according to Subsection ~~EF~~ **F** of 16.19.4.16 NMAC, remains the responsibility of the pharmacist at the hub pharmacy via an electronic link. [16.19.33.9 NMAC - N, 05-14-10]

**(17) A remote tele-pharmacy is limited to filling no more than 200 prescriptions per day. If filling more than 200 prescriptions per day, the remote tele-pharmacy shall be converted to a retail pharmacy and is subject to all applicable requirements in 16.19.6 NMAC.**

**(18) No drug compounding shall occur at any remote tele-pharmacy.**

**(19) All records required by this part shall be kept on-site at the tele-pharmacy for at least three years and shall be readily available for inspection by the board or boards' agent**

**HISTORY OF 16.19.33 NMAC: [RESERVED]**