

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 New Mexico. ~~The remote tele-pharmacy must be greater than 25 miles from an existing community pharmacy to qualify under these rules.~~
[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.~~

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 operation and in compliance with Paragraph (4) of Subsection A of 16.19.33.9 NMAC.

C. “Continuous video supervision” means a constant live video link with not less than four camera views which allow for real time live monitoring of the remote tele-pharmacy remote dispensing site which is recorded for a minimum of ~~thirty one hundred eighty (18030)~~ **thirty (30)** days.

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

E. “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.

F. “Hub pharmacist” means a New Mexico registered pharmacist who oversees the ~~day to day operations~~ **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 pharmacy and all prescription orders prior to dispensing.

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” defines how often a pharmacist must physically visit the remote tele-pharmacy. **The board reserves the right to modify this requirement as deemed appropriate for public safety:**

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

J. “Remote tele-pharmacy” means a 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.

K. “Remote tele-pharmacy technician” means a New Mexico 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.

L. “Practice of tele-pharmacy” means the provision of pharmacist care by ~~registered pharmacies and pharmacists~~ **licensed pharmacies and registered New Mexico pharmacists** through the use of telecommunications or other technologies to patients or their agents at a remote **tele-pharmacy** site.
[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 or make pharmacy services available in communities that have 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 boards executive director for approval. ~~The applicant must provide sufficient evidence that the proposed location is in an area of the state lacking reasonable 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.

(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 **to the public** unless a 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 ~~thirty one hundred eighty (180)~~ **30** 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 present at the hub pharmacy or at the remote site.

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

(5) The pharmacist in charge of the hub pharmacy shall produce a policy and procedure manual for the safe and effective operation of the remote tele-pharmacy and the oversight by the hub pharmacy. This manual 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 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.

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

(7) The pharmacist employed by the hub pharmacy must 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.~~ 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 at both the remote tele-pharmacy and at the hub pharmacy for the board of pharmacy inspection.

(8) 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 ration of pharmacy technicians to pharmacists may be made in accordance with Subsection B of 16.19.22.10 NMAC.

(9) 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 visits to the remote tele-pharmacy.

(10) 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 approve each prescription before it leaves the remote tele-pharmacy site.~~

(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.

(11) Patient counseling shall be done by a pharmacist via an **HIPAA-compliant** electronic link. The pharmacist shall counsel the patient or the patient's agent on all new prescriptions and refills. All counseling, according to Subsection E 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]

HISTORY OF 16.19.33 NMAC: [RESERVED]