TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 6 PHARMACIES

16.19.6.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[16.19.6.1 NMAC - Rp, 16 NMAC 19.6.1, 03-30-02]

16.19.6.2 SCOPE: All pharmacies, resident and nonresident, as defined in 61-11-2 (S), (Y) NMSA 1978, and all persons or entities that own or operate, or are employed by, a pharmacy for the purpose of providing pharmaceutical products or services.
[16.19.6.2 NMAC - Rp, 16 NMAC 19.6.2, 03-30-02]

16.19.6.3 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.
[16.19.6.3 NMAC - Rp, 16 NMAC 19.6.3, 03-30-02]

16.19.6.4 DURATION: Permanent
[16.19.6.4 NMAC - Rp, 16 NMAC 19.6.4, 03-30-02]

16.19.6.5 EFFECTIVE DATE: March 30, 2002, unless a later date is cited at the end of a section.
[16.19.6.5 NMAC - Rp, 16 NMAC 19.6.5, 03-30-02]

16.19.6.6 OBJECTIVE: The objective of Part 6 of Chapter 19 is to ensure the safe and competent delivery of quality pharmaceutical products and services to the public by establishing standards for the operation of pharmacies, including but not limited to minimum space requirements and standards for equipment, accessories, personnel, dispensing, labeling and advertising.
[16.19.6.6 NMAC - Rp, 16 NMAC 19.6.6, 03-30-02]

16.19.6.7 DEFINITIONS:

A. "Contracted" means having a written agreement (to include" business associate agreements" as required by federal law) between parties to ensure the authenticity and prescribing authority of each prescriber transmitting prescriptions, sufficient security to prevent the fraudulent creation or alteration of prescriptions by unauthorized parties, and assurance that "network vendors" or electronic prescription transmission intermediaries involved in the transmission and formatting of the prescription can provide documentation of chain of trust of who has had access to prescription content. Electronic prescription transmissions by non "contracted" parties will be invalid.

B. "Drug utilization review" (DUR) means evaluating or reviewing the patient record in order to determine the appropriateness of the drug therapy for a patient and which includes the prospective drug review in 16.19.4 NMAC and the verification of data entries including the correct interpretation and input of written prescriptions and the drug regimen review (NMSA 61-11-2L) as required by the board.

C. "Electronically transmitted prescriptions" means communication of original prescriptions, refill authorizations, or drug orders, including controlled substances to the extent permitted by federal law, from an authorized licensed prescribing practitioner or his or her authorized agent directly or indirectly through one or more "contracted" parties to the pharmacy of the patient's choice by electronic means including, but not limited to, telephone, fax machine, routers, computer, computer modem or any other electronic device or authorized means.

D. "Electronic signature" means an electronic sound, symbol or process attached to or logically associated with a prescription record.

E. "Network vendor" means prescription transmission intermediary "contracted" by business associate agreements with appropriate parties involved, including point of care vendors, pharmacy computer vendors, pharmacies, to transmit the prescription information only having access to the prescription content to make format modification to facilitate secure and accurate data transmission in a format that can be received and deciphered by the pharmacy.

F. "Point of care vendor" means an entity contracted with a prescriber to generate or transmit electronic prescriptions authorized by a practitioner directly to a pharmacy or to a "contracted" intermediary or

"network vendor", who will ultimately transmit the prescription order to a patient's pharmacy of choice. Vendor must provide an unbiased listing of provider pharmacies and not use pop-ups or other paid advertisements to influence the prescriber's choice of therapy or to interfere with patient's freedom of choice of pharmacy. Presentation of drug formulary information, including preferred and non-preferred drugs and co-pay information if available, is allowed.

G. "Prescriber" means a licensed practitioner who generates a prescription order and assumes responsibility for the content of the prescription.

H. "Remote pharmacist DUR site means a remote pharmacist practice site electronically linked to the New Mexico licensed pharmacy it operates through at which a pharmacist conducts drug utilization reviews. No dispensing will occur from a remote pharmacist DUR site.

[16.19.6.7 NMAC - Rp, 16 NMAC 19.6.7, 03-30-02; A, 06-30-06; A, 12-15-08]

16.19.6.24 NONRESIDENT PHARMACIES:

A. Definitions.

(1) "Board" means the New Mexico Board of Pharmacy.

(2) "Nonresident Pharmacy" means any pharmacy located outside New Mexico that ships, mails or delivers in any manner prescription drugs to New Mexico patients or consumers.

(3) "Prescription drugs" means any drug required by federal or New Mexico law or regulation to be dispensed only by a prescription and includes "dangerous drugs" and "controlled substances" as defined by federal and New Mexico law.

(4) "Resident state" means the state in which the Nonresident Pharmacy is a resident.

B. Licensure requirement.

(1) No nonresident pharmacy shall ship, mail or deliver prescription drugs to a patient in this state unless licensed by the Board. In addition, no nonresident pharmacy shall ship, mail or deliver controlled substances to a patient in this state unless registered by the Drug Enforcement Administration and the Board for controlled substances.

(2) Separate Licensure. Any person that ships, mails or delivers prescription drug to New Mexico patients from more than one nonresident pharmacy shall obtain a separate New Mexico Nonresident Pharmacy license for each pharmacy.

C. Requirements for obtaining licensure.

(1) Application. Each nonresident pharmacy applying for licensure or renewal of licensure shall submit an application to the Board which includes the following minimum information:

(a) The address of the principle office of the nonresident pharmacy and the name and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to persons in New Mexico. A report containing this information shall be made on an annual basis and within ten days after any change of office location, corporate officer or pharmacist in charge;

(b) Proof that the nonresident pharmacy maintains a valid license, permit or registration to operate the pharmacy in compliance with the laws of the resident state;

(c) A copy of the most recent inspection report resulting from an inspection of the nonresident pharmacy conducted by the regulatory or licensing agency of the resident state;

(d) If compounded sterile preparations (CSP) are to be shipped into NM, a copy of the most recent CSP operations inspection report conducted by the regulatory or licensing agency of the resident state (or party recognized by that agency to perform such inspection, or party recognized by the board) which demonstrates the pharmacy operates in conformance with the requirements of applicable USP/NF General Chapters numbered below 1000. The inspection must have occurred within the 12 months immediately preceding receipt of the license application by the board. The board may deny licensure unless the applicant submits documentation satisfactory to the board that any deficiencies noted in the inspection report have been corrected. For entities also acting as Outsourcing Facilities, the required standard of operation shall be cGMP.

(ed) The policy and procedure manual required by 16.19.6.24.D.(2).;

(fe) Proof that the nonresident pharmacy has a toll-free telephone service available to New Mexico patients;

(gf) The name and address of a resident in New Mexico for service of process;

(hg) If the nonresident pharmacy wants to ship, mail or deliver controlled substances to New Mexico patients, then the pharmacy must submit an application for controlled substances under 16.19.20 NMAC; and

(i~~h~~) All fees required by 16.19.12 NMAC.

(2) Agent of Record. Each nonresident pharmacy that ships, mails or delivers prescription drugs to a patient in New Mexico shall designate a resident agent in New Mexico for service of process. If a nonresident pharmacy does not designate a registered agent, the shipping, mailing, or delivering of prescription drugs in the State of New Mexico shall be deemed an appointment by such nonresident pharmacy of the Secretary of State to be its true and lawful attorney upon whom may be served all legal process in any action or proceeding against such pharmacy growing out of or arising from such delivery.

D. Conditions of licensure.

(1) Compliance. Each nonresident pharmacy licensed by the Board must comply with the following:

(a) All statutory and regulatory requirements of the State of New Mexico regarding controlled substances, drug product selection, and the labeling, advertising, and dispensing of prescription drugs including all requirements that differ from federal law or regulations, unless compliance would violate the laws and regulations of the resident state;

(b) Maintain, at all times, a valid license, permit, or registration to operate the pharmacy in compliance with the laws of the resident state;

(c) Maintain, if applicable, a federal registration for controlled substances;

(d) Supply, upon request from the Board or the regulatory or licensing authority of the resident state, all information needed to carry out the Board's responsibilities under state and federal law;

(e) Provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the nonresident pharmacy who has access to the patient's records. A nonresident pharmacy shall provide the toll-free telephone service during its regular hours of operation, but not less than six days a week and for a minimum of forty hours a week. The toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(2) Policy and Procedure Manual. Each nonresident pharmacy shall develop and provide the Board with a policy and procedure manual that sets forth:

(a) Normal delivery protocols and times;

(b) The procedure to be followed if the patient's medication is not available at the nonresident pharmacy, or if delivery will be delayed beyond the normal delivery time;

(c) The procedure to be followed upon receipt of a prescription for an acute illness, which policy shall include a procedure for delivery of the medication to the patient from the nonresident pharmacy at the earliest possible time (i.e., courier delivery), or an alternative that assures the patient the opportunity to obtain the medication at the earliest possible time;

(d) The procedure to be followed when the nonresident pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available.

E. Disciplinary proceedings.

(1) The Board may withhold, suspend, or revoke any nonresident pharmacy license held or applied for upon the grounds established by law or regulations, including, without limitation, the failure to comply with the conditions specified in 16.19.6.24.C. The Board shall suspend or revoke a nonresident pharmacy license when the license, permit, or registration to operate the pharmacy in the resident state has been suspended or revoked. A certified copy of the record of suspension or revocation by the resident state is conclusive evidence.

(2) Upon receipt of information indicating that the nonresident pharmacy may have violated the laws or regulations of the resident state, the Board may file a complaint against the nonresident pharmacy with the regulatory or licensing authority of the resident state.

F. Limitations.

(1) Nothing in this Regulation shall be construed to authorize the dispensing of contact lenses by Nonresident Pharmacies.

(2) Nothing in this Regulation is intended to replace or modify any requirements that a nonresident business may be subject to under any other law or regulation.

[16.19.6.24 NMAC - Rp, 16 NMAC 19.6.24, 03-30-02]