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. "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.

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

D. "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.

E. "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.

F. "Prescriber" means a licensed practitioner who generates a prescription order and assumes responsibility for the content of the prescription.
[16.19.6.7 NMAC - Rp, 16 NMAC 19.6.7, 03-30-02; A, 06-30-06]

16.19.6.8 PROCEDURE FOR NEW LICENSURE OF BUSINESS FOR DISTRIBUTION OF DRUGS AND FOR TRANSFER OF OWNERSHIP OF LICENSED BUSINESSES:

A. Applicant shall submit required application and fee to the Board of Pharmacy office.

B. The Board, at its discretion, may require all persons interested in the ownership, operation or management, pursuant to the applicant, to meet with the Board to determine that all persons are qualified and cognizant of the laws and regulations pertaining to the distribution of dangerous drugs.

C. After preliminary approval of the application, the applicant shall submit a "Request for Inspection" and the inspection fee, where applicable, in advance of fourteen days of the requested date for inspection. All subsequent "Request for Inspection" shall be submitted in advance of fourteen days of the requested date for inspection.

D. The Board shall review the license application and the inspection report at its next meeting and shall cause the license to be issued or denied.

E. The license provided for herein shall terminate upon the sale or transfer of ownership. Operation of a business subsequent to the date of such transfer or sale without a new application and approval by the Board shall constitute a violation of the law under 61-11-14(I), and is subject to the penalties contained in the Pharmacy Act. Any pharmacy license exempt from minimum standards by Section 61-11-26 of the Pharmacy Act, will be considered to be a new license upon change of ownership and will be required to meet the standards set forth in the Board of Pharmacy 16.19.6.10, before a new license will be issued for such pharmacy. Note Change in Ownership as defined in 16.19.6.20.
[16.19.6.8 NMAC - Rp, 16 NMAC 19.6.8, 03-30-02]

16.19.6.9 PHARMACIST-IN-CHARGE:

A. The term "pharmacist-in-charge" means a pharmacist licensee in the state of New Mexico who has been designated pharmacist-in-charge pursuant to New Mexico Statute Section 61-11-15. Failure to perform any of the following duties will constitute a violation of 61-11-20(A)(1). It shall be the duty and responsibility of the pharmacist-in-charge consistent with the regulations governing professional conduct and in compliance with all applicable laws and regulations:

(1) to establish for the employees of the pharmacy, written policies and procedures for procurement, storage, compounding and dispensing of drugs;

(2) to supervise all of the professional employees of the pharmacy;

(3) to supervise all of the non-professional employees of the pharmacy in so far as their duties relate to the sale and storage of drugs;

(4) to establish and supervise the method and manner for the storing and safekeeping of drugs;

(5) to establish and supervise the record keeping system for the purchase, sale, possession, storage, safekeeping and return of drugs;

(6) to notify the board immediately upon his knowledge that his service as pharmacist-in-charge have been or will be terminated;

(7) inform the board in writing, within 10 days, of the employment or termination of any pharmacy technician; the information shall include name and location of pharmacy, name of employee, social security number, and date of hire or termination;

(8) to complete the New Mexico board of pharmacy self assessment inspection form as provided by the board and to submit the signed and dated form with the pharmacy renewal application to the board office.

B. Every licensed pharmacy will be under continued daily supervision of a registered pharmacist who shall have direct control of the pharmaceutical affairs of the pharmacy.

C. Upon termination of the pharmacist-in-charge each pharmacy owner shall immediately designate a successor pharmacist-in-charge and immediately notify the state board of pharmacy of such designation. The owner shall request the license application form to be completed by the successor pharmacist-in-charge and filed with the board within 10 days. The failure to designate a successor pharmacist-in-charge and notify the board of such designation shall be deemed a violation of Section 61-11-15, Pharmacy Act.
[16.19.6.9 NMAC - Rp, 16 NMAC 19.6.9, 03-30-02; A, 06-30-06]

16.19.6.10 MINIMUM STANDARDS:

A. The restricted area to be occupied by the prescription department shall be an undivided area of not less than 240 square feet. The floor area shall extend the full length of the prescription compounding counter. This area shall provide for the compounding and dispensing and storage of all dangerous or restricted drugs, pharmaceuticals, or chemicals under proper condition of sanitation, temperature, light, ventilation, segregation and security. No space in this area shall provide for an office, auxiliary store room or public restroom(s).

(1) A private restroom, for exclusive use by the pharmacy staff, may be attached to the restricted area. This restroom does not count as square footage for the restricted area.

(2) An office for the exclusive use by the pharmacy may be attached to the restricted area. No general store accounting functions may be performed in this office. This area will not be considered as square footage for the restricted area.

(3) An auxiliary storage area for the exclusive use of the pharmacy may be attached to the restricted area. No items may be stored in this area that are not directly related to the operations performed in the restricted area. This area will not be considered as square footage for the restricted area.

(4) Each pharmacy shall provide facilities whereby a pharmacist may professionally counsel a patient or a patients' agent and protect the right to privacy and confidentiality.

B. An exception to the minimum space footage requirement may be considered by the Board on an individual basis. The Board may consider such factors as:

(1) Rural area location with small population.
(2) No pharmacy within the same geographical area.
(3) No prescription area of less than 120 square feet will be acceptable.
(4) All special waivers will be subject to review annually for reconsideration.

C. The prescription compounding counter must provide a minimum of 16 square feet of unobstructed compounding and dispensing space for one pharmacist and a minimum of 24 square feet for two or more pharmacists when on duty concurrently.

D. The restricted floor area shall be unobstructed for a minimum width of thirty inches from the prescription compounding center.

E. The pharmacy restricted area shall be separated from the merchandising area by a barrier of sufficient height and depth to render the dangerous drugs within the pharmacy inaccessible to the reach of any unauthorized person. All windows, doors, and gates to the restricted area shall be equipped with secure locks. The restricted area shall be locked in the absence of a pharmacist on the premises.

F. The restricted area shall contain an adequate sink with hot and cold water.

G. The restricted area shall contain a refrigerator capable of maintaining the adequate temperature.

H. The restricted area of a retail pharmacy established in conjunction with any other business other than a retail drug store, shall be separated from the merchandising area of the other business by a permanent barrier or partition from floor to roof with entry doors that may be securely locked when a pharmacist is not on duty.

[16.19.6.10 NMAC - Rp, 16 NMAC 19.6.10, 03-30-02]

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS:

A. The pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparations of drugs and parenteral products appropriate to the scope of pharmaceutical services provided. The following items shall be in the pharmacy:

(1) An updated reference source, appropriate to each practice site, either electronic or paper version;
(2) One copy of the most recently published New Mexico pharmacy laws, rules and regulations and available revisions, either electronic or paper version

B. PARENTERAL PHARMACEUTICALS

(1) Purpose: To ensure that the citizens of New Mexico receive routine safe and competent delivery of parenteral products and nutritional support throughout the state. To establish guidelines for licensure and inspection of such facilities by the state board of pharmacy.

(2) Definitions

(a) "Parenteral products pharmacy" is a retail pharmacy which prepares and distributes prescriptions for sterile products intended for parenteral administration to patients either at home or in or out of an institution licensed by the state.

(b) "Parenteral product" means any preparation administered by injection through one or more layers of skin tissue.

(c) "Sterile" means a preparation that has undergone a valid sterilization process and is devoid of all living microorganisms, packaged in such a way to ensure the retention of this characteristic.

(d) "Preparation" means a sterile product which has been subjected to manipulation by a pharmacist under aseptic conditions to render the product suitable for administration.

(e) "Aseptic conditions" means a cabinet or facility capable of obtaining ISO class 5 clean air as defined by the federal standards 209E and which is certified by a testing agency at least every six months.

(f) "Aseptic technique" means proper manipulation of articles within a ISO class 5 clean air room or station to maintain sterility.

(g) "Disinfectant" means a chemical compound used to kill and or control microbial growth within a ISO class 5 area or its surroundings and is approved for such use by the environmental protection agency.

(h) "Antimicrobial soap" means soap containing an active ingredient that is active both in vitro and vivo against skin microorganisms.

(i) "Surgical hand scrub" means an antimicrobial containing preparation which significantly decreases the number of microorganisms on intact skin.

(j) "SOP" means standard operating procedures. These are written standards for performance for tasks and operations within a facility.

(k) "Quality control" means procedures performed on preparations to assess their sterility and/or freedom from other contamination.

(l) "Quality assurance" means the procedures involved to maintain standards of goods and services.

(m) "ISO class 5 environment" means having less than 100 particles 0.5 microns or larger per cubic foot.

(n) "ISO class 8 environment" means having less than 100,000 particles 0.5 microns or larger per cubic

foot.

(o) "Critical area" means any area in the controlled area where products or containers are exposed to the environment.

(p) "Process validation" means documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

(q) "Positive pressure controlled area" means the clean room is to have a positive pressure differential relative to the adjacent pharmacy.

(r) "Barrier isolator" is an enclosed containment device which provides a controlled ISO class 5 environment. The device has four components; the stainless steel shell, HEPA filtration of entering and exiting air flows, glove ports for people interaction and an air lock for moving products into and out of the controlled environment.

(s) "Plan of care" means an individualized care plan for each patient receiving parenteral products in a home setting to include the following:

(i) a description of actual or potential drug therapy problems and their proposed solutions;

(ii) a description of desired outcomes of drug therapy provided;

(iii) a proposal for patient education and counseling; and

(iv) a plan specifying proactive objective and subjective monitoring (e.g. vital signs, laboratory test, physical findings, patient response, toxicity, adverse reactions, and non compliance) and the frequency with which monitoring is to occur.

(t) USP/NF standards means USP/NF Chapter 797 titled "pharmacy compounding - sterile products".

(u) "Cytotoxic drugs" shall be defined in the most current American hospital formulary service (AHFS).

(3) Pharmacist-in-Charge: In order to obtain a license, all parenteral product pharmacies must designate a pharmacist in charge of operations who is:

(a) licensed to practice pharmacy in the state of New Mexico;

(b) responsible for the development, implementation and continuing review of written SOP's consistent with USP/NF standards which are used by the operation in their daily operation;

(c) pharmacist on staff who is available for twenty-four hour seven-day-a-week services;

(d) responsible for establishing a system to assure that the products prepared by the establishment are administered by licensed personnel or properly trained and instructed patients;

(e) responsible for developing an appropriate and individualized plan of care in collaboration with patient or caregiver and other healthcare providers for each patient receiving parenteral products in a home setting.

(4) Physical Requirements:

(a) The parenteral products pharmacy must have sufficient floor space to assure that the products are properly prepared and stored to prevent contamination or deterioration prior to administration to the patient and meet the following:

(i) be separated physically from other pharmacy activities and enclosed on all sides except for doors and/or windows for the passage of materials;

(ii) the minimum size of a retail pharmacy must be 240 square feet; a retail pharmacy with preparation of sterile products capabilities must have 340 square feet; the stand alone parenteral product pharmacy must have a minimum of 240 square feet;

(iii) addition of a parenteral area in existing pharmacies will require submission of plans for remodeling to the board office for approval and inspection prior to licensure;

(iv) a new parenteral pharmacy must comply with Sections 8, 9, 10 and 11 of the regulations.

(b) Equipment and materials. The parenteral products pharmacy has sufficient equipment and physical facilities to safely compound and store such products and includes the following:

(i) either a ISO class 5 clean air work station or a room which meets ISO class 5 conditions;

(ii) refrigeration capacity for proper storage of prepared parenterals at 2C to 8C after preparation and until prescriptions are received by the patient or their agent;

(iii) if bulk reconstitution of antibiotics is performed the facility has a freezer capable of freezing and storing the product at -20C for periods not to exceed the manufacturer's recommendations;

(c) References. Parenteral products pharmacies maintain in their library at least one current edition reference book from each category listed below in addition to other required references:

(i) drug monograph reference, i.e., USP-DI, AHFS: drug information service, martindale's extra pharmacopoeia, or other suitable reference;

(ii) stability and incompatibility reference; i.e., trissell's handbook of parenteral medications, king/cutter IV incompatibilities, or other suitable reference;

(iii) reference on pharmaceutical technology and compounding; i.e., remington's pharmaceutical sciences, block's disinfection sterilization and preservation, or other suitable reference;

(iv) periodicals, i.e., American journal of hospital pharmacy, ASHP's clinical pharmacy, American journal of parenteral and enteral nutrition, or other suitable periodical.

(5) Documentation Requirements for Parenteral Product Pharmacies: Written policies and procedures must be available for inspection and review by authorized agents of the board of pharmacy. Written policies and procedures must be

submitted to the state board of pharmacy prior to the issuance of any license. These records must include but are not limited to:

(a) cleaning, disinfection, evaluation and maintenance of the preparation area;
(b) regular recertification of the clean air unit or units by independent testing agencies;
(c) surveillance of parenteral solutions for microbiological contamination;
(d) surveillance of parenteral solutions for particulate contamination;
(e) personnel qualifications, training and performance guidelines;
(f) facility and equipment guidelines and standards;
(g) SOP's for dispensing all solutions and medications;
(h) SOP's for disposal of physical, chemical and infectious waste;
(i) quality control guidelines and standards;
(j) quality assurance guidelines and standards;
(k) SOP's for determination of stability, incompatibilities or drug interactions.

(6) Record keeping and Patient Profile: The parenteral products pharmacy is required to maintain complete records of each patient's medications which include but are not limited to the following:

(a) prescription records including the original Rx, refill authorization, alterations in the original Rx, and interruptions in therapy due to hospitalization;

(b) patient's history including pertinent information regarding allergy or adverse drug reactions experienced by the patients;

(c) patients receiving parenteral products in a home setting are contacted at a frequency appropriate to the complexity of the patient's health problems and drug therapy as documented on patient specific plan of care and with each new prescription, change in therapy or condition;

(d) documentation that the patient receiving parenteral products in a home setting or their agent has received a written copy of their plan of care and training in the safe administration of their medication.

C. STERILE PHARMACEUTICAL PREPARATION

(1) Pharmacies compounding sterile pharmaceuticals shall prepare products in an appropriate aseptic environment which meets ISO class 5 requirements. Devices used to maintain a ISO class 5 environment will:

(a) be certified in the course of normal operation by an independent contractor according to Federal Standard 209E et seq. for operational efficiency at least every 6 months and when moved, certification records will be maintained for 3 years;

(b) have pre-filters which are inspected periodically and inspection/replacement date documented according to written policy; and

(c) have a positive pressure controlled area that is certified as at least a ISO class 8 which is functionally separate from other areas of the pharmacy and which minimizes the opportunity for particulate and microbial contamination; this area shall:

(i) have a controlled aseptic environment or contain a device which maintains an aseptic environment;

(ii) be clean, lighted, and at an average of 80-150 foot candles;

(iii) be a minimum of 100 sq. ft to support sterile compounding activities;

(iv) be used only for the compounding of sterile pharmaceuticals using appropriate aseptic technique including gowning and gloving;

(v) be designed to avoid outside traffic and airflow;

(vi) be ventilated in a manner which does not interfere with aseptic environment control conditions;

(vii) have non-porous, washable floor coverings, hard cleanable walls and ceilings (which may include acoustical ceiling tiles coated with an acrylic paint) to enable regular disinfection; (contain only compounding medication and supplies and not be used for bulk storage;

(viii) a self contained, ISO class 5 barrier isolator not located in the clean room is acceptable; the barrier isolator may only be located in an area which is maintained under sanitary conditions and traveled only by persons engaged in sterile product preparation. Such barrier isolators must be certified by an independent certification contractor according to ISO class 5 conditions, as defined by federal standard 209E et seq. prior to use and at six-month intervals; certification records will be maintained for 3 years;

(d) store medications and supplies on shelves above the floor;

(e) develop and implement a disposal process for packaging materials, used supplies, containers, syringes, and needles; this process shall be performed to enhance sanitation and avoid accumulation in the controlled area;

(f) prohibit particle generating activities in the controlled area:

(i) removal of medications or supplies from cardboard boxes shall not be done in the controlled area;

(ii) cardboard boxes or other packaging/ shipping material which generate an unacceptable amount of particles shall not be permitted. The removal of immediate packaging designed to retain sterility or stability will be allowed;

(g) cytotoxic drugs shall:

(i) be prepared in a vertical flow biological safety cabinet, micro-biological isolation chamber or equivalent containment device;

(ii) be prepared in a cabinet thoroughly cleaned prior to use for preparation of other products; said cleaning will be documented;

(iii) be prepared in a cabinet located in a controlled area as described in 11.C.(1).(c);

(iv) be disposed of according to written policies and procedures maintained at the facility;

(h) maintain a library of specialty references appropriate for the scope of services provided; reference material may be hard copy or computerized.

(2) Requirements for training.

(a) All pharmacists prior to compounding sterile pharmaceuticals, or supervising pharmacy personnel compounding sterile pharmaceuticals, all shall have completed a minimum of 20 contact hours of didactic, experiential training and competency evaluation through demonstration and testing (written or practical) as outlined by the pharmacist-in-charge and described in the policy and procedures or training manual. Such training shall be evidenced by completion of a recognized course in an accredited college of pharmacy or an ACPE approved course which shall include instruction and hands-on experience in the following areas:

(i) aseptic technique;

(ii) critical area contamination factors;

(iii) environmental monitoring;

(iv) facilities;

(v) equipment and supplies;

(vi) sterile pharmaceutical calculations and terminology;

(vii) sterile pharmaceutical compounding documentation;

(viii) quality assurance procedures;

(ix) proper gowning and gloving technique;

(x) the handling of cytotoxic and hazardous drugs; and

(xi) general conduct in the controlled area.

(b) All pharmacist interns prior to compounding sterile pharmaceuticals shall have completed a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy); or

(ii) completion of a course sponsored by an ACPE approved provider.

(c) All pharmacy technicians who compound sterile pharmaceuticals shall have a high school or equivalent education and be a certified pharmacy technician, and complete a minimum of 40 hours of instruction and experience in the areas listed in paragraph 1. Such training will be obtained through the:

(i) completion of a structured on-the-job didactic and experiential training program at this pharmacy (not transferable to another pharmacy) which provides 40 hours of instruction and experience in the areas listed in paragraph 1; or

(ii) completion of a course sponsored by an ACPE approved provider which provides 40 hours of instructions and experience in the areas listed in paragraph 1.

(d) All pharmacists compounding sterile chemotherapy drugs or supervising pharmacy interns or technicians compounding sterile chemotherapy drugs shall, effective December 31, 2007, have completed a board approved training program in chemotherapy drug preparation. All pharmacy interns and technicians must complete this training prior to preparing sterile chemotherapy drug products.

(e) Documentation of Training. A written record of initial and in-service training and the results of written or practical testing and process validation of pharmacy personnel shall be maintained and contain the following information:

(i) name of person receiving the training or completing the testing or process validation;

(ii) date(s) of the training, testing, or process validation;

(iii) general description of the topics covered in the training or testing or of the process validated;

(iv) name of person supervising the training, testing, or process validation;

(v) signature of the person receiving the training or completing the testing or process validation and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training, testing, or process validation of personnel.

(f) No product intended for patient uses shall be compounded by an individual until the process validation test indicates that the individual can competently perform aseptic procedures.

(g) On an annual basis the pharmacist-in-charge shall assure continuing competency of pharmacy personnel through in-service education, training, and process validation to supplement initial training. A written record of such training will be maintained for 3 years.

(3) Patient or Caregiver Training for Home Sterile Products.

(a) The pharmacist shall maintain documentation that the patient has received training consistent with regulation 16.19.4.17.5 NMAC.

(b) The facility shall provide a 24-hour toll free telephone number for use by patients of the pharmacy.

(c) There shall be a documented, ongoing quality assurance program that monitors patient care and pharmaceutical care outcomes, including the following:

(i) routine performance of prospective drug use review and patient monitoring functions by a pharmacist;

(ii) patient monitoring plans that include written outcome measures and systems for routine patient assessment;

(iii) documentation of patient training; and

(4) Quality Assurance/compounding and preparation of sterile pharmaceuticals.

(a) There shall be a documented, ongoing performance improvement control program that monitors personnel performance, equipment, and facilities:

(i) all aspects of sterile product preparation, storage, and distribution, including details such as the choice of cleaning materials and disinfectants and monitoring of equipment accuracy shall be addressed in policy and procedures;

(ii) if bulk compounding of parenteral solutions is performed using non-sterile chemicals, appropriate end product testing must be documented prior to the release of the product from quarantine; the test must include appropriate tests for particulate matter and pyrogens;

(iii) there shall be documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits; a plan for corrective action of problems identified by quality assurance audits shall be developed which includes procedures for documentation of identified problems and action taken; a periodic evaluation as stated in the policy and procedures of the effectiveness of the quality assurance activities shall be completed and documented;

(iv) the label of each sterile compounded product shall contain: patient name; if batch filling, lot or control number; solution, ingredient names, amounts; expiration date and time, when applicable; directions for use (only if the patient is the end user; not in a hospital setting), including infusion rates, specific times scheduled when appropriate; name or initials of person preparing the product and , if prepared by supportive personnel, the name or identifying initials and the name or initials of the pharmacist that completed the final check; when appropriate, ancillary instructions such as storage instructions or cautionary systems, including cytotoxic warning labels and containment bags; 8 device instructions when needed.

(b) There shall be a mechanism for tracking and retrieving products which have been recalled.

(c) Automated compounding devices shall:

(i) have accuracy verified on a routine basis at least every thirty days per manufacturer's specifications;

(ii) be observed every thirty days by the operator during the mixing process to ensure the device is working properly;

(iii) have data entry verified by a pharmacist prior to compounding; and

(iv) have accuracy of delivery of the end product verified according to written policies and procedures.

(d) If batch preparation of sterile products is being performed, a worksheet (log) must be maintained for each batch. This worksheet shall consist of formula, components, compounding directions or procedures, a sample label and evaluation and testing requirements, if applicable, and shall be used to document the following:

(i) all solutions and ingredients and their corresponding amounts, concentrations and volumes;

(ii) component manufacturer and lot number;

(iii) lot or control number assigned to batch;

(iv) date of preparation;

(v) expiration date of batch prepared products;

(vi) identity of personnel in preparation and pharmacist responsible for final check;

(vii) comparison of actual yield to anticipated yield, when appropriate.

(5) Application of Regulation: Pharmacies licensed by the board prior to adoption of this regulation shall comply with the controlled area standards defined in section 11.C.(1).(c). by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy, or relocate the pharmacy after the effective date of this regulation, Section 11(2) A.3. shall apply. All other portions of this regulation apply on the effective date.

[16.19.6.11 NMAC - Rp, 16 NMAC 19.6.11, 03-30-02; A, 01-15-2005]

16.19.6.12 NOTICE OF EMPLOYEE CHANGE: Proprietors of pharmacies must report on the annual application for renewal of pharmacy license the names and registry numbers of all registered pharmacist employees and registered interns and shall notify the secretary of the Board of Pharmacy within ten (10) days, in writing, of any change in personnel.

[16.19.6.12 NMAC - Rp, 16 NMAC 19.6.12, 03-30-02]

16.19.6.13 CONSPICUOUS DISPLAY REQUIREMENTS:

A. Every person shall have his or her license or registration and the license for the operation of the business conspicuously displayed in the pharmacy or place of business to which it applies or in which he or she is emplyed. All articles, including the following shall be in the vicinity of all prescription departments in full view of patrons:

(1) the pharmacy license
(2) the prohibition of the return of drugs sign
(3) the current Board of Pharmacy inspection report
(4) the current controlled substance registration

B. Name tags, including job title and the designation R.Ph., shall be required of all pharmacists while on duty.

[16.19.6.13 NMAC - Rp, 16 NMAC 19.6.13, 03-30-02]

16.19.6.14 PROHIBITION OF RESALE OF DRUGS:

A. Drugs, medicines, sickroom supplies and items of personal hygiene shall not be accepted for return or exchange of any pharmacist or pharmacy after such articles have been taken from the premises where sold or distributed**.**

B. Prescriptions returned to stock: The pharmacy shall maintain a record of prescriptions which are returned to stock. The record shall include patient name, date filled, prescription number, drug name, drug strength, and drug quantity. The record shall be retrievable within 72 hours.

[16.19.6.14 NMAC - Rp, 16 NMAC 19.6.14, 03-30-02]

16.19.6.15 DISPOSITION OF DANGEROUS DRUGS OR CONTROLLED SUBSTANCES: Permission shall be obtained, in writing, from the Board, after inspection, before any inventory of dangerous drugs or controlled substances may be sold, transferred, disposed of, or otherwise removed from the current premises. All sales shall be subject to the laws of the State.

[16.19.6.15 NMAC - Rp, 16 NMAC 19.6.15, 03-30-02]

16.19.6.16 ROBBERY, BURGLARY, FIRE, FLOOD REPORT:

A. When a pharmacy is involved in a robbery, burglary, fire, flood or any unusual event in which dangerous drugs might be missing or damaged, the owner shall immediately file with the Board a signed statement of the circumstances of such occurrence and evidence that local authorities were notified, if applicable.

B. When a business is sold or an ownership transfer is initiated and a new license application is submitted, the Board may require examination of any stock which may be determined to be adulterated, deteriorated or questionable quality. Merchandise considered to be unfit for sale may be embargoed if the owner does not voluntarily consent to destruction. In the event the drugs are embargoed, the owner of the product must bear the expense of assay to prove purity, strength and product quality.

[16.19.6.16 NMAC - Rp, 16 NMAC 19.6.16, 03-30-02]

16.19.6.17 SIGNS TO BE REMOVED WHEN PHARMACY DISCONTINUES OPERATION: When a pharmacy discontinues operation, the permit issued by the Board shall be immediately surrendered to the Board office, all drug signs and symbols, either within or without the premises, shall be immediately removed; all drugs, devises, poisons shall be removed or destroyed:

A. SIGNS: Any store, shop, laboratory or place of business which has upon it or in it a sign or words "pharmacist", "pharmaceutical chemist", "apothecary", "druggist", "pharmacy", "drug store", "drugs", "drug sundries", "prescriptions", or any of these words, or words of similar import either in English or any other language, or which is advertised by any sign containing any of these words, is defined by law to be a drug store or pharmacy and must obtain a license from the board of pharmacy. Any such place of business not licensed by the Board shall remove any such sign or words which it may have upon or in it.

B. Waiver: The board may waive this requirement pursuant to a petition for waiver. Waivers granted by the board are limited to use by the party and business specified in the waiver document and other limitations set forth. Such petitions shall include:

(1) name of the party;
(2) address of the business;
(3) type of business;
(4) reason for waiver request;
(5) supporting documents; and
(6) photographs of the business demonstrating the use of the sign or words in question.

C. Use of pharmacy, pharmacist and other names: Any "advertiser", as defined by Paragraph (2) of Subsection A of 16.19.21 NMAC, using the names "pharmacist", "pharmacy", "apothecary", "apothecary shop", "drug store", "druggist", "drug sindries", "prescriptions", or any other combination of these words or any other words of similar import that indicate to the public that the advertiser is a pharmacy, is prohibited unless the following occurs:

(1) the advertiser is or has a licensed pharmacy in New Mexico; or

(2) the advertiser is or has a non-resident pharmacy licensed in New Mexico; or

(3) the advertiser has a clear statement, included with such advertisement, stating to the effect, "the advertiser is not a licensed pharmacy and does not fill prescriptions or practice pharmacy"; and

(4) the advertiser must disclose the name of the licensed pharmacy where prescriptions are filled for New Mexico residents and such disclosure would be clear and concise; and

(5) any "confidential information", as defined by NMSA 61-11-2D, is obtained by persons authorized by law to receive such information.

(6) pharmacists registered in this state may advertise their professional services except such advertisement shall not solicit prescription drug (dangerous drug) sales unless in conjunction with a licensed pharmacy.

[16.19.6.17 NMAC - Rp, 16 NMAC 19.6.17, 03-30-02; A, 09-30-03]

16.19.6.18 LABELING OR TO LABEL: As used in Section 61-11-2 of the Pharmacy Act "labeling" or "to label". The act of affixing, applying or attaching a display of written, printed or graphic matter upon or in the immediate container of any human use drug, repackaging or dispensed on the order of a practitioner, shall be defined as "labeling" or "to label", and is a function restricted to registered pharmacists and registered pharmacist interns as required by Section 61-11-21 of the Pharmacy Act, except that the pharmacist labeling requirement shall not apply to Board Regulation Article 15. As used in Section 26-1-11 Drug and Cosmetic Act "label" or "labeling" means the manufacturer or repackagers label required on the commercial container, when such substance is offered for sale, or distributed by the manufacturer or repackager.

A. PRESCRIPTION DRUG DISPENSING CONTAINER REQUIREMENTS: Prescription drug dispensing container requirements to be included on the label by the manufacturer. Both pharmacist and drug manufacturer are responsible for packaging a drug product in accordance with packing requirements specified in the monographs for drug products recognized in the official compendium as defined in 26-1-2 L. All drug products introduced or delivered into interstate commerce after August 27, 1978, must provide information for the pharmacist to be utilized when dispensing the drug to maintain the identity, strength, quality and purity of the product. The compendia standards for proper dispensing containers became effective on April 1, 1977, and applies to both containers used by manufacturers and containers used by pharmacists for dispensing compendia drugs. Manufacturers of non-compendia drug products must use terminology defined in an official compendium to describe a suitable container for dispensing the product. Proper container descriptions include standards of tightness of seal (well-closed or tight), light-resistant, and moisture permeability and other special instruction such as "Keep in a cold place, "Avoid exposure to excessive heat", etc.

B. DISPENSING CONTAINER INFORMATION: The label attached to the dispensing container shall identify the contents by generic or trade name, or a compounded prescription containing more than three drugs or trade name products, may be labeled "Compound" at the discretion of the pharmacist or prescribing physician, and shall contain the expiration date, per USP/NF's guidelines, as well as the quantity dispensed. This information required by NMSA Drug and Cosmetic Act 26-1-16 B; except, to those instances where the prescribing practitioner specifically requests that such information be omitted from the label.

[16.19.6.18 NMAC - Rp, 16 NMAC 19.6.18, 03-30-02]

16.19.6.19 CHANGE IN LOCATION OF A PHARMACY: Before a licensed pharmacy changes the location of the business, or the physical dimensions or elements of physical security, a new application shall be submitted to the Board, setting forth such changes. Upon approval and completion of the change, a Request for Inspection will be submitted to the Chief Inspector. There will be no charge for the new application, but the inspection will carry the same fee as applies for a new pharmacy inspection.

[16.19.6.19 NMAC - Rp, 16 NMAC 19.6.19, 03-30-02]

16.19.6.20 TRANSFER OF OWNERSHIP: A transfer of ownership occurs upon.

A.. The sale of the pharmacy to another individual or individuals by the present owner.

B. The addition or deletion of one or more partners in a partnership.

C. The death of a singular or sole owner.

D. The change of ownership of 30% or more of the voting stock of a corporation since the issuance of the license or last renewal application. A new license application will be required to be filed in each of the above circumstances. As stated in the Pharmacy Act Section 61-11-14(I), licenses are not transferable, and shall expire on December 31 of each year unless renewed.

[16.19.6.20 NMAC - Rp, 16 NMAC 19.6.20, 03-30-02]

16.19.6.21 GUIDELINES TO PREVENT FALSE AND MISLEADING ADVERTISING:

A. Definitions as used in this section:

(1) "advertising" or "to advertise" means to inform customers by any means such as, but not limited to, shelf tags, preticketing, display card, handbills, billboards, and advertisements in the newspapers, magazines, the internet, radio and television or by mail;

(2) "advertiser" means any person or firm which advertises dangerous drug prices or services, defined as the practice of pharmacy (NMSA 61-11-2BB), to consumers in this state;

(3) "article" includes services as well;

(4) "price disclosure" is defined as in-store verbal disclosure of price, disclosure of prices by telephone, price lists, posters in-store containing retail prices for selected drugs indicating "our price".

B. Guidelines:

(1) An advertisement shall in no way stimulate demand or promote overuse or abuse of a dangerous drug or drugs. Prescription drugs are so intimately related to the public health that any ad which tends to promote overuse or abuse of a drug would have an adverse effect on public health, safety and welfare.

(2) The advertiser who does more than state his asking price must tell the truth in such a way that it cannot be misunderstood. Truthful price advertising, offering real bargains may be a benefit to all. But the advertiser must shun sales "gimmicks" and/or adverbs which infer exclusively when they are not factual, i.e., "cheapest", "lowest", which lure customers into a belief that they are getting bargains when in fact they are not.

(3) No comparisons should be made or implied between the price at which an article is offered for sale and some other reference price unless the nature of the reference price is explicitly identified and the advertiser has a reasonable basis to substantiate the reference price.

(4) Comparative pricing is generally defined as the practice whereby a firm or business displays, states, or advertises, directly or by implication two or more prices for his product or services; the actual current prices and another reference price. A reference price may not be implied by a statement such as "same 40%" unless it is substantiated pursuant to Paragraph (3) of Subsection B of 16.19.21 NMAC.

(5) No advertisement should be made expressly or impliedly offering lowered prices as a result of some unusual circumstances, unless the circumstances are true and the prices are actually lower than the advertiser's usual prices (i.e., clearance or special purchases, etc.)

(6) A firm should not advertise a "sale" or other temporary change in prices without disclosing as explicitly as possible, the terms of quantities available, and the period in which the advertised prices will be available.

(7) An advertised price for an article should not be compared with a price for another article unless the price for the article is explicitly identified, and the advertiser has a reasonable basis to substantiate the existence of that price. In addition, one of the following conditions must be met:

(a) the comparability of the two articles can be established by reference to established standards of identity or performance; or

(b) the advertiser has otherwise established that the two articles are substantially identical in all significant respects; or

(c) the article is specifically identified.

(8) A retailer can be reasonably certain that his product is substantially identical to other products if he knows that all are made by the same manufacturer to the same specifications.

C. PRESCRIPTION DRUG ADVERTISING: Every advertisement other than price disclosure of a prescription drug shall contain the following information:

(1) the proprietary or trade name of the drug product;

(2) the established name of the drug product;

(3) the established name and quantity of each active ingredient in the drug product;

(4) the declaration of the established name and quantity of each active ingredient is optional if the drug product contains more than three active ingredients. However, this option does not apply to drug products containing aspirin, phenacetin, and caffeine in combination with one or two other active ingredients;

(5) the name of the manufacturer, packager or distributor;

(6) the dosage form;

(7) the price charged for a specific number of dosage units or quantity of the drug product;

(8) the price is to include all charges to the customer;

(9) the following services are considered to be included in the price to the consumer. If any of these services are not included in the price, the advertisement shall indicate those not provided:

(a) professional fees or cost or product and mark-up;

(b) patient Rx records;

(c) delivery services;

(d) charge privileges;

(e) pharmaceutical counseling;

(f) emergency after hours service;

(g) tax or insurance information;

(h) the hours pharmaceutical services are available to the customer.

D. PROHIBITED DRUG ADVERTISING

(1) There shall be no advertising, other than price disclosure, of a prescription drug or OTC drug which is a controlled substance regulated by the New Mexico Controlled Substances Act.

(2) There shall be no advertising, other than price disclosure, of a prescription drug product that is required by the federal Food and Drug Administration to contain a box warning statement on the label indicating there is evidence of significant incidence of fatalities or serious damage associated with the use of the drug product.

(3) Advertisements are not permitted for a drug evaluated by the Drug Efficacy Study Group, and for which no claim has been evaluated as higher than "possibly effective".
[16.19.6.21 NMAC - Rp, 16 NMAC 19.6.21, 03-30-02; A, 09-30-03]

16.19.6.22 COMPUTERIZED PRESCRIPTION INFORMATION:

A. Computers for the storage and retrieval of prescription information do not replace the requirement that a prescription written by a practitioner or telephoned to the pharmacist by a practitioner and reduced to hardcopy be retained as permanent record. Computers shall be maintained as required by the Pharmacy Act; the Drug, Device, and Cosmetic Act; the Controlled Substance Act; and the board of pharmacy regulations.

B. The computer shall be capable of producing a printout of prescription information within a 72 hour period on demand, with certification by the practitioner stating it is a true and accurate record. Requested printouts include: patient specific; practitioner specific; drug specific; or date specific reports. The printout shall include:

(1) the original prescription number;
(2) the practitioner's name;
(3) full name and address of patient;
(4) date of issuance of original prescription order by the practitioner and the date filled;
(5) name, strength, dosage form, quantity of drug prescribed;
(6) total number of refills authorized by the practitioner;
(7) the quantity dispensed is different than the quantity prescribed, then record of the quantity dispensed;
(8) in the case of a controlled substance, the name, address and DEA registration number of the practitioner and the schedule of the drug;
(9) identification of the dispensing pharmacist; computer-generated pharmacist initials are considered to be the pharmacist of record unless overridden manually by a different pharmacist who will be the pharmacist of record.

C. Permanent records of electronic prescriptions, transmitted directly over approved secure electronic prescribing networks or other board approved transmissions standards, do not have to be reduced to hardcopy provided the following requirements are met.

(1) Electronic prescription information or data must be maintained in the original format received for ten years.
(2) Documentation of business associate agreements with "network vendors", electronic prescription transmission intermediaries and pharmacy software vendors involved in the transmission and formatting of the prescription who can provide documentation of chain of trust of who has had access to prescription content is available.
(3) Reliable backup copies of the information are available and stored in a secure manner as approved by the board.
(4) All elements required on a prescription and record keeping requirements are fulfilled including identification of the dispensing pharmacist of record.

D. Electronically archived prescription records of scanned images of indirect written or faxed prescriptions are permitted provided the following requirements are met:

(1) images of scanned prescriptions are readily retrievable and can be reproduces in a manner consistent with state and federal laws within a seventy-two hour period;
(2) the identity of the pharmacist approving the scanned imaging and of the pharmacist responsible for destroying the original document after three years is clearly documented;
(3) the electronic form shows the exact and legible image of the original prescription;
(4) the original paper prescription document must be maintained for a minimum of three years and the electronic image of the prescription for ten years;
(5) the prescription is not for a controlled substance except as allowed by federal law;
(6) reliable backup copies of the information are available and stored in a secure manner as approved by the board;
(7) all elements required on a prescription and record keeping requirements are fulfilled including identification of the dispensing pharmacist of record.

E. Electronic records of prescriptions and patient prescription records may be stored offsite on secure electronic servers provided the following requirements are met:

(1) records are readily retrievable;
(2) all Health Insurance Portability and Accountability Act and board of pharmacy patient privacy requirements are met;
(3) reliable backup copies of the information are available and stored in a secure manner as approved by the board.
[16.19.6.22 NMAC - Rp, 16 NMAC 19.6.22, 03-30-02; A, 06-30-06]

16.19.6.23 PRESCRIPTIONS:

A. A valid prescription is an order for a dangerous drug given individually for the person for whom prescribed, either directly from the prescribing practitioner to the pharmacist, or indirectly by means of a written order signed

by the practitioner. Signed by the practitioner includes handwritten signature, stamped or printed images of the practitioners handwritten signature or electronic signature as defined in Paragraph (1) of Subsection F of 16.19.6.23 NMAC. Every prescription record shall contain the name and address of the prescriber, the name and address of the patient, the name and strength of the drug, the quantity prescribed, directions for use, the date of issue, and preferably the diagnosis or indication.

B. A prescription may be prepared by a secretary or agent, i.e., office nurse under supervision, for the signature of the practitioner and where applicable; a prescription may be communicated to the pharmacist by an employee or agent of the registered practitioner. The prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulation.

C. Prescription information received from a patient, other than a signed written prescription from a practitioner, has no legal status as a valid prescription. A pharmacist receiving such prescription information must contact the prescribing physician for a new prescription.

D. Exchange of prescription information between pharmacies for the purpose of refilling is authorized under the following conditions only.

(1) The original prescription entry shall be marked in the pharmacy computer system. Pharmacies not using a computer shall mark the hard copy.

(2) The prescription shall indicate that it has been transferred and pharmacy location and file number of the original prescription.

(3) In addition to all information required to appear on a prescription, the prescription shall show the date of original fillings as well as the number of valid refills remaining.

(4) Transfer of controlled substances Schedules III, IV, and V shall not be allowed electronically except as permitted by federal law. Any manual transfer must be within any rule adopted by the federal DEA under Title 21 CFR 1306.26.

E. Fax Machines: Fax prescription means a valid prescription which is transmitted by an electronic device which sends an exact image of a written prescription signed by the practitioner to a pharmacy. The prescribing of controlled substances by fax must comply with all state and federal laws. No pharmacist may dispense a drug solely on the basis of a prescription received by fax except under the following circumstances:

(1) the pharmacist shall exercise professional judgment regarding the accuracy and authenticity of the prescription consistent with existing federal and state statutes and regulations;

(2) the original fax prescription shall be printed and stored in the pharmacy as required by state and federal law and board rules, and may serve as the record of the prescription;

(3) the fax prescription shall include name and fax number of the pharmacy, the prescriber's phone number, for verbal confirmation, time and date of transmission, as well as any other information required by federal and state statute or regulation;

(4) in institutional practice, the fax machine operator must be identified by a statement in the facility policy and procedures manual;

(5) the receiving fax machine must be physically located in a restricted area to protect patient confidentiality;

(6) electronically generated prescriptions may be transmitted directly to the pharmacy via telephone lines or indirectly through one or more "contracted" parties via valid "network vendors" directly to a pharmacy's fax machine;

(7) electronically generated prescriptions faxed from a practitioner's office computer shall include the prescriber's name, phone and fax number, time and date of transmission as well as any other information required by federal and state statutes or regulation;

(8) electronically generated prescriptions faxed from a practitioner's "contracted" "point of care vendor" directly to the pharmacy must include the name and phone number of the "point of care vendor";

(9) "point of care vendors", "network vendors" or other prescription transmission intermediaries not compliant with the requirements of this section will be considered an invalid source;

(10) the pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations; in the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from a "point of care vendor" or "network vendor" which has not been prohibited by the board.

F. Electronic Transmission of Prescriptions

(1) Requirements for electronically transmitted prescriptions or drug orders, including controlled substances as permitted by federal law.

(a) The receiving computer or other similar electronic device used to view the prescription shall be located within the pharmacy or pharmacy department with only authorized personnel having access.

(b) The electronically transmitted prescription or drug order shall contain all information required by state and federal law including the prescriber's name, address and phone number, time and date of transmission.

(c) The prescribing practitioner's electronic signature, or other secure method of validation shall be provided with the electronically transmitted prescription or drug order.

(d) The electronically transmitted prescriptions may serve as the hard copy record of the prescription so long as the electronically transmitted prescription information can be stored in the original format as when received and is

readily retrievable so as to comply with federal and state recordkeeping requirements.

(e) The electronic transmission of a prescription or drug order shall maintain patient confidentiality with no intervening person or other entity accessing or altering the prescription content. The accessing or altering prohibition does not include format modification for transmission purposes by approved secure electronic prescribing networks.

(f) Electronically transmitted prescriptions or drug orders shall be sent only to the pharmacy of the patient's choice.

(2) "Point of care vendors", "network vendors" or other prescription transmission intermediaries not compliant with the requirements of this section will be considered an invalid source.

(3) The pharmacist shall exercise professional judgment regarding the accuracy and authenticity of prescriptions consistent with federal and state statutes and regulations. In the absence of unusual circumstances requiring further inquiry, the pharmacy and each of its associated pharmacists is entitled to rely on the accuracy and authenticity of electronically transmitted prescriptions from a "point of care vendor" or "network vendor" which has not been prohibited by the board.

G. Transmission of prescriptions to answering machines and electronic voice recording devices. Prescription information retrieved by a pharmacist from an answering machine or voice recording device from an authorized practitioner or approved agent is considered to be a direct transmission of a prescription order.

H. Confidentiality of patient records and prescription drug orders.

(1) Confidential information. As provided in 61-11-2.D, confidential information in the patient record, including the contents of any prescription or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient; the nature, extent, or degree of illness suffered by any patient; or any medical information furnished by the prescriber, may be released only as follows:

(a) pursuant to the express written consent or release of the patient or the order of direction of a court;

(b) to the patient or the patient's authorized representative;

(c) to the prescriber or other licensed practitioner then for the patient;

(d) to another licensed pharmacist where the best interest of the patient require such release;

(e) to the board or its representative or to such other person or governmental agencies duly authorized by the law to receive such information; a pharmacist shall utilize the resources available to determine, in the professional judgment of the pharmacist, that any person requesting confidential patient information pursuant to this rule are entitled to receive that information;

(f) in compliance with Health Insurance Portability and Accountability Act regulations regarding protected health information.

(2) Exceptions. Nothing in this rule shall prohibit pharmacists from releasing confidential patient information as follows:

(a) transferring a prescription to another pharmacy as required by the provision of patient counseling;

(b) providing a copy of a non-refillable prescription to the person for whom the prescription was issued which is marked "For Information Purposed Only";

(c) providing drug therapy information to physicians or other authorized prescribers for their patients;

(d) as required by the provision of patient counseling regulations.

[16.19.6.23 NMAC - Rp 16 NMAC 19.6.23, 03-30-02; A, 06-30-06]

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

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

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

(g) 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

(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]

16.19.6.25 CENTRALIZED PRESCRIPTION DISPENSING: The purpose of these regulations is to provide mandatory standards for centralized prescription dispensing by a retail or nonresident pharmacy.

A. Definitions as used in this section.

(1) "Centralized prescription dispensing" means the dispensing or refilling of a prescription drug order by a retail or nonresident pharmacy.

(2) "Dispensing" as defined in the NMSA, Section 61-11-2(1), and pursuant to 61-11-21(C) dispensing is limited to a registered pharmacist.

B. Operational standards and minimum requirements.

(1) A retail pharmacy may outsource prescription drug order dispensing to another retail or nonresident pharmacy provided the pharmacies:

(a) have the same owner or;

(b) have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations; and

(c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to dispense or process a prescription drug order.

(2) The pharmacist-in-charge of the dispensing pharmacy shall ensure that:

(a) the pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency; such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and

(b) the dispensed prescriptions are shipped in containers which are sealed in a manner as to show evidence of opening or tampering.

(3) A retail or nonresidential dispensing pharmacy shall comply with the provisions of 16.19.6 NMAC and this section.

C. Notifications to patients.

(1) A pharmacy that out-sources prescription dispensing to another pharmacy shall:

(a) prior to out-sourcing the prescription, notify patients that their prescription may be outsourced to another pharmacy; and

(b) prior to outsourcing the prescription, give the name of that pharmacy or if the pharmacy is part of a network pf pharmacies under common ownership and any of the network of pharmacies may dispense the prescription, the patient shall be notified of this fact; such notification may be provided through a one-time written notice to the patient or through the use of a sign in the pharmacy; and

(c) if the prescription is delivered directly to the patient by the dispensing pharmacy upon request by the patient and not returned to the requesting pharmacy, the pharmacist employed by the dispensing pharmacy shall ensure that the patient receives written notice of available counseling; such notice shall include days and hours of availability and his or her right to request counseling and a toll-free number from which the patient or patient's agent may obtain oral counseling from a pharmacist who has ready access to the patient's record; for pharmacies delivering more that 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week; the facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

D. Prescription labeling.

(1) The dispensing pharmacy shall:

(a) place on the prescription label the name and address or name and pharmacy license number of the pharmacy dispensing the prescription and the name and address of the pharmacy which receives the dispensed prescription;

(b) indicate in some manner which pharmacy dispensed the prescription (e.g., filled by ABC pharmacy for XYZ pharmacy); and

(c) comply with all other prescription labeling requirements.

E. Policies and Procedures.

(1) A policy and procedure manual as it relates to centralized dispensing shall be maintained at both pharmacies and be approved by the board or its' agent and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy's operations. The manual shall:

(a) outline the responsibilities of each of the pharmacies;

(b) include a list of the name, address, telephone numbers, and all license/registration numbers of the pharmacies involved in centralized prescription dispensing; and

(c) include policies and procedures for:

(i) notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription dispensing and providing the name of that pharmacy;

(ii) protecting the confidentiality and integrity of patient information;

(iii) dispensing prescription drug orders when the filled order is not received or the patient comes

in before the order is received;

(iv) complying with federal and state laws and regulations;

(v) operating a continuous quality improvement program for pharmacy services designated to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care and resolve identified problems;

(vi) procedure identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications to the prescription record or patient profile, and the final check of the completed prescription;

(vii) identify the pharmacist responsible for counseling the patient pursuant to the requirements of 16.19.4.16 NMAC; and

(viii) annually reviewing the written policies and procedures and documenting such review.

F. Records.

(1) Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided:

(a) the records maintained in the alternative system contain all of the information required on the manual record; and

(b) the data processing system is capable of producing a hard copy of the record upon request of the board, its' representative, or other authorized local, state, or federal law enforcement or regulatory agencies within 48 hours.

(2) Each pharmacy shall comply with all the laws and rules relating to the maintenance of records and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy and each pharmacist's or technician's involvement.

(3) The requesting pharmacy shall maintain records which indicate the date:

(a) the request for dispensing was transmitted to the dispensing pharmacy; and

(b) the dispensed prescription was received by the requesting pharmacy, including the method of delivery (e.g., private, common, or contract carrier) and the name of the person accepting delivery.

(4) The dispensing pharmacy shall maintain records which indicate:

(a) the date the prescription was shipped to the requesting pharmacy;

(b) the name and address where the prescription was shipped; and

(c) the method of delivery (e.g., private, common, or contract carrier).

[16.19.6.25 NMAC - N, 06-30-06]

HISTORY OF 16.19.6 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the State Records Center and Archives:

BOP 69-2, Rules and Regulations of the State Board of Pharmacy, 6-13-69.

BOP 69-3, New Mexico Laws and Regulations, Pharmacy Act, Drug and Cosmetic Act, Narcotic Drug Act, Poisons Act, Board of Pharmacy Rules and Regulations, 8-15-69.

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act, 7-31-72.

Regulation No. 6, Pharmacies, 2-7-80.

Regulation No. 6, Pharmacies, 10-23-85.

Regulation No. 6, Pharmacies, 2-2-87.

Regulation No. 6, Pharmacies, 7-27-90.

History of Repealed Material:

BOP 72-1, New Mexico Board of Pharmacy Rules and Regulations Promulgated Pursuant to New Mexico Drug and Cosmetic Act, Pharmacy Act, Controlled Substances Act - Repealed, 10-29-85.

16 NMAC 19.6, Pharmacists - Pharmacies, filed 08-27-99, repealed effective 03-30-02.