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

16.19.6.1 ISSUING AGENCY: Board of Pharmacy
[16.19.6.1 NMAC - Rp, 16 NMAC 19.6.1, 03/30/2002; A, 12/15/2020]

16.19.6.2 SCOPE: All pharmacies, resident and nonresident, as defined in Subsections S and Z of Section 61-11-2 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, 3/30/2002; A, 12/15/2020]

16.19.6.3 STATUTORY AUTHORITY: Paragraph (6) of Subsection A of Section 61-11-6 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, 3/30/2002]

16.19.6.4 DURATION: Permanent
[16.19.6.4 NMAC - Rp, 16 NMAC 19.6.4, 3/30/2002]

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, 3/30/2002]

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, 3/30/2002]

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 (Subsection L of Section 61-11-2 NMSA 1978) 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, 3/30/2002; A, 6/30/2006; A, 12/15/2008]

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 14 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 Subsection I of Section 61-11-14 NMSA 1978, and is subject to the penalties contained in the Pharmacy Act. Any pharmacy license exempt from minimum standards by the Pharmacy Act, Section 61-11-26 NMSA 1978, 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 NMAC, before a new license will be issued for such pharmacy. Note change in ownership as defined in 16.19.6.20 NMAC.

[16.19.6.8 NMAC - Rp, 16 NMAC 19.6.8, 3/30/2002]

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 Section 61-11-15 NMSA 1978. Failure to perform any of the following duties will constitute a violation of Paragraph (1) of Subsection A of Section 61-11-20 NMSA 1978. 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:

(a) the procurement, storage, compounding and dispensing of drugs;

(b) the operation and security for remote pharmacist drug utilization review sites where applicable;

(c) error prevention and reporting procedures according to the requirements of 16.19.25.8 NMAC;

(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 the Pharmacy Act, Section 61-11-15 NMSA 1978.
[16.19.6.9 NMAC - Rp, 16 NMAC 19.6.9, 3/30/2002; A, 6/30/2006; A, 12/15/2008]

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. The counter shall be of adequate height of at least 36 inches, if necessary, five-percent or at least one work station will comply with the American with Disabilities Act.

D. The restricted floor area shall be unobstructed for a minimum width of 30 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, 3/30/2002; A, 5/14/2010]

16.19.6.11 MINIMUM EQUIPMENT AND ACCESSORY STANDARDS: 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; an updated reference source, appropriate to each practice site, either

electronic or paper version; and one copy of the most recently published New Mexico pharmacy laws, rules and regulations and available revisions, either electronic or paper version.
[16.19.6.11 NMAC - Rp, 16 NMAC 19.6.11, 3/30/2002; A, 01/15/2005; A, 01/15/2008; A, 5/14/2010; A, 01/20/2013; A, 06/28/2014]

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 10 days, in writing, of any change in personnel.
[16.19.6.12 NMAC - Rp, 16 NMAC 19.6.12, 3/30/2002]

16.19.6.13 CONSPICUOUS DISPLAY REQUIREMENTS NOTICE OF PERMANENT CLOSURE OF PHARMACIES:

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 employed. 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
(5) the "patient's bill of rights" as approved by the board.

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

C. Pharmacies permanently closing shall notify the public and the board of pharmacy of the closure at least 30 days prior to the final day of service. The notice shall include the last date of service and the name, address, and phone number of the location where patient records will be transferred and /or stored. Notice must also occur by one of the following; newspaper notice, radio broadcast, or other method as approved by the executive director of the board.
[16.19.6.13 NMAC - Rp, 16 NMAC 19.6.13, 3/30/2002; A, 03/01/2008; A, 12/05/2010]

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, 3/30/2002]

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.

A. Dispensed pharmaceuticals, collection and disposal: Patient dispensed legend and OTC medications that are unwanted or expired may be returned to an authorized pharmacy for destruction. The pharmacy must submit a protocol or subsequent changes to the board or the board's agent, for approval. Once approved the pharmacy is authorized to collect pharmaceuticals for destruction. A protocol is to be submitted to the board of pharmacy for staff approval. Such protocol must include:

(1) Secure and enclosed collection unit that does not allow for unauthorized access.
(2) A description of the dedicated area for collection unit inside the pharmacy within site of the authorized pharmacy staff.
(3) Direction of collection that allows for safe and secure disposition.
(4) Name of contracted disposal company that is licensed for pharmaceutical destruction.
(5) Frequency of collection and destruction by the disposal company.
(6) Records of collection and destruction supplied by the disposal company.

B. Items accepted at a take back site may include:

(1) dangerous drugs (prescription drugs);

(2) controlled substances if authorized under federal law or rule;

(3) over-the-counter medications;

(4) veterinary medications;

(5) medicated ointments and lotions;

(6) liquid medication in glass or leak-proof containers.

C. Items NOT accepted at a take back site may include:

(1) needles;

(2) thermometers;

(3) bloody or infectious waste;

(4) personal care products;

(5) controlled substances (unless authorized by federal law);

(6) hydrogen peroxide;

(7) empty containers;

(8) business waste.

D. Collected medications are not for re-dispensing.

E. Directions for take back for patients and list of accepted and non-accepted products must be posted on the collection unit.

F. Suspension of the pharmacy's authority to collect and dispose of dispensed pharmaceutical shall occur upon violation of the approved protocol. The pharmacy may petition the board for removal of that suspension.

[16.19.6.15 NMAC - Rp, 16 NMAC 19.6.15, 3/30/2002; A, 5/14/2010]

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, 3/30/2002]

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", "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 16.19.6.21 NMAC, using the names "pharmacist", "pharmacy", "drug store", "druggist", " drug

sundries", "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 Subsection D of Section 61-11-2 NMSA 1978, 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, 3/30/2002; A, 9/30/2003; A, 12/15/2020; A 10/10/2023]

16.19.6.18 LABELING OR TO LABEL: As used in the Pharmacy Act, Section 61-11-2 NMAC 1978, "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 the Pharmacy Act, Section 61-11-21 NMSA 1978, except that the pharmacist labeling requirement shall not apply to board Regulation Article 15. As used in the Drug and Cosmetic Act Section 26-1-11 NMSA 1978 "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 Subsection L of Section 26-1-2 NMSA 1978. 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 the Drug and Cosmetic Act, Subsection B of Section 26-1-16 NMSA 1978; 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, 3/30/2002]

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, 3/30/2002]

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 thirty percent 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, Subsection I of Section 61-11-14 NMSA 1978, 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, 3/30/2002]

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 (Subsection BB of Section 61-11-2 NMSA 1978), 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" 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 forty percent" unless it is substantiated pursuant to Paragraph (3) of Subsection B of 16.19.6.21 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, 3/30/2002; A, 9/30/2003; A, 12/15/2020]

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 10 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 72 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 10 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;

(8) the original paper prescription document for a non-controlled substance must be maintained on the licensed premises for a period of 120 days from the initial date of dispensing;

(9) the original paper prescription document for a controlled substance must be maintained on the licensed premises for a period of two years from the initial date of dispensing.

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.

F. Original paper prescription documents may be stored offsite after the minimum period of storage on the licensed premises has been reached, provided that the following requirements are met:

(1) the storage area is maintained so that records are secure and prevented from unauthorized access;

(2) the storage area is maintained with appropriate fire suppression safeguards and climate control capabilities;

(3) all Health Insurance Portability and Accountability Act and board of pharmacy patient privacy requirements are met;

(4) the pharmacist-in charge maintains a record-keeping system that records storage location(s) and documents an inventory of original paper prescription documents that are maintained offsite;

(5) original paper prescription records must be able to be produced within three business days upon the request of the board or an authorized officer of the law.

[16.19.6.22 NMAC - Rp, 16 NMAC 19.6.22, 3/30/2002; A, 6/30/2006; A, 5/14/2010]

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 filling or 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) An original unfilled non-controlled substance prescription that is transferred shall be subject to the same record keeping requirements as filled prescriptions.

(5) Transfer or forwarding of controlled substance prescriptions shall not be allowed electronically except as permitted by federal law.

(6) A pharmacy may not refuse to transfer original prescription information to another pharmacy who is acting on behalf of a patient and who is making a request for this information as specified in this subsection. The transfer of original prescription information must be done in a timely manner.

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 Subsection D of Section 61-11-2 NMSA 1978, 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.

I. Prescription adaptation

(1) A pharmacist, using professional judgment, may determine in filling a new non-controlled substance prescription whether it is necessary to attempt to contact the prescriber before performing the following adaptations:

(a) change the quantity, dosage, dosage form, or directions for use of the medication dispensed if it meets the *intent of the prescriber*, or

(b) complete *missing information* on a prescription if there is sufficient evidence to support the change.

(c) The pharmacist will document the prescription adaptation as part of the original prescription record.

(d) The pharmacist will notify the prescriber of the prescription adaptation within 24 hours; and will maintain documentation of notification.

(e) The pharmacist will provide patient counseling, in accordance with Subsection F of 16.19.4.16 NMAC, to include information pertinent to the prescription adaptation.

[16.19.6.23 NMAC - Rp 16 NMAC 19.6.23, 3/30/2002; A, 6/30/2006; A, 03/22/2015; A, 12/15/2020; A 10/10/2023]

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. For purposes of this definition only, "delivers" includes the provision of dispensing process pharmacy services such as prescription entry, prospective drug review, or prescription verification.

(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 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 30 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 New Mexico, 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 current good manufacturing practices (cGMP).

(e) The policy and procedure manual required by Paragraph (2) of Subsection D of 16.19.6.24 NMAC;

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

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

(h) 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) All fees required by 16.19.12 NMAC.

(j) An application that is not successfully completed within 12 months of the date of initial receipt by the board will be considered withdrawn. For consideration of license issuance, a new application and fee are required.

(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.

(3) A nonresident pharmacy may apply for license renewal by submitting a renewal application on a form provided by the board.

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 40 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) the procedure for ensuring proper medication storage conditions until the medication is delivered to the patient

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 Subsection C of 16.19.6.24 NMAC. 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, 3/30/2002; A, 06/09/2017; A, 11/28/2017. A. 12/15/2020; A 10/10/2023]

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 Paragraph (1) of Section 61-11-2, and pursuant to Subsection C of Section 61-11-21 NMSA 1978, 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 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 prior to outsourcing the prescription:

(a) notify patients that their prescription may be outsourced to another pharmacy; and

(b) give the name of that pharmacy or if the pharmacy is part of a network of 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

(2) 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 than fifty percent 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 six 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 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;

(2) The dispensing pharmacy shall indicate in some manner which pharmacy dispensed the prescription (e.g., filled by ABC pharmacy for XYZ pharmacy) and 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.

(2) The manual shall include policies and procedures for:

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

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

(c) dispensing prescription drug orders when the filled order is not received or the patient comes in before the order is received;

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

(e) 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;

(f) 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;

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

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

(j) An application that is not successfully completed within 12 months of the date of initial receipt by the board will be considered withdrawn. For consideration of license issuance, a new application and fee are required.

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, 6/30/2006; A, 06/07/2015; 09/06/2015]

16.19.6.26 REMOTE PHARMACIST DUR SITES:

A. General requirements.

(1) A New Mexico licensed pharmacy may employ one or more pharmacists for the purpose of conducting drug utilization reviews in remote practice sites provided that all security requirements are met.

(2) All pharmacists employed to work at a remote DUR practice site must be New Mexico licensed pharmacists.

(3) All remote pharmacist DUR sites will operate under a New Mexico licensed pharmacy and under the authority of its pharmacist-in-charge.

(4) No drug inventory shall be kept at any remote pharmacist DUR site and no dispensing shall take place from a remote DUR site.

(5) The remote pharmacists will not be considered in the computation of the technician to pharmacist ration.

(6) Procedure identifying the pharmacist responsible for each aspect of the prescription preparations.

B. Personnel.

(1) The pharmacist-in-charge:

(a) shall provide a written policy and procedure document outlining the operation and security of each remote pharmacist DUR location; the document shall be available at each practice site;

(b) shall keep a continuously updated list of all remote DUR sites to include address, phone number and hours of operation for each site; the record shall be retained as part of the records of the licensed pharmacy;

(c) is responsible for ensuring that the New Mexico licensed pharmacy and each remote pharmacist has entered into a written agreement outlining all conditions and policies governing the operation of the remote site;

(d) shall ensure that all computer equipment used at the remote site is in good working order and complies with all security requirements.

(2) Remote pharmacist:

(a) shall be a New Mexico licensed pharmacist;

(b) shall be trained in the use of all equipment necessary for secure operation of the remote site.

C. Operations.

(1) If the remote DUR site is located within a home there must be a designated area in which all of the pharmacist's work will be performed.

(2) All computer equipment used at the remote DUR sites must be able to establish a secure connection which the site is operating. Remote equipment must be configured so that patient information is not stored at the remote site electronically or in printed form.

(3) Computer equipment may only be used for remote DUR. No other use of equipment will be allowed.

(4) Computer equipment must be locked or shut down whenever the pharmacist is absent.

(5) All remote DUR sites are subject to unannounced inspection by representatives of the New Mexico board of pharmacy during established hours of operation.

D. Security.

(1) Remote pharmacist DUR sites shall have adequate security to maintain patient confidentiality.

(2) Must utilize equipment that prevents unauthorized storage or transfer of patient information.

(3) If the remote site is in a home, the equipment must be located in a designated area where patient information cannot be viewed by anyone other than the remote pharmacist.

[16.19.6.26 NMAC - N, 12/15/2008]

16.19.6.27 AUTOMATED DRUG DISTRIBUTION SYSTEMS IN LICENSED HEALTH CARE FACILITIES:

A. Scope: This section applies only to the use of automated drug distribution systems located within the facilities specified in Subsection B of this section.

B. Definitions as used in this section.

(1) **"Automated drug distribution system"**, or **"automated medication system"** or, **"system"** means a mechanical system that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains transaction information and records.

(2) **"Health care facility"** means a facility licensed under 16.19.11 NMAC or an inpatient hospice facility licensed under 16.19.10.12 NMAC.

(3) **"Managing pharmacy"** means an in-state retail pharmacy licensed by the board, pursuant to 16.19.6 NMAC that controls and is responsible for the operation of an automated drug distribution system.

(4) **"Multi-disciplinary committee"** means the pharmacist-in-charge, or the consultant pharmacist, and one or more representatives of the health care facility.

(5) **"Override medication"** means:

(a) A drug that may be removed from an automated medication system prior to pharmacist review because the multi-disciplinary committee has determined that the clinical status of the patient would be compromised by delay;

(b) a drug determined by the multi-disciplinary committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, which may be removed from an automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.

C. Authorization: A managing pharmacy may use an automated drug distribution system to supply medications for patients of a health care facility. The automated drug distribution system may be located in a health care facility that is not at the same location as the managing pharmacy. When located within a health care facility, the system is considered to be an extension of the managing pharmacy. When the automated drug distribution system is used to deliver routine doses of controlled substances, the managing pharmacy submit and maintain a separate registration with the drug enforcement administration.

D. Notification: At least 60 days prior to the initial use of an automated drug distribution system, the pharmacist-in-charge of the managing pharmacy must provide the board with written notification of the following:

(1) the physical address at which the automated drug distribution system will be located;

(2) the health facility's board of pharmacy registration type and number;

(3) the managing pharmacy's registration number, address, and pharmacist-in-charge;

(4) written policies and procedures that govern the operation of the system; the policies and procedures must address the requirements of Subsection F of this section and the rules of the board; and

(5) the managing pharmacy pharmacist-in-charge must notify the board within 10 days whenever an automated drug distribution system is taken permanently out of service.

E. Operation of automated drug distribution systems: The pharmacist-in-charge shall assure compliance with all requirements of the Pharmacy Act, Drug Device and Cosmetic Act, Controlled Substances Act and be responsible for the following:

(1) maintaining a record of each transaction or operation;

(2) controlling access to the automated medication system;

(3) maintaining policies and procedures for:

(a) operating the automated medication system;

(b) training personnel who use the automated medication system;

(c) maintaining patient services whenever the automated medication system is not operating;

(d) defining a procedure for a pharmacist to grant access to the drugs in the automated medication system or to deny access to the drugs in the automated medication system;

(e) maintaining security of the automated medication system;

(f) assuring that a patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(g) assuring that the automated medication system maintains the integrity of the information in the system and protects patient confidentiality;

(h) establishing a procedure for stocking or restocking the automated medication system; and

(i) insuring compliance with all requirements for packaging, storing, and labeling.

(4) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a drug except an override medication.

(5) A pharmacist shall perform retrospective drug use review for an override medication.

(6) The pharmacist-in-charge shall convene or identify a multi-disciplinary committee, which is charged with advising on the operations of the automated medication system.

F. Stocking or restocking of an automated medication system:

(1) responsibility for accurate stocking and restocking of an automated medication system lies with the pharmacist-in-charge and with any pharmacist tasked with supervising such functions;

(2) the stocking or restocking of an automated medication system, where performed by someone other than a pharmacist, shall follow one of the following procedures to ensure correct drug selection:

(a) a pharmacist shall conduct and document a daily audit of drugs placed or to be placed into an automated medication system, which audit may include random sampling;

(b) a barcode verification, electronic verification, or similar verification process shall be utilized to assure correct selection of drugs placed or to be placed into an automated medication system; the utilization of a barcode, electronic, or similar verification process shall require an initial quality assurance validation, followed by a quarterly quality assurance review by a pharmacist; when a barcode verification, electronic verification, or similar verification process is utilized as specified in this section, stocking and restocking functions may be performed by a pharmacy technician or by a registered nurse trained and authorized by the pharmacist-in-charge.

(3) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the drug stocking, restocking or verification process.

(4) Any drug that has been removed from the automated medication system shall not be replaced into the system unless: the drug's purity, packaging, and labeling have been examined according to established policies and procedures.

G. Quality Assurance Program: The pharmacist-in-charge shall be responsible for implementing and maintaining a quality assurance program for the automated medication system. The program shall provide for:

(1) review of override medication utilization;

(2) investigation and reporting of any medication error related to drugs distributed or packaged by the automated medication system;

(3) review of any discrepancy or transaction reports and identification of patterns of inappropriate use or access of the automated drug distribution system;

(4) review of the operation of the automated medication system;

(5) integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the managing pharmacy; and

(6) assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

H. Records: The managing pharmacy pharmacist-in-charge shall maintain, for at least three years, the following records related to the automated medication system in a readily retrievable manner:

(1) managing pharmacy's distribution records for all dangerous drugs, including controlled substances, transferred to each automated medication system;

(2) perpetual inventories of controlled substances contained within each automated medication system;

(3) at the time of any event involving the contents of the automated drug distribution system, the device shall automatically produce on demand, a written or electronic record showing:

(a) the date and time of transaction;

(b) the type of transaction;

(c) the nature of the emergency;

(d) the name, strength, and quantity of medication;

(e) the name of the patient for whom the drug was ordered;

(f) the name or identification code (electronic signature) of the person making the transaction;

(g) the name of the prescribing practitioner;

(h) the name of the pharmacist conducting the drug utilization review; and

(i) the identity of the device accessed.

(4) A delivery record shall be generated on demand for all drugs supplied to a facility for use by an automated drug distribution system which shall include:

(a) date of receipt;

(b) drug name;

(c) dosage form;

(d) strength;

(e) quantity;

(f) identity of device; and

(g) documentation of individual accepting delivery.

(5) Any report or analysis generated as part of the quality assurance program required by Subsection G of this section.

I. The multi-disciplinary committee shall:

(1) establish the criteria and process for determining which drug qualifies as an override medication;

(2) develop policies and procedures regarding the operation of the automated drug distribution system;

(3) conduct an annual review of override medications.

[16.19.6.27 NMAC - N, 06/07/2015; A, 09/06/2015]

16.19.6.28 AUTOMATED FILLING SYSTEMS:

A. Definitions. The following definitions shall apply to this section:

(1) **"Automated filling system"** means an automated system used by a pharmacy in the state of New Mexico to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication that is then subject to final product check by a pharmacist prior to dispensing, vacuum tube drug delivery systems, or automated dispensing and storage systems used to dispense medication directly to a patient or to an authorized health care practitioner for immediate distribution or administration to the patient.

(2) **"Electronic verification system"** means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

(3) **"Manufacturer unit of use package"** means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

(4) **"Prepacked"** means any drug that has been removed from the original packaging of the manufacturer or an FDA repackager and is placed in a properly labeled dispensing container by a pharmacy for use in an automated filling system for the purpose of dispensing to the ultimate user from the establishment in which the prepacking occurred.

(5) **"Repackager"** means a repackager registered with the United States food and drug administration (FDA).

B. Medication stocking. Automated filling systems (hereinafter "system") may be stocked or loaded by a pharmacist or by an intern pharmacist or pharmacy technician under the direct supervision of a pharmacist.

C. Pharmacist verification. Except as otherwise provided herein, a licensed pharmacist shall inspect and verify the accuracy of the final contents of any dispensing container filled or packaged by a system, and any label affixed thereto, prior to dispensing, pursuant to Paragraph (1) of Subsection B of 16.19.4.16 NMAC.

D. Verification criteria. The pharmacist verification requirements of Subsection C of 16.19.6.28 NMAC shall be deemed satisfied if all the following are met:

(1) pharmacy personnel establish and follow a policy and procedure manual that complies with Subsection E of 16.19.6.28 NMAC;

(2) the filling process is fully automated from the time the filling process is initiated until a completed, labeled, and sealed prescription is produced by the system that is ready for dispensing to the patient; no manual intervention with the medication or prescription may occur after the medication is loaded into the system; for purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(3) a pharmacist performs a prospective DUR and verifies the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automated fill process; the identity of the verifying pharmacist shall be recorded in the pharmacy's records;

(4) a pharmacist verifies the correct medication and strength, prepacked container, or manufacturer unit of use package was properly stocked, filled, and loaded in the system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer unit of use packages or prepacked medication previously verified by a pharmacist;

(5) the medication to be dispensed is selected, filled, labeled, and sealed in the dispensing container by the system or dispensed by the system in a manufacturer's unit of use package or a prepacked container;

(6) an electronic verification system is used to verify the proper prescription label has been affixed to the correct medication and strength, prepacked container, or manufacturer unit of use package for the correct patient;

(7) daily random quality testing is conducted by a pharmacist on a sample size of prescriptions filled by the system; the required sample size shall not be less than two percent of the prescriptions

filled by the automated system on the date tested or two percent of the prescriptions filled by the automated system on the last day of system operation, as designated in writing by the pharmacist-in-charge; proof of compliance with this subsection and random quality testing date(s) and results shall be documented and maintained in the pharmacy's records;

(8) the product dispensed is a solid oral dosage form; and

(9) the product dispensed is not a controlled substance listed in DEA or Schedule II of 16.19.20 NMAC.

E. Policies and procedures. Pharmacists verifying prescriptions pursuant to Subsection D of 16.19.6.28 NMAC shall follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be established by, and reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records. The required annual review shall be documented in the pharmacy's records. At a minimum, pharmacy personnel shall establish and follow policies and procedures for the following:

(1) maintaining the system and any accompanying electronic verification system in good working order;

(2) ensuring accurate filling, loading, and stocking of the system;

(3) ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(4) reporting, investigating, and addressing filling errors and system malfunctions;

(5) testing the accuracy of the system and any accompanying electronic verification system; at a minimum, the system and electronic verification system shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification system that changes or alters the filling or electronic verification process;

(6) training persons authorized to access, stock, or load the system in equipment use and operations;

(7) tracking and documenting prescription errors related to the system that are not corrected prior to dispensing to the patient;

(8) conducting routine and preventive maintenance and, if applicable, calibration;

(9) removing expired, adulterated, misbranded, or recalled drugs;

(10) preventing unauthorized access to the system, including, assigning, discontinuing, or changing security access;

(11) identifying and recording persons responsible for stocking, loading, and filling the system;

(12) ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(13) ensuring proper drug storage within the system, consistent with the manufacturer's specifications and the *United States Pharmacopoeia* (USP);

(14) maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification system to ensure proper and accurate functioning.

F. Recordkeeping. Records and documentation required by this section shall be maintained in the pharmacy's records electronically or in writing for a minimum of three years. Records shall be made available for inspection and produced to the board or the board's agent upon request.

G. Prepacking. A pharmacist, or a pharmacist intern or pharmacy technician under the direct supervision of a licensed pharmacist, may prepack drugs for other than immediate dispensing purposes provided that the following conditions are met:

(1) prepacking occurs at the licensed pharmacy utilizing the system;

(2) only products which will be dispensed directly to the patient may be prepacked;

(3) containers utilized for prepacking shall meet standards specified by the USP, which has been incorporated herein by reference (e.g. preservation, packaging, storage and labeling section of the general notices and requirements); where needed, light resistant containers shall be used;

(4) any prepacked drug must have a label affixed to it which contains, at a minimum, the name and strength of the drug, quantity, the name of the manufacturer or distributor, the expiration date and lot number, the date prepacked, and the identity of the person who prepacked it;

(5) a record of drugs prepacked must be kept, and include the following: the name and strength of the drug, lot number, name of manufacturer or distributor, expiration date (per USP requirements), date of prepacking, total number of dosage units (tabs, caps) prepacked, quantity per prepacked container, number of dosage units (tabs, caps) wasted, initials of prepacker and of pharmacist performing final check;

(6) all drugs prepacked by a pharmacist intern or pharmacy technician must undergo a final check by the pharmacist.

[16.19.6.28 NMAC - N, 06/07/2015]

16.19.6.29 REMOTE PHARMACY TECHNICIAN DATA ENTRY SITES:

A. General requirements.

(1) A New Mexico licensed pharmacy located in New Mexico may employ one or more certified pharmacy technicians for the purpose of data input in remote practice sites provided that all security requirements are met.

(2) All pharmacy technicians employed to work at a remote data entry practice site must be registered as a certified pharmacy technician with the board and have a minimum of one year experience performing data entry functions as a certified pharmacy tech.

(3) All remote pharmacy technician data entry sites will operate under a New Mexico licensed pharmacy located in New Mexico under the authority of its pharmacist-in-charge.

(4) No drug inventory shall be kept at any remote pharmacy technician data entry site and no dispensing shall take place from a remote pharmacy technician data entry site.

(5) All remote pharmacy technician data entry sites will have a procedure for identifying the pharmacy technician and the pharmacist responsible for each aspect of the prescription preparations.

(6) All remote pharmacy technician data entry sites will have quality monitoring and improvement programs in place.

B. Personnel.

(1) The pharmacist-in-charge shall:

(a) provide a written policy and procedure document outlining the operation and security of each remote pharmacy technician data entry sites location; the document shall be available at each practice site;

(b) keep a continuously updated list of all remote pharmacy technician data entry sites to include address, phone number and hours of operation for each site; the record shall be retained as part of the records of the licensed pharmacy;

(c) is responsible for ensuring that the New Mexico licensed pharmacy and each remote data entry pharmacy technician has entered into a written agreement outlining all conditions and policies governing the operation of the remote site;

(d) ensure that all computer equipment used at the remote site is in good working order, provides data protection and complies with all security and HIPAA requirements.

(2) Data entry pharmacy technician shall:

(a) be a certified pharmacy technician registered with the board and reside in New Mexico;

(b) have a minimum of one year experience performing data entry functions as a certified pharmacy technician;

(c) be trained in the use of all equipment necessary for secure operation of the remote site.

C. Operations.

(1) If the remote pharmacy technician data entry sites is located within a home there must be a designated area in which all of the pharmacy technicians work will be performed.

(2) All computer equipment used at the remote pharmacy technician data entry sites must be able to establish a secure connection which the site is operating. Remote equipment must be configured so that patient information is not stored at the remote site electronically or in printed form.

(3) Computer equipment may only be used for remote pharmacy technician data entry. No other use of equipment will be allowed.

(4) Computer equipment must be locked or shut down whenever the pharmacy technician is absent.

(5) All remote pharmacy technician data entry sites are subject to unannounced inspection by representatives of the New Mexico board of pharmacy during established hours of operation.

D. Security.

(1) Remote pharmacy technician data entry sites shall have adequate security to maintain patient confidentiality.

(2) Must utilize equipment that prevents unauthorized storage or transfer of patient information.

(3) If the remote site is in a home, the equipment must be located in a designated area where patient information cannot be viewed by anyone other than the remote pharmacy technician.

[16.19.6.29 NMAC - N, 12/13/2015]

16.19.6.30 REPACKAGING AND DISTRIBUTION BY A PHARMACY

A. Scope: This section applies only to repackaging by a pharmacy licensed by the board under the conditions specified in this section.

B. Definitions as used in this section:

(1) **"administer"** means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion or any other means as a result of an order of a licensed practitioner;

(2) **"board"** means the New Mexico Board of Pharmacy;

(3) **"distribute"** means the delivery of a drug or device other than by administering or dispensing;

(4) **"finished drug product"** of a prescription drug is defined as that form of the drug which is, or is intended, to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging and labeling;

(5) **"FD&C Act"** means the Federal Food Drug and Cosmetic Act;

(6) **"repackaging"** means the of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug, excluding:

(a) placing medication in a different container to dispense directly to the patient pursuant to a patient-specific prescription;

(b) removing a drug product from the original container at the point of care for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient.

(7) **"USP"** means United States Pharmacopoeia;

(8) **"USP standards"** means standards published in the current official United States pharmacopoeia-national formulary.

C. A pharmacy licensed by the board may repackage under the following conditions:

(1) The pharmacy must qualify for an exemption from registration and listing requirements under Section 510 of the FD&C Act. Specifically, under Section 510(g)(1), the registration and listing requirements of Section 510 do not apply to: pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

(2) The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.

(3) The drug repackaged is a finished drug product of a prescription drug that is:

(a) a non-sterile solid or liquid oral dosage form;

(b) approved under Section 505 of the FD&C Act;

(c) repackaged by or under the direct supervision of a pharmacist, and undergoes a final check by a pharmacist;

(d) handled and repackaged in accordance with all applicable USP chapters numbered less than <1000>;

(e) assigned a beyond use date in accordance with USP standards;

(f) repackaged, stored, and shipped in a way that does not conflict with approved drug product labeling;

(g) not adulterated by preparing, packing, or holding the drug product under insanitary conditions; and

(h) repackaged into a sealed unit-dose container, unless distributed in an appropriately labeled and packaged form to a contracted correctional facility for distribution to an inmate upon release.

(4) The repackaged drug product is distributed under the following conditions:

(a) by a managing pharmacy for use in an automated drug distribution system to supply medications for patients of a health care facility licensed under 16.19.11 NMAC, or inpatient hospice facility licensed under 16.19.10.12 NMAC, in accordance with 16.19.6.27 NMAC, or emergency kit;

(b) to a correctional facility, licensed by the board under 16.19.10.11 NMAC, for administration to an inmate, or for distribution of a properly labeled take home supply to an inmate upon release to avoid interruption in prescribed treatment, pursuant to a patient-specific prescription or order;

(c) to a clinic licensed by the board under 16.19.10.11 NMAC, and under the same ownership as the repackaging pharmacy, for administration to a patient of the clinic pursuant to a patient-specific prescription or order.

(5) All units of repackaged medication must be labeled with the following information:

(a) name, address, and telephone number of repackaging pharmacy, unless the repackaged drug is used in an automated drug distribution system in accordance with 16.19.6.27 NMAC;

(b) name, strength, and quantity of the drug;

(c) lot number or control number;

(d) name of manufacturer;

(e) beyond use date;

(f) date drug was repackaged;

(g) name or initials of repackager; and

(h) federal caution label, if applicable.

(6) A record of drugs repackaged must be maintained, and include the following:

(a) date of repackaging;

(b) name and strength of drug;

(c) manufacturer assigned drug lot number, and expiration date;

(d) name of drug manufacturer;

(e) assigned beyond-use date and lot number or control number;

(f) total number of dosage units (tabs, caps) repackaged;

(g) quantity per each repackaged unit container;

(h) number of dosage units wasted; and

(i) initials of repackager, and of pharmacist performing final check.

(7) Records as required by the Pharmacy Act including the Drug, Device, and Cosmetic Act; the Controlled Substance Act; and board regulations shall be maintained.

[16.19.6.30 NMAC - N, 11/28/2017; A, 5/07/2024]

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, 6/13/1969.

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, 8/15/1969.

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, 7/31/1972.

Regulation No. 6, Pharmacies, 2/7/1980.

Regulation No. 6, Pharmacies, 10/23/1985.

Regulation No. 6, Pharmacies, 2/2/1987.

Regulation No. 6, Pharmacies, 7/27/1990.

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, 10/29/1985.

16 NMAC 19.6, Pharmacists - Pharmacies, filed 08/27/1999, Repealed effective 3/30/2002.