16.19.6.7 DEFINITIONS:

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

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

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

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

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

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

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

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

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

Commented [T1]: Suggested update to assist with flow of definition.

16.19.6.24 NONRESIDENT PHARMACIES:

A. Definitions.

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

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

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

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

B. Licensure requirement.

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

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

C. Requirements for obtaining licensure.

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

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

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

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

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

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

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

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

(h) All fees required by 16.19.12 NMAC.

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

D. Conditions of licensure.

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

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

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

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

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

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

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

(a) Normal delivery protocols and times;

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

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

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

E. Disciplinary proceedings.

(1) The Board may withhold, suspend, or revoke any nonresident pharmacy license held or applied for upon the grounds established by law or regulations, including, without limitation, the failure to

comply with the conditions specified in 16.19.6.24.C. The Board shall suspend or revoke a nonresident pharmacy license when the license, permit, or registration to operate the pharmacy in the resident state has been suspended or revoked. A certified copy of the record of suspension or revocation by the resident state is conclusive evidence.

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

F. Limitations.

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

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

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

16.19.6.26 REMOTE PHARMACIST DUR SITES:

A. General requirements.

(1) A New Mexico licensed pharmacy located in New Mexico 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 located in New Mexico 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.~~

(5~~6~~) Procedure identifying the pharmacist responsible for each aspect of the prescription preparations.

Commented [T2]: Can this be removed since there is no ratio?

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 located in New Mexico 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 can not be viewed by anyone other than~~t~~ the remote pharmacist.

[16.19.6.26 NMAC - N, 12-15-08]

16.19.4.16 RESPONSIBILITIES OF PHARMACIST AND PHARMACIST INTERN:

A. The following responsibilities require the use of professional judgement and therefore shall be performed only by a pharmacist or pharmacist intern:

(1) receipt of all new verbal prescription orders and reduction to writing;

(2) initial identification, evaluation and interpretation of the prescription order and any necessary clinical clarification prior to dispensing;

(3) professional consultation with a patient or his agent regarding a prescription;

(4) evaluation of available clinical data in patient medication record system;

(5) oral communication with the patient or patient's agent of information, as defined in this section under patient counseling, in order to improve therapy by ensuring proper use of drugs and devices;

(6) professional consultation with the prescriber, the prescriber's agent, or any other health care professional or authorized agent regarding a patient and any medical information pertaining to the prescription;

(7) drug regimen review, as defined in 61-11-2L;

(8) professional consultation, without dispensing, will require that the patient be provided with the identification of the pharmacist or pharmacy intern providing the service.

B. Only a pharmacist shall perform the following duties:

(1) final check on all aspects of the completed prescription including sterile products and cytotoxic preparations, and assumption of the responsibility for the filled prescription, including, but not limited to, appropriateness of dose, accuracy of drug, strength, labeling, verification of ingredients and proper container;

(2) evaluation of pharmaceuticals for formulary selection within the facility;

(3) supervision of all supportive personnel activities including preparation, mixing, assembling, packaging, labeling and storage of medications;

(4) ensure that supportive personnel have been properly trained for the duties they may perform;

(5) any verbal communication with a patient or patient's representative regarding a change in drug therapy or performing therapeutic interchanges (i.e. drugs with similar effects in specific therapeutic categories); this does not apply to substitution of generic equivalents;

(6) any other duty required of a pharmacist by any federal or state law.

C. Patient records.

(1) A reasonable effort must be made to obtain, record and maintain at least the following information:

(a) name, address, telephone number, date of birth (or age) and gender of the patient;

(b) individual medical history, if significant, including disease state or states, known allergies and drug reactions and a comprehensive list of medications and relevant devices; and

(c) pharmacists comments relevant to the individuals drug therapy.

(2) Such information contained in the patient record should be considered by the pharmacist or pharmacist intern in the exercise of their professional judgement concerning both the offer to counsel and the content of counseling.

D. Prospective drug review.

(1) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:

(a) clinical abuse/misuse;

(b) therapeutic duplication;

(c) drug-disease contraindications;
(d) drug-drug interactions;
(e) incorrect drug dosage;
(f) incorrect duration of drug treatment;
(g) drug-allergy interactions;
(h) appropriate medication indication.

(2) Upon recognizing any of the above, a pharmacist, using professional judgment, shall take appropriate steps to avoid or resolve the potential problem. These steps may include requesting and reviewing a controlled substance prescription monitoring report or another states' reports if applicable and available, and consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

E. Prescription monitoring program (PMP) report for opioid prescriptions. When presented with an opioid prescription for a patient, obtaining and reviewing a PMP report for that patient can be an important tool that assists the pharmacist in identifying issues or problems that put his or her patient at risk of prescription drug abuse, overdose, or diversion. A pharmacist shall use professional judgment based on prevailing standards of practice in determining whether to obtain and review a PMP report before dispensing an opioid prescription to that patient, and shall document his or her action regarding such reports.

(1) A pharmacist shall request and review a PMP report covering at least a one year time period and another states' report, where applicable and available if;

(a) a pharmacist becomes aware of a person currently exhibiting potential abuse or misuse of opioids (i.e. over-utilization, early refills, multiple prescribers, appears overly sedated or intoxicated upon presenting a precription for an opioid or an unfamiliar patient requesting an opioid by specific name, street name, color, or identifying marks, or paying cash when the patient has prescription insurance);

(b) a pharmacist receives an opioid prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area);

(c) a pharmacist receives an opioid prescription for an unfamiliar patient who resides outside the usual pharmacy geographic patient population area;

(d) a pharmacist receives an initial prescription for any long-acting opioid formulations, including oral and transdermal dosage forms (e.g fentanyl or methadone);

(e) a pharmacist becomes aware of a patient receiving an opioid concurrently with a benzodiazepine or carisoprodol;

(2) The pharmacist shall document the review of these PMP reports.

(3) Upon recognizing any of the above conditions described in Paragraph (1) of Subsection E of 16.19.4.16 NMAC, a pharmacist, using professional judgement, shall take appropriate steps to avoid or resolve the potential problem. These steps may include consulting with the prescriber and counseling the patient. The pharmacist shall document steps taken to resolve the potential problem.

(4) After obtaining an initial PMP report on a patient, a pharmacist shall use professional judgment base on prevailing standards of practice, in deciding the frequency of requesting and reviewing further prescription monitoring reports and other states' reports for that patient. Except that PMP reports shall be reviewed a minimum of once every three months during the continuous use of opioids for each established patient. The pharmacist shall document the review of these reports.

(5) In the event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving a report.

(6) A prescription for an opioid written for a patient in a long term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness is exempt from Subsection E of 16.19.4.16 NMAC. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner. The pharmacist shall document whether the patient is "terminally ill" or an "LTCF patient".

F. Counseling.

(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist or pharmacist intern shall personally offer to counsel on matters which will enhance or optimize drug therapy with each patient or the patient's agent. Upon receipt of a refill prescription drug order a pharmacy technician may query the patient or patient's agent regarding counseling by the pharmacist or pharmacist intern concerning drug therapy. Such counseling shall be in person, whenever practicable, or by telephone, and shall

include appropriate elements of patient counseling which may include, in their professional judgement, one or more of the following:

(a) the name and description of the drug;

(b) the dosage form, dosage, route of administration, and duration of drug therapy;

(c) intended use of the drug and expected action;

(d) special directions and precautions for preparation, administration and use by the patient;

(e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur;

(f) techniques for self-monitoring drug therapy;

(g) proper storage;

(h) prescriptions refill information;

(i) action to be taken in the event of a missed dose;

(j) the need to check with the pharmacist or practitioner before taking other medication; and

(k) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) [REPEALED]

(3) Alternative forms of patient information may be used to supplement patient counseling when appropriate. Examples include, but not limited to, written information leaflets, pictogram labels and video programs.

(4) Patient counseling, as described above and defined in this regulation shall not be required for in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).

(5) A pharmacist shall in no way attempt to circumvent or willfully discourage a patient or patient's agent from receiving counseling. However, a pharmacist shall not be required to counsel a patient or patients's agent when the patient or patients's agent refuses such consultation.

(6) When the patient or agent is not present when the prescription is dispensed including, but not limited to, a prescription that was shipped by the mail, the pharmacist shall ensure that the patient receives written notice of available counseling. Such notice shall include days and hours of availability, and: (1) of his or her right to request counseling; and (2) a toll-free telephone number in 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.

(7) In every pharmacy there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers a notice concerning available counseling.

G. [REPEALED]

H. Regulatory assessment. Profiles, either electronic or hard copy, shall be available for inspection, and shall provide the capability of storing the described historical information. The profiles must demonstrate that an effort is being made to fulfill the requirements by the completion of the detail required. A patient record shall be maintained for a period of not less than three years from the date of the last entry in the profile record.

[08-27-90; 16.19.4.16 NMAC - Rn, 16 NMAC 19.4.16, 03-30-02; 16.19.4.16 NMAC - Rn, 16.19.4.17 NMAC, 12-15-02; A, 02-01-04; A, 11-30-04; A, 01-15-05; A, 01-31-07; A, 08-31-12; A, 10-25-12; A, 10-19-16]

61-11-14. Pharmacy licensure; wholesale drug distribution business licensure; requirements; fees; revocation. (Repealed effective July 1, 2024.)

A. Any person who desires to operate or maintain the operation of a pharmacy or who engages in a wholesale drug distribution business in this state shall apply to the board for the proper license and shall meet the requirements of the board and pay the fee for the license and its renewal.

B. The board shall issue the following classes of licenses that shall be defined and limited by regulation of the board:

(1) retail pharmacy;
(2) nonresident pharmacy;
(3) wholesale drug distributor;
(4) drug manufacturer;
(5) hospital pharmacy;
(6) industrial health clinic;
(7) community health clinic;
(8) department of health public health offices;
(9) custodial care facility;
(10) home care services;
(11) emergency medical services;
(12) animal control facilities;

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

A. Definitions as used in this section.

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

(2) "Centralized prescription processing" means the processing by a resident or nonresident pharmacy of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive services. Each function may be performed by the same or different persons and at the same or different locations ….

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

~~"Processing" ….~~

B. Operational standards and minimum requirements.

(1) A resident or nonresident pharmacy may centralize prescription dispensing or processing provided the~~A retail pharmacy may outsource prescription drug order dispensing or processing 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) The pharmacist-in-charge of the processing pharmacy shall ensure that…

a) an audit trail is maintained that records and documents the unique and secure user identifier(s) of the pharmacist(s), pharmacy technician(s), and intern(s) and the function(s) performed by each, at the time the functions are performed, for each step of prescription handling that is required to be performed by a pharmacist, pharmacy technician, or intern..

b) The audit trail and prescription information shall be maintained or stored in original hard copy form or in any other media that facilitates the reproduction of the original hard copy and shall be provided within 72 hours of any request by the Board or its designee.

c) Patient records shall be kept confidential, but shall be made available to persons authorized to inspect them under applicable State and Federal statutes and regulations.

(43) A ~~retail~~resident 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 or processing to another pharmacy shall prior to outsourcing the prescription:

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(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 that 50% of their prescriptions by mail or other common carrier, the hours of availability shall be a minimum of 60 hours per week and not less than 6 days per week; the facility must have sufficient toll-free phone lines and personnel to provide counseling within 15 minutes.

3) The provisions of subsection (1) do not apply to orders delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

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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~~The prescription label shall show the name, address, telephone number and, if applicable, the DEA number of either the dispensing or processing pharmacy. ~~and the name and address of the pharmacy which receives the dispensed prescription~~;

(2) Provide a telephone number where the patient can reach a pharmacist regarding refills or questions about the prescription. ~~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.

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(1) A policy and procedure manual as it relates to centralized dispensing or processing 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 or processing.

(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 or processing 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.

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 processed or 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 or processing 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**~~**(a)** the name and address where the prescription was shipped; and

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

[16.19.6.25 NMAC - N, 06-30-06; A, 06-07-15; 09-06-15]