TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING CHAPTER 19 PHARMACISTS **PART 10** LIMITED DRUG CLINICS

ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, 16.19.10.1 NM.

[02-15-1889...02-15-96; 16.19.10.1 NMAC - Rn, 16 NMAC 19.10.1, 03-30-02; A, 08-12-13]

16.19.10.2 SCOPE: All public health clinics, industrial health clinics, emergency medical services, and animal control clinics, and all individuals or entities that own or operate, or are employed by, such clinics for the purpose of providing pharmaceutical products and services.

[02-15-96; 16.19.10.2 NMAC - Rn, 16 NMAC 19.10.2, 03-30-02]

16.19.10.3 STATUTORY AUTHORITY: Section 61-11-6.A(6) NMSA 1978 requires the Board of Pharmacy provide for the licensing of industrial public health clinics and for the inspection of their facilities and activities. Pursuant to Section 61-11-14(B) (13) NMSA 1978, the Board is authorized to issue drug permits, as defined and limited by Board regulation, for wholesalers, retailers and distributors of veterinary drugs. Section 26-1-16(A) NMSA 1978 prohibits the sale, disposal or possession of any dangerous drug except by individuals and entities identified in the statute, including clinics licensed by the Board. [02-15-96; A, 03-31-98; 16.19.10.3 NMAC - Rn, 16 NMAC 19.10.3, 03-30-02]

16.19.10.4 **DURATION:** Permanent.

[02-15-96; 05-15-96; A, 12-15-97; 16.19.10.4 NMAC - Rn, 16 NMAC 19.10.4, 03-30-02]

16.19.10.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.

[02-15-96; 16.19.10.5 NMAC - Rn, 16 NMAC 19.10.5, 03-30-02]

16.19.10.6 **OBJECTIVE:** The objective of Part 10 of Chapter 19 is to ensure safe and competent maintenance, delivery and administration of drugs by emergency medical services and in industrial, public health, and animal control clinic settings.

[02-15-96; 16.19.10.6 NMAC - Rn, 16 NMAC 19.10.6, 03-30-02]

16.19.10.7 **DEFINITIONS:** All terms defined in the Pharmacy Act or elsewhere in the Board Regulations shall have the same meanings in this regulation unless otherwise defined below:

"Clinic", means any facility where one or more licensed practitioners diagnose and treat patients, Α. and where drugs are stored, dispensed, distributed or administered for the diagnosis and treatment of the facility's patients; provided that this definition shall not include the privately owned practice of any licensed practitioner or group of licensed practitioners exempt under Section 61-11-22 of the Pharmacy Act.

В. "Dispensing Unit", means a container or containers of a drug entity, either prepackaged (repackaged per Board requirements) or the manufacturer's original container(s), containing a quantity suitable for the prescribed treatment or condition.

"Distribute" means delivery of a dispensing unit (as defined in this section) by a licensed С. practitioner to a patient of the clinic by means other than dispensing.

"Drug Storage Area", means an area restricted to the storage, dispensing and distribution of D. dangerous drugs.

E. "Medical Records", means the medical information gathered and maintained for a clinic's patient, including but not restricted to the patients weight, height, sex, D.O.B., allergies, diagnosis and treatments.

"Transfer", means the direct delivery, physically or electronically, of dangerous drug stock F. unopened containers, except samples, from a clinic or the clinic's supplier to a pharmacy to be dispensed by the pharmacy to patients of the clinic.

[02-15-96; 16.19.10.7 NMAC - Rn, 16 NMAC 19.10.7, 03-30-02]

MEDICAL STATIONS AND FIRST AID STATIONS: 16.19.10.8

A. The New Mexico Board of Pharmacy acknowledges the establishment of Medical Stations and First Aid Stations for employees in or of industrial plants and business organizations. In order to protect the people who utilize such facilities, laws and safeguards pertaining to drugs must be observed. Medications must occasionally be used and therefore require Board of Pharmacy supervision.

B. The variety and quantity of medications allowed at an Industrial Health Clinic must be kept to a minimum and must be only sufficient to meet the needs of the individual station.

C. The physician in charge of and responsible for the station must order the legend drugs to be used in such station. In order to purchase and stock any controlled substances, the responsible physician must obtain a separate controlled substance registration.

D. All legend drugs must be under lock when the nurse or physician is not in attendance. Extra precautions should be provided for security of controlled substances.

E. A record book indicating the following information shall be kept to account for the receipt and administration of all legend drugs:

- (1) Date received
- (2) Quantity received
- (3) Date of administration
- (4) Name of patient
- (5) Name of medication
- (6) Dosage administration
- (7) Name of physician responsible for the order

[03-07-80; 08-27-90; 16.19.10.8 NMAC - Rn, 16 NMAC 19.10.8, 03-30-02]

16.19.10.9 [RESERVED]

[07-15-97; 12-15-99; 16.19.10.9 NMAC - Rn, 16 NMAC 19.10.9, 03-30-02]

16.19.10.10 ANIMAL CONTROL CLINICS:

A. The New Mexico Board of Pharmacy acknowledges the establishment of animal control clinics. In order to protect the people who utilize such clinics, laws and safeguards pertaining to drugs must be observed. Medications must occasionally be used and therefore require Board of Pharmacy supervision.

B. The veterinarian in charge of and responsible for the clinic must specify the dangerous drugs to be used in such clinic. In order to purchase and stock any controlled substances, the clinic must obtain a separate controlled substance registration to be issued under the name of the clinic.

C. All dangerous drugs must be under lock when the veterinarian or his designee is not in attendance. Extra precautions should be provided for security of controlled substances.

D. A record indicating the following information shall be kept to account for the administration of all dangerous drugs:

- (1) Date of administration;
- (2) Type of animal;
- (3) Name of medication;
- (4) Dosage administered;

(5) Name of veterinarian responsible for the order;

(6) Name of individual administering the dose.

E. SCHEDULE II - Controlled substances administration records must be kept in a separate record with the same information recorded.

F. SCHEDULE III AND IV controlled substances may be kept in the same record in which dangerous drugs are recorded provided a mechanism is employed to identify these entries (such as a red "C" marked in the margin of these entries).

G. The record must be kept up-to-date at all times and is subject to inspection by the Board of Pharmacy Drug inspectors.

Any clinic licensed by the Board of Pharmacy is required to have a consultant pharmacist.

(1) If the animal control facility does not use any controlled substance in its' operation, a consultant pharmacist should visit the facility at least annually.

(2) If the animal control facility uses any controlled substance in its' operation, a consultant pharmacist should visit the facility at least quarterly.

[03-07-80; 07-29-93; 16.19.10.10 NMAC - Rn, 16 NMAC 19.10.10, 03-30-02]

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16.19.10.11 PUBLIC HEALTH CLINICS:

A. CLINIC LICENSURE:

(1) All clinics where dangerous drugs are administered, distributed or dispensed shall obtain a limited drug permit as described in Section 61-11-14 B (6) of the Pharmacy Act which consists of the following types:

- (a) Class A clinic drug permit for clinics where:
 - (i) dangerous drugs are administered to patients of the clinic;
 - (ii) more than 12,500 dispensing units of dangerous drugs are dispensed or

distributed annually;

(iii) clinics dispensing only one class of dangerous drug or controlled

substance, such as oral contraceptives or methadone, may be approved by the board as a Class B3 clinic; (b) Class B clinic drug permit for clinics where dangerous drugs are:

(i) administered to patients of the clinic; and

(ii) dispensed or distributed to patients of the clinic. Class B drug permits

shall be issued by categories based on the number of dispensing units of dangerous drugs to be dispensed or distributed annually, as follows: 1. CATEGORY 1 up to 2,500 dispensing units; 2. CATEGORY 2 from 2,501 - 7,500 dispensing units; 3. CATEGORY 3 from 7,501 - 12,500 dispensing units;

(c) Class C clinic drug permit for clinics where dangerous drugs are administered to patients of the clinic.

(d) Class D clinic drug permit for school based emergency medicine (SBEM) clinic (which does not include a Class A, B, or C school based health clinic) - any school based facility that chooses to possess a stock supply of emergency dangerous drugs; these emergency dangerous drugs are albuterol aerosol canisters with spacers and epinephrine standard-dose and pediatric-dose auto-injectors; these emergency dangerous drugs are for administration to students of the school; these emergency dangerous drugs shall be the property of the facility; these facilities will not stock of any other dangerous drug.

B. FORMULARIES:

(1) For all clinic types, drug procurement and storage is limited to the drugs listed in the dispensing formulary for the clinic. The formulary shall be developed by the pharmacy and therapeutics committee of the facility, or if no such committee exists, by the pharmacist and medical director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of ampicillin are considered one drug.

(2) For all clinic types, drug procurement and storage is limited to the drugs listed in the administration formulary for on-site administration. The formulary shall be developed by the pharmacy and therapeutics committee of the facility, or if no such committee exists, by the pharmacist and medical director of the clinic. The formulary drugs shall be appropriate for the scope of medical services provided at the clinic facility. A dangerous drug with the same generic name is considered one drug within the formulary (ie) all dosage forms and packages of ampicillin are considered one drug.

(3) For Class D, (SBEM) clinic may only stock the approved dangerous drugs; albuterol aerosol canisters with spacers and epinephrine standard-dose and pediatric-dose auto-injectors.

(4) A clinic may petition the board for an alternative dispensing formulary as set forth in Subsection R of 16.19.10.11 NMAC.

C. CONSULTANT PHARMACIST:

(1) Any facility licensed as a clinic by the board which does not employ a staff pharmacist must engage the services of a consultant pharmacist, whose duties and responsibilities are described in Subsection C of 16.19.4.11 NMAC.

(2) The consultant pharmacist shall wear an identification badge listing his name and job title while on duty in the clinic.

D. PHARMACY TECHNICIANS AND SUPPORT PERSONNEL:

(1) Pharmacy technicians, working in a clinic under the supervision of the pharmacist, may perform activities associated with the preparation and distribution of medications, including prepackaging medications and the filling of a prescription or medication order. These activities may include counting, pouring, labeling and reconstituting medications.

(2) The pharmacist shall ensure that the pharmacy technician has completed the initial training required in Subsection A of 16.19.22.9 NMAC.

(3) A written record of the initial training and education will be maintained by the clinic pursuant to requirements of Subsection C of 16.19.22.9 NMAC.

(4) The permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the pharmacist in charge or consultant pharmacist.

(5) Support personnel may perform clerical duties associated with clinic pharmacy operations, including computer data entry, typing of labels, processing of orders for stock, duties associated with maintenance of inventory and dispensing records.

(6) The pharmacist is responsible for the actions of personnel; allowing actions outside the limits of the regulations shall constitute unprofessional conduct on the part of the pharmacist.

(7) Name tags including job title, shall be required of all personnel while on duty in the

clinic.

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PROCUREMENT OR RECEIPT OF DANGEROUS DRUGS:

(1) The system of procurement for all drugs shall be the responsibility of the pharmacist.

(2) Records of receipt of dangerous drugs and inventories of controlled substances shall be maintained as required by the Drug, Device and Cosmetic Act 26-1-16 and the Controlled Substances Act 30-31-16 and board of pharmacy regulation 16.19.20 NMAC.

REPACKAGING:

(1) Repackaging from bulk containers to dispensing units for distribution at locations other than the site of repackaging requires FDA registration, whether or not the repackaged drugs enter interstate commerce. (See FDA Regulations Title 21, Sections 207, 210 and 211).

(2) Repackaging of drug from bulk containers into multiple dispensing units for future distribution to clinic patients at the site of repackaging may be done by a physician, dentist, pharmacist, or by a pharmacy technician under the supervision of the pharmacist as defined in Subsection B of 16.19.22.7 NMAC. All drugs repackaged into multiple dispensing units by a pharmacy technician must undergo a final check by the pharmacist.

- (3) A record of drugs repackaged must be maintained, to include the following.
 - (a) Date of repackaging.
 - (**b**) Name and strength of drug.
 - (c) Lot number or control number.
 - (d) Name of drug manufacturer.
 - (e) Expiration date (per USP requirements).
 - (f) Total number of dosage units (tabs, caps) repackaged (for each drug).
 - (g) Quantity per each repackaged unit container.
 - (h) Number of dosage units (tabs, caps) wasted.
 - (i) Initials of repackager.
 - (j) Initials of person performing final check. All dispensing units of repackaged medication must be labeled with the following

information.

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- (a) Name, strength, and quantity of the drug.
- (b) Lot number or control number.
- (c) Name of manufacturer.
- (d) Expiration date.
- (e) Date drug was repackaged.
- (f) Name or initials of repackager.
- (g) Federal caution label, if applicable.

(5) Repackaged units must be stored with the manufacturer's package insert until relabeled for dispensing. as specified under Subsection G of 16.19.10.11 NMAC.

G. CLINIC DISPENSING OR DISTRIBUTING:

(1) Drugs shall be dispensed or distributed only to clinic patients on the order of a licensed practitioner of the clinic.

(2) The clinic practitioner shall record the prescribed drug therapy on the patient medical record indicating the name, strength, quantity and directions for use of the prescribed drug. This information shall be initialed or signed by the practitioner. A separate prescription form in addition to the medical record may be used.

(3) The prescription order may then be prepared by the practitioner, pharmacist or technician under the supervision of the pharmacist and a dispensing label affixed to the dispensing unit of each drug. The following information shall appear on the label affixed to the dispensing unit.

- (a) Name of patient.
- (b) Name of prescriber.
- (c) Date of dispensing.
- (d) Directions for use.
- (e) Name, strength, and quantity of the drug.
- (f) Expiration date.
- (g) Name, address and phone number of the clinic.
- (h) Prescription number, if applicable.

(4) The pharmacist or practitioner must then provide a final check of the dispensing unit and sign or initial the prescription or dispensing record.

(5) Refill prescription orders must also be entered on the patient's medical record and the dispensing record.

H. PATIENT COUNSELING:

(1) Each clinic licensed by the board shall develop and provide to the board policies and procedures addressing patient counseling which are at least equivalent to the requirements of Subsection F of 16.19.4.16 NMAC.

(2) If the consultant pharmacist is absent at the time of dispensing or distribution of a prescription from clinic drug stock to a clinic patient, the patient shall be provided written information when appropriate on side effects, interactions, and precautions concerning the drug or device provided. The clinic shall make the consultant pharmacist's phone number available to patients for consultation on drugs provided by the clinic.

I. DISPENSING RECORDS: A record shall be kept of the dangerous drugs dispensed indicating the date the drug was dispensed, name and address of the patient, the name of the prescriber, and the quantity and strength of the drug dispensed. The individual recording the information and the pharmacist or clinic practitioner who is responsible for dispensing the medication shall initial the record.

J. SAMPLE DRUGS: Samples of medications which are legend drugs or which have been restricted to the sale on prescription by the New Mexico board of pharmacy are subject to all the record keeping, storage and labeling requirements for prescription drugs as defined by NMSA 26-1-16 and other applicable state and federal laws.

K. DRUG STORAGE:

(1) Space for the storage and dispensing of drugs shall have proper ventilation, lighting, temperature controls, refrigeration and adequate security as defined by the board or its' agent. Minimum space requirements for main drug storage areas are as follows:

- (a) for Class A clinics 240 square foot room;
- (**b**) for Class B clinics;
 - (i) categories 1, and 2 48 square foot room; and
 - (ii) category 3 96 square foot room;

(c) for Class C clinics - an area adequate for the formulary.

(d) for Class D clinics - an area adequate for the formulary:

(i) medication is stored in its original packaging until the time of

administration, and secured in a secondary tamper-evident container;

(ii) the dangerous drug is stored in a restricted area, secure but unlocked, and readily accessible to authorized, trained personnel;

(iii) for Class D clinics only, the pre-licensing inspection may be completed by a New Mexico board of pharmacy state drug inspector's approval of record keeping procedures; the policy and procedure manual; any other required forms or documents; and photographs of the proposed dangerous drug storage area, secondary tamper-evident container, and drug storage area thermometer; this pre-licensing inspection may not require an onsite inspection.

(2) Controlled substances must be stored as defined in 16.19.20.48 NMAC.

(3) All drug containers in the facility shall be clearly and legibly labeled as required under Subsection F of 16.19.10.11 NMAC – (REPACKAGING and Sections 26-1-10 and 26-1-11 of the Drug, Device and Cosmetic Act).

(4) Purchase, storage and control of drugs shall be designed to prevent having outdated, deteriorated, impure or improperly standardized drugs in the facility.

(5) Access to the drug storage area shall be limited to clinic practitioners, the pharmacist, and supportive personnel who are performing pharmacy-related functions.

(6) Clinics licensed by the board prior to adoption of this regulation are exempt from the minimum space requirements set forth in Paragraph (1) of Subsection K of 16.19.10.11 NMAC. When these facilities change ownership, remodel the drug storage area, or relocate after May 15, 1996, the requirements of Paragraph (1) of Subsection K of 16.19.10.11 NMAC shall apply.

L. DISPOSITION OF UNWANTED OR OUTDATED DRUGS:

(1) The pharmacist shall be responsible for removal of recalled, outdated, unwanted or otherwise unusable drugs from the clinic inventory.

(2) Options for disposal are destruction under the supervision of the pharmacist or return to the legitimate source of supply.

M. REFERENCE MATERIAL: Adequate reference materials are to be maintained in the clinic. These shall include a current product information reference such as USPDI, facts and comparisons, or American hospital formulary service; a copy of the state drug laws and regulations and a poison treatment chart with the regional poison control center's telephone number.

PROCEDURES MANUAL:

(1) Written policies and procedures shall be developed by the pharmacy and therapeutics committee, or if none, by the pharmacist-in-charge and clinic's executive director, and implemented by the pharmacist-in-charge.

The policy and procedure manual shall include but not be limited to the following:

(a) a current list of the names and addresses of the pharmacist-in-charge, consultantpharmacist, staff pharmacist(s), supportive personnel designated to provide drugs and devices, and the supportive personnel designated to supervise the day-to-day pharmacy related operations of the clinic in the absence of the pharmacist;

(b) functions of the pharmacist-in-charge, consultant pharmacist, staff pharmacist(s)

and supportive personnel;

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- (c) clinic objectives;
- (d) formularies;
- (e) a copy of the written agreement, if any, between the pharmacist and the clinic;
- (f) date of the last review or revision of policy and procedure manual; and
- (g) policies and procedures for
 - (i) security;
 - (ii) equipment;
 - (iii) sanitation;
 - (iv) licensing;
 - (v) reference materials;
 - (vi) drug storage;
 - (vii) packaging and repackaging;
 - (viii) dispensing and distributing;
 - (ix) supervision;
 - (**x**) labeling and relabeling;
 - (xi) samples;
 - (**xii**) drug destruction and returns;
 - (xiii) drug and device procuring;
 - (xiv) receiving of drugs and devices;
 - (**xv**) delivery of drugs and devices;
 - (**xvi**) record keeping; and
 - (xvii) scope of practice.

(3) The procedures manual shall be reviewed on at least an annual basis. A copy of the manual shall be kept at the clinic at all times.

(4) A written agreement defining specific procedures for the transfer, storage, dispensing and record keeping of clinic dangerous drug stock from a licensed New Mexico pharmacy will be included in the procedures manual. The agreement will be signed by a clinic official and pharmacy official and reviewed annually.

O. PATIENT RECORD: clinics shall maintain patient records as defined in Subsection C of 16.19.4.16 NMAC.

DRUG TRANSFER TO A PHARMACY:

(1) Dangerous drug stock unopened containers, except samples, may be transferred physically or electronically to a pharmacy licensed in New Mexico for dispensing to clinic patients.

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include:

- (a) record of transfer shall be maintained at the clinic and the pharmacy. It will
 - (i) date of transfer or shipment;
 - (ii) name and strength of drug;
 - (iii) package size;
 - (iv) number of packages;
 - (v) manufacturer or repackager; and

(vi) lot number and expiration date, unless transferred from a clinic supplier

to a pharmacy.

(b) A copy of the transfer or shipment record will be provided to the pharmacy at the time of transfer. This record will be compared with the drugs for accuracy and retained by the pharmacy as the receipt document separate from other receiving records of the pharmacy.

(c) Transferred clinic drugs will be stored in the restricted area of the pharmacy and physically separated from all other pharmacy drugs.

(d) Drugs returned to the clinic by the pharmacy will be documented in a transfer record as described in Subparagraph (a) of Paragraph (1) of Subsection P of 16.19.10.11 NMAC. A copy will be maintained by the pharmacy and the clinic.

(2) A clinic may petition the board for an alternative drug transfer system as set forth in Subsection Q of 16.19.10.11 NMAC.

(3) The formulary of transferred drugs for pharmacy dispensing is restricted to the clinic's scope of practice.

Q. PHARMACY DISPENSING: Clinic drug stock may be transferred to, and maintained by, a pharmacy for dispensing to clinic patients as provided in this regulation. Clinic drug stock may be dispensed by the pharmacy if:

(1) the drugs are dispensed only to a clinic patient with a valid prescription from a practitioner of that clinic;

(2) clinic prescriptions for clinic drugs are maintained separately from other prescriptions of the pharmacy;

(3) the prescription is dispensed in a container with a label attached which reads "DISPENSED FOR (clinic name and address) BY (pharmacy name and address)";

(4) all packaging and labeling requirements for prescriptions dispensed by a pharmacy have been met; and

(5) patient records and counseling requirements have been maintained separately for all clinic patients whose prescriptions were filled by the pharmacy from clinic drug stock.

PETITION FOR ALTERNATIVE PLAN:

(1) A clinic may petition the board for an alternative visitation schedule, dispensing formulary, or drug transfer system (each an "alternative plan") as follows.

(a) Prior to implementation of any alternative plan, the clinic shall provide to the board a written petition that describes the proposed alternative plan and justifies the request. The petition shall include an affidavit that states that the clinic has a current policy and procedures manual on file, has adequate security to prevent diversion of dangerous drugs, and is in compliance with all rules applicable to the clinic. The affidavit shall be signed by the medical director, the consultant pharmacist, and the owner or chief executive officer of the clinic. In addition, a petition for an alternative drug transfer system must include a detailed, written description of the proposed alternative transfer system in the policy and procedures manual describing:

- (i) drug ownership;
- (ii) drug ordering;
- (iii) drug shipping;
- (iv) drug receiving;
- (v) drug accountability system;
- (vi) formulary for transfer; and
- (vii) records of transfer.

(b) The board may approve or deny the petition for an alternative plan, at the board's discretion. The board may consider the following:

- (i) degree of compliance by the clinic on past compliance inspections;
- (ii) size and type of the patient population;
- (iii) number and types of drugs contained in the clinic's formulary;

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(iv) the clinic's objectives; and

(v) impact on the health and welfare of the clinic's patients.

(2) A copy of the board approved alternative plan shall be maintained at the clinic's license location for review by the board or its agent.

(3) The board may terminate the alternative plan if the board determines that the clinic's status or other circumstances justifying the alternative plan have changed.

Class D (SBEM) clinic:

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(1) Only trained personnel may administer epinephrine. Trained personnel can be a school employee, agent or volunteer who has completed epinephrine administration training documented by the school nurse, school principal or school leader and approved by the New Mexico department of health and who has been designated by the school principal or school leader to administer epinephrine on a voluntary basis outside of the scope of employment. Epinephrine is administered on the standing order of a health care practitioner employed or authorized by the New Mexico department of health. If administering epinephrine, written policies and procedures must be maintained on the premises. These policies and procedures must follow New Mexico department of health requirements as well as any policy or procedure requirement listed in 16.19.10.11 NMAC. Documentation of New Mexico department of health required training must be maintained on-site for each trained and authorized person.

(2) Only a school nurse may administer albuterol to a student who is perceived to be in respiratory distress. Written policies and procedures must be maintained at the licensed location. Documentation of New Mexico department of health required training must be maintained on-site for each nurse.

(3) The following records must be kept on-site and available for inspection for three years:

(a) receipt records;

(b) destruction or other disposition records;

(c) storage records; storage records include daily (on school days) documented drug storage area temperature; documented verification that medication is sealed in its original packaging until the time of administration, and secured but unlocked in a secondary tamper-evident container; dangerous drugs are stored in a restricted area, unlocked, and readily accessible to trained personnel; policies and procedures must be in place to ensure proper drug storage conditions on non-school days;

(d) usage records; if a dangerous drug is used, a record must be kept; the consultant pharmacist must be notified within a 72-hour period in order to review the record; in addition, all New Mexico department of health guidelines must be followed;

(e) annual self-assessment form; this form will be supplied by the New Mexico board of pharamcy and shall be reviewed by the consultant pharmacist at least annually;

(f) consultant pharmacist record of activities and comments;

(g) a current copy of facility's New Mexico board of pharmacy registration and the consultant pharmacist's current license will be posted in the drug storage area;

(h) policy and procedure manual.

(4) Albuterol and epinephrine must be stored in a secure but unlocked, temper evident, container. This container must be in a restricted area but readily accessible to trained personnel. A list of the contents, including expiration dates, must be posted on the outside of the container. [05-15-96; 16.19.10.11 NMAC - Rn, 16 NMAC 19.10.11, 03-30-02; A, 08-12-13; A, 10-24-14; A, 12-13-15]

16.19.10.12 INPATIENT HOSPICE FACILITIES:

A. Licensure:

(1) All inpatient hospice facilities which maintain custody of patients' drugs, and such drugs are administered by the facilities' designated personnel shall obtain a custodial care facility license as described in 16.19.11.7.A or 7.B NMAC.

(2) All inpatient hospice facilities where dangerous drugs are acquired and maintained for administration, to patients of the facility shall obtain a limited drug permit as described in 16.19.10.11(A).

(3) All inpatient hospice facilities holding a limited drug permit where controlled substances are maintained for administration from stock to patients of the facility shall obtain controlled substance registration as described in 16.19.20.8 NMAC through 16. 19.20.10 NMAC.

B. Consultant Pharmacist: All licensed inpatient hospice facilities shall engage the services of a pharmacist whose duties and responsibilities are described in 16.19.4.11(2) NMAC.

Drug Control:

(1) Inpatient hospice facilities holding a license as described in 16.19.11 NMAC shall comply with 16.19.11 NMAC.

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(2) Inpatient hospice facilities holding a license as described in 16.19.10.11.A NMAC shall comply with 16.19.10.11.A.(1), 11.C through 11.K.

D. Procedure Manual:

(1) Inpatient hospice facilities holding a license as described in 16.19.11 NMAC shall comply with 16.19.11.H.(1) NMAC.

(2) Inpatient hospice facilities holding a license as described in 16.19.10.11. A shall comply with 16.19.10.11(12).

E. Fees:

(1) Inpatient hospice facilities holding a license as described in 16.19.11 NMAC shall submit application with license fees as described in 16.19.12.14 NMAC.

(2) Inpatient hospice facilities holding a license as described in 16.19.10.11.A NMAC shall submit application with fees as described in 16.19.12.15 NMAC.

(3) Inpatient hospice facilities holding a license as described in 16.19.10.11.A NMAC shall submit application with fees as described in 16.19.12.18 NMAC for initial inspection of facility prior to issuance of license.

(4) An inpatient hospice facility whose board license has expired and who seeks reinstatement shall submit application with fees as described in 16.19.12.20 NMAC. [12-15-97; 16.19.10.12 NMAC - Rn, 16 NMAC 19.10.12, 03-30-02]

HISTORY OF 16.19.10 NMAC:

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

Regulation No. 10, Industrial Health Clinic, 2-7-80.

Regulation No. 10, Industrial Health Clinic, 10-23-85.

Regulation No. 10, Industrial Health Clinic, 2-2-87.

Regulation No. 10, Industrial Health Clinic, 7-27-90.

History of Repealed Material: [RESERVED]

Other History:

16 NMAC 19.10, Pharmacists - Limited Drug Clinics, filed 02-02-96; 16 NMAC 19.10, Pharmacists - Limited Drug Clinics, Filed 05-02-96; 16 NMAC 19.10, Pharmacists - Limited Drug Clinics, filed 03-09-98, reformatted and renumbered to 16.19.10 NMAC, Limited Drug Clinics, effective 03-30-2002.