

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 11 NURSING HOME DRUG CONTROL

16.19.11.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM, (505) 841-9102.

[16.19.11.1 NMAC - Rp 16 NMAC 19.11.1, 12-15-02]

16.19.11.2 SCOPE: All nursing homes and custodial care facilities; all health care professionals who provide pharmaceutical products or services, including the ordering and administration of drugs, to patients in nursing homes and custodial care facilities. Hospital based Skilled Nursing Facilities are not subject to this regulation - See Part 7.

[16.19.11.2 NMAC - Rp 16 NMAC 19.11.2, 12-15-02]

16.19.11.3 STATUTORY AUTHORITY: Section 61-11-6.A(6) NMSA 1978 authorizes the Board of Pharmacy to license nursing home drug facilities and all places where dangerous drugs are dispensed or administered and to provide for the inspection of their facilities and activities. Section 61-11-14.B(9) NMSA 1978 directs the Board to issue drug custodial licenses for licensed nursing homes and to adopt regulations that define and limit those licenses.

[16.19.11.3 NMAC - Rp 16 NMAC 19.11.3, 12-15-02]

16.19.11.4 DURATION: Permanent

[16.19.11.4 NMAC - Rp 16 NMAC 19.11.4, 12-15-02]

16.19.11.5 EFFECTIVE DATE: December 15, 2002, unless a later date is cited at the end of a Section.

[16.19.11.5 NMAC - Rp 16 NMAC 19.11.5, 12-15-02]

16.19.11.6 OBJECTIVE: The objective of Part 11 of Chapter 19 is to establish standards for the ordering, administration, maintenance and disposal of drugs for patients in nursing homes, skilled nursing facilities, and long-term care and custodial care facilities and to ensure that the facilities' pharmaceutical services are organized and carried out for the benefit and safety of the patients.

[16.19.11.6 NMAC - Rp 16 NMAC 19.11.6, 12-15-02]

16.19.11.7 DEFINITIONS:

A. Licensed Facility - Any facility, skilled nursing facility, intermediate care or any other upper level of care facility as defined by Health and Human Services Department that is required to maintain custody of patients drugs in a drug room, and such drugs are administered by the facilities' designated personnel.

B. Licensed Custodial Care Facility - Any facility or business, including non-profit entity which provides care and services on a continuing basis, for two or more in-house residents, not related to the operator, and which maintains custody of the residents' drugs.

C. Consultant Pharmacist - means a pharmacist who is responsible to the administrator of the facility and the Board of Pharmacy for the development of the drug storage and distribution and record keeping requirements of a licensed nursing home facility, and as further defined in 16.19.4.11 NMAC.

D. Designated Agent - A licensed nurse, certified nurse practitioner, physician assistant, pharmacist or pharmacist clinician authorized by a practitioner and employed in a facility to whom the practitioner communicates a prescription drug order.

E. Prescription Drug Order - An order from a practitioner or a practitioner's designated agent to a pharmacist for a drug or device to be dispensed.

[16.19.11.7 NMAC - Rp 16 NMAC 19.11.7, 12-15-02]

16.19.11.8 MINIMUM STANDARDS:

A. MINIMUM STANDARDS FOR THE DISTRIBUTION, STORAGE, HANDLING AND RECORD KEEPING OF DRUGS:

(1) The pharmaceutical service shall be organized and maintained primarily for the benefit and safety of the patient.

(2) All medications administered to patients shall be by direct order of a physician, or other licensed practitioner, as defined in the Pharmacy Act, 61-11-2P.

(3) The pharmaceutical service shall be under the direction of a registered pharmacist, who may be on a part-time or consultant basis.

(4) Policies relating to the control, distribution and administration of medications shall be developed by the pharmacist. Preparation of a written procedures manual shall be the responsibility of the pharmacist.

(5) An automatic stop-order policy shall be adopted to provide guidance in these instances where medications ordered are not specifically limited as to time or number of doses.

(6) Adequate facilities to be provided for storage of medications. Proper labeling is required on each patient's medication container.

(7) Complete records - In addition to those records specifically required by federal and state laws, records shall be maintained of the receipt, use, or disposition of medications. The receipt and destruction journal shall show:

- (a) date;
- (b) patient's name;
- (c) pharmacy's name;
- (d) name of drug;
- (e) strength and dosage form;
- (f) prescription number;
- (g) quantity;
- (h) initials of person accepting delivery; and
- (i) inventory of drugs to be destroyed.

(8) Appropriate current drug reference sources shall be provided at the facility.

(9) In licensed nursing homes an emergency drug supply shall be maintained to be used in a medical emergency situation, contents and quantity to be determined by a physician, nursing director and the pharmacist of each institution. In licensed custodial care facilities an emergency drug supply may be used. This emergency drug supply shall be accessed only when licensed personnel are on duty. In licensed custodial care facilities without a 24-hour/365 day per year on-site nurse, the emergency drug tray shall not contain any controlled substances. Licensed custodial care facilities, with a 24-hour/365 day per year on-site nurse may use an emergency drug tray containing controlled substances. A list of the contents of the emergency drug supply shall be attached to the outside of the tray.

(10) Medication errors and drug reactions should be documented and a method of reporting shall be addressed in the pharmacy procedure manual.

B. POLICY AND PROCEDURES MANUAL:

(1) The pharmacist shall be responsible for the preparation of a written procedures manual, the aim of which shall be:

- (a) To improve communications with the facility;
- (b) To improve patient care;
- (c) To aid in personnel training;
- (d) To increase legal protection;
- (e) To aid in evaluating performance;
- (f) To promote consistency and continuity.

(2) There shall be a copy of the policy and procedure manual at each facility location. This copy must be read and initialed by all personnel responsible for the procurement, administration or control of the patient's medication.

(3) The consultant pharmacist shall make an annual review of the procedures manual. Findings of which shall be reported to the facility administration.

(4) Guidelines for developing a pharmaceutical procedures manual;

(a) Drug Policy: A written policy concerning methods and procedures for the pharmaceutical services stating the appropriate methods and procedures for obtaining, dispensing and administering drugs and biologicals.

(b) Prescription Drug Orders: The designated agent of the facility may transcribe prescription drug orders from a licensed practitioner and transmit those orders via telephone or facsimile to the pharmacy.

(c) Licensed practitioners will identify the designated agents of a facility by written authorization according to the facility's policy and procedures manual.

(d) The facility shall have a medication administration record (MAR) documenting medications administered to residents, including over-the-counter medications. This documentation shall include:

- (i) Name of resident;
- (ii) Date given;
- (iii) Drug product name;
- (iv) Dosage and form;
- (v) Strength of drug;
- (vi) Route of administration;
- (vii) How often medication is to be taken;
- (viii) Time taken and staff initials;
- (ix) Dates when the medication is discontinued or changed;
- (x) The name and initials of all staff administering medications.

(e) Any medications removed from the pharmacy container or blister pack must be given immediately and documented by the person assisting.

(f) All PRN medications shall have complete detail instructions regarding the administering of the medication. This shall include:

- (i) Symptoms that indicate the use of the medication;
- (ii) Exact dosage to be used;
- (iii) The exact amount to be used in a 24 hour period.

(g) Describe medication storage, procedures, and function at the nursing stations.

(h) Describe the medication administration system used with means of verifying accuracy of delivered dosage. Describe the procedure for recording missed or refused doses and the procedure followed for missed or refused doses.

(i) State that medications prescribed for one patient shall not be administered to any other patient.

(j) Describe policy concerning self-administration of medications by patients. A physician's order shall be required before any resident is allowed to self-administer medications.

(k) State procedures for documenting medication errors and drug reactions:

(i) Should a staff member of the facility notice an error, possible overdose, or any discrepancy in any of the prescriptions filled by the pharmacy, they will immediately contact the pharmacy. If necessary, the pharmacy will contact the physician.

(ii) In the event of an adverse drug reaction the facility will immediately contact the physician.

(l) List labeling and storage requirements of medications in conformity with the official compendium (USP/NF).

(5) OTHER INFORMATION

(a) Emergency Drug Tray - use, inventory control, replacement of drugs, security when licensed staff is not on duty.

(b) Location of Emergency Drug Tray.

(c) 24-hour emergency pharmaceutical services.

(d) Part-time or consultant pharmacist hours on premises.

(e) In-service training.

(f) Drug information service.

(g) Automatic stop orders.

(h) Controlled substances - inventory, security and control.

(i) Renewal of physician's orders.

(j) A policy concerning "PASS" medications.

(k) Discontinued medication.

(l) Records and standards of storage of over-the-counter drugs.

(m) Drug receipt and disposition records.

(6) DRUG DISTRIBUTION

(a) All dangerous drugs shall be obtained from a properly licensed facility. Stock dangerous drugs acquired, maintained and administered by or at the nursing home shall be listed in the nursing home

policy and procedure manual. The stock dangerous drugs shall be used when a licensed nurse (LPN or RN) is on duty. The following is the approved list of stock dangerous drugs:

- (i) Sterile normal saline and water - injectable;
- (ii) Sterile normal saline and water - irrigation;
- (iii) Tuberculin testing solution;
- (iv) Vaccines as recommended by the centers for disease control (CDC) and prevention's advisory committee on immunization practices and appropriate for the facility population served;
- (v) Any additional nursing home stock dangerous drugs must be defined and listed in the policy and procedure manual and must be approved by the board of pharmacy or board's agent prior to obtaining or using.

(b) No drugs will be compounded by other than a pharmacist unless done in accordance with that exemption in the State Pharmacy Act - Section 61-11-22.

(c) The pharmacist shall be responsible for the proper removal and destruction of unused, discontinued, outdated or recalled drugs.

(d) The pharmacist shall require the person receiving a patient's drugs from the pharmacist or his agent to sign a drug receipt record listing those prescriptions received from the pharmacy.

(e) The pharmacist shall provide the staff with a receipt listing those prescriptions removed from the facility.

(f) Medications will be released to patients on discharge from the facility only upon the authorization of the physician.

(7) DRUG CONTROL

(a) All state and federal laws relating to storage, administration and disposal of controlled substances and dangerous drugs shall be complied with.

(b) Separate sheets shall be maintained for controlled substances records indicating the following information for each type and strength of controlled substances: date, time administered, name of patient, dose, physician's name, signature of person administering dose, and balance of controlled substance in the container.

(c) All drugs shall be stored in locked cabinets, locked drug rooms, or state of the art locked medication carts.

(d) Medication requiring refrigeration shall be kept in a secure locked area of the refrigerator or in the locked drug room.

(e) All refrigerated medications will be kept in separate refrigerator or compartment from food items.

(f) Medications for each patient shall be kept and stored in their originally received containers, and stored in separate compartments. Transfer between containers is forbidden, waiver shall be allowed for oversize containers and controlled substances at the discretion of the drug inspector.

(g) Prescription medications for external use shall be kept in a locked cabinet separate from other medications.

(h) No drug samples shall be stocked in the licensed facility.

(i) All drugs shall be properly labeled with the following information:

- (i) Patient's full name;
- (ii) Physician's name;
- (iii) Name, address and phone number of pharmacy;
- (iv) Prescription number;
- (v) Name of the drug and quantity;
- (vi) Strength of drug and quantity;
- (vii) Directions for use, route of administration;
- (viii) Date of prescription (date of refill in case of a prescription renewal);
- (ix) Expiration date where applicable: The dispenser shall place on the label a suitable beyond-use date to limit the patient's use of the medication. Such beyond-use date shall be not later than (a) the expiration date on the manufacturer's container, or (b) one year from the date the drug is dispensed, whichever is earlier;

(x) Auxiliary labels where applicable;

(xi) The Manufacturer's name;

(xii) State of the art drug delivery systems using unit of use packaging require items i and ii above, provided that any additional information is readily available at the nursing station.

(j) Customized Patient Medication Packages: In lieu of dispensing one, two, or more prescribed drug products in separate containers or standard vial containers, a pharmacist may, with the consent of the patient, the patient's care-giver, the prescriber, or the institution caring for the patient, provide a customized patient medication package. The pharmacist preparing a patient medication package must abide by the guidelines as set forth in the current edition of the U. S. Pharmacopoeia for labeling, packaging and record keeping.

(k) Repackaging of Patient Medication Packages: In the event a drug is added to or discontinued from a patient's drug regimen, when a container within the patient medication package has more than one drug within it, the pharmacist may repackage the patient's patient medication package and either add to or remove from the patient medication packaged as ordered by the physician. The same drugs returned by the patient for repackaging must be reused by the pharmacist in the design of the new patient medication package for the new regimen, and any drug removed must either be destroyed, returned to the DEA or returned to the patient properly labeled. Under no circumstances may a drug within a container of a patient medication package which contains more than one drug be returned to the pharmacy stock.

(l) Return of Patient Medication Package Drugs: Patient medication packages with more than one drug within a container may not under any circumstances be returned to a pharmacy stock.

(m) Patient Medication Packages with only one drug within a container:

(i) Non-Institutional: A patient medication package stored in a non-institutional setting where there is no assurance of storage standards may not be returned to pharmacy stock;

(ii) Institutional: A patient medication package stored in an institutional setting where the storage and handling of the drugs are assured and are consistent with the compendia standards may be returned to the pharmacy stock provided the following guidelines are followed: (1) the drug is to be kept within the patient medication package and is to remain sealed and labeled until dispensed; (2) the expiration date of drug shall become 50% of the time left of the expiration for the drug; (3) no Schedule II drugs may be returned to inventory; and (4) proper record keeping for the addition of other scheduled drugs into inventory must be done.

(8) DRUG INFORMATION

(a) The pharmacist shall be accessible for providing drug information.

(b) A current reference books shall be located in each nursing station.

(c) Each nursing station shall have poison control information and phone number and a conversion chart for pharmaceutical weights and measures, and as a part of the drug procedures manual.

(9) EMERGENCY DRUG SUPPLY

(a) There shall be an accountability record indicating the following:

(i) Name of drug, strength, and amount of medication used;

(ii) Date used;

(iii) Time;

(iv) Patient's name;

(v) Physician's name;

(vi) Nurse administering drug;

(vii) Nature of emergency.

(b) Pharmacist shall make notation of date and time medication replacement is made on the line following that line containing withdrawal information and sign his name, unless the pharmacy chooses to change out the complete emergency box each time it is used. The pharmacy shall keep a record of each time the box is changed and a list of all drugs that were replaced in the box.

(10) Destruction of dispensed drugs for patients in health care facilities or institutions:

(a) The drugs are inventoried and such inventory is verified by the consultant pharmacist. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of drug destruction;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist destroying drugs;

(ix) signature of witness(es); and

(x) method of destruction.

(b) The drugs are destroyed in a manner to render the drugs unfit for human consumption and disposed of in compliance with all applicable state and federal requirements.

(c) The actual destruction of the drug is witnessed by the consultant pharmacist and one of the following:

- (i) An agent of the New Mexico board of pharmacy;
- (ii) Facility administrator;
- (iii) The director of nursing.

(11) A consultant pharmacist may utilize a waste disposal service or reverse distributor to destroy dangerous drugs and controlled substances in health care facilities, boarding homes or institutions provided the following conditions are met:

(a) The inventory of drugs is verified by the consultant pharmacist. The following information must be included on this inventory:

- (i) Name and address of the facility or institution;
- (ii) Name and pharmacist license number of the consultant pharmacist;
- (iii) Date of packaging and sealing of the container;
- (iv) Date the prescription was dispensed;
- (v) Unique identification number assigned to the prescription by the pharmacy;

- (vi) Name of dispensing pharmacy;
 - (vii) Name, strength and quantity of drug;
 - (viii) Signature of consultant pharmacist packaging and sealing container;
- and

- (ix) Signature of the witness.

(b) The consultant pharmacist seals the container or drugs in the presence of the facility administrator, the director of nurses or an agent of the board of pharmacy.

(c) The sealed container is maintained in a secure area at the facility or pharmacy until transferred to the waste disposal service or the reverse distributor by the consultant pharmacist, facility administrator, director of nursing or agent of the board of pharmacy.

(d) A record of the transfer to the waste disposal service or reverse distributor is maintained and attached to the inventory of drugs. Such records shall contain the following information:

- (i) Date of the transfer;
- (ii) Signature of the person who transferred the drugs to the waste disposal service or reverse distributor;
- (iii) Name and address of the waste disposal service or reverse distributor;
- (iv) Signature of the employee of the waste disposal service or the reverse distributor who receives the container; and
- (v) The waste disposal service or reverse distributor shall provide the facility with proof of destruction of the sealed container.

(12) Record Retention: All records required above shall be maintained by the consultant pharmacist and the health care facility or institution for three years from the date of destruction.

[16.19.11.8 NMAC - Rp 16.19.11.8, 12-15-02; A, 10-24-14; A, 12-13-15]

HISTORY OF 16.19.11 NMAC:

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

Regulation No. 11, Nursing Home Drug Control Regulation, 2-7-80.

Regulation No. 11, Nursing Home Drug Control Regulations, 10-24-85.

Regulation No. 11, Nursing Home Drug Control Regulations, 12-17-85.

Regulation No. 11, Nursing Home Drug Control Regulations, 2-2-87.

Regulation No. 11, Nursing Home Drug Control Regulations, 7-27-90.

History of Repealed Material:

16 NMAC 19.11, Nursing Home Drug Control, filed 3-9-98 was repealed effective 12-15-02.

Other History:

Regulation No. 11, Nursing Home Drug Control Regulations, filed 7-27-90 was renumbered and reformatted into first version of the New Mexico Administrative Code as 16 NMAC 19.11, Nursing Home Drug Control, filed 2-2-96.

16 NMAC 19.11, Nursing Home Drug Control, filed 2-2-96 was replaced by 16 NMAC 19.11, Nursing Home Drug Control, filed 3-9-98.

16 NMAC 19.11, Nursing Home Drug Control, filed 3-9-98 was replaced by 16.19.11 NMAC, Nursing Home Drug Control, effective 12-15-02.