

This is an amendment to 16.19.7 NMAC, Sections 1, 3, 7, 9, 11 and 16, effective June 9, 2019.

16.19.7.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy [~~1650 University Blvd, NE, Ste. 400B, Albuquerque, NM 87102 (505) 841-9102~~].
[8/16/1999; 16.19.7.1 NMAC – Rn, 16 NMAC 19.7.1, 3/30/2002; A, 6/9/2019]

16.19.7.3 STATUTORY AUTHORITY: [~~Section 61-11-6A.(6)~~] Paragraph (6) of Subsection (A) of Section 61-11-6 NMSA 1978 requires that the Board of Pharmacy provide for the licensing of hospital pharmacies and the drug rooms of hospitals and the inspection of their facilities and activities.
[8/16/1999; 16.19.7.3 NMAC - Rn, 16 NMAC 19.7.3, 3/30/2002; A, 6/9/2019]

16.19.7.7 DEFINITIONS:

A. "Automated Medication Management System" means automated devices that compound, measure, count, or package and deliver a specified quantity of dosage units for a designated drug product and which collects, controls and maintains all transaction information.

B. "Bar-Code" means a graphic composed of [~~parallel~~] variously patterned bars and spaces [~~of various widths~~] or other geometric patterns intended for use in the detection and automatic processing of item identities or other intelligence by electro-optical means.

C. "Dispensing" as defined in [~~the NMSA, Section 61-11-2(I)~~] Subsection (I) of Section 61-11-2 NMSA 1978, and pursuant to [~~61-11-21(C)~~] Subsection (C) of Section 61-11-21 NMSA 1978 dispensing is limited to a registered pharmacist.

D. "Electronic Signature" means a unique security code or other identifier which specifically identifies the person entering information to a data processing system.

E. "Facility" means a hospital or other inpatient institution which has a pharmacy within the premises.

F. "Formulary" means a list of drugs approved for use in a facility by its medical staff through the Pharmacy and Therapeutics Committee or its equivalent.

G. "Hard Copy" means a paper-based record keeping system that is readable without the use of a special device, i.e., computer, microfiche reader, etc.

H. "Hospital" means any place offering in-patient skilled nursing, overnight care on a 24 hour basis for diagnosing, treating and providing medical or surgical care for patients.

I. "Hospital-based Skilled Nursing Facility" means a long-term care facility or unit thereof that is an integral and subordinate part of the hospital, is operated with other departments of the hospital under common governance and professional supervision such that the skilled nursing facility and the hospital are subject to the bylaws and operating decisions of common governing board, is fully integrated with all other services of the hospital, is owned, operated and managed by the hospital and is physically located within said hospital.

J. "In-house Clinic" means a clinic located in a hospital which has a pharmacy within the premises. The clinic is a facility where one or more licensed practitioners diagnose and treat patients, 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 NMSA 1978 of the Pharmacy Act.

K. "Integrated Healthcare System" means an integrated network of healthcare services provided by a single corporation or system. Systems offer comprehensive care which may include, acute, urgent care, long term or home health.

L. "Medication Profile" means a record and drug listing for each patient based on available information, containing but not limited to, patient name, patient age, sex, patient weight, current diagnosis, allergies or sensitivities, and current therapy.

M. "Medication-use Measurement Program" means a program that entails measuring, assessing, and improving the prescribing or ordering; preparation and dispensing; administration; and monitoring of medications.

N. "Parenteral Products" means any preparation administered by injection through one or more layers of skin tissue.

O. "Pharmacist-in-Charge" means a pharmacist employed by the facility on either a part-time or

full-time basis as the activity of service requires and as outlined in 16.19.6.9 NMAC.

P. "Pharmacy and Therapeutics Committee" means an advisory committee of the medical staff of the facility recommending policy regarding evaluation, selection, and therapeutics of drugs.

Q. "Policy and Procedures Manual" shall outline the scope of services for safe delivery of quality pharmaceutical care for all patients.

[8/16/1999; 16.19.7.7 NMAC - Rn, 16 NMAC 19.7.7, 3/30/2002; A, 6/9/2019]

16.19.7.9 FACILITIES:

A. The hospital pharmacy shall be enclosed and locked if a pharmacist is not present in the facility. Adequate security systems shall be maintained and be consistent with the security plan of the facility.

B. The pharmacist-in-charge shall control access to the pharmacy and develop an emergency access procedure that may include the following situations or conditions:

(1) The hospital administrator or designee may possess a key to the pharmacy for emergency access.

(2) For the purposes of withdrawing limited doses of a drug for administration in emergencies when the pharmacy is closed, if the drugs are not available in floor or emergency drug supplies, the following is applicable:

(a) Only one designated licensed nurse per shift may remove drugs from the pharmacy. The quantity of drugs shall not exceed the quantity needed to last until the pharmacist is in the facility:

(b) A record shall be made at the time of withdrawal by the authorized person removing the drugs. The record shall contain the following:

(i) name of patient;

(ii) name of drug, strength, and dosage form;

(iii) dose prescribed;

(iv) quantity taken;

(v) time and date; and

(vi) signature (first initial and last name or full signature) or electronic

signature of person making the withdrawal.

(c) The original or direct copy of the medication order may substitute for such record, providing the medication order meets all of the requirements of ~~[16.19.7.9.B(2)(b) NMAC]~~ Subparagraph (b) of Paragraph (2) of Subsection (B) of 16.19.7.9 NMAC (record).

(d) The nurse withdrawing the drug shall place upon the record of withdrawal an example of the medication removed.

(e) An electronic record of the withdrawal is required when the nurse is withdrawing more than a 72 hour supply.

(f) The pharmacist shall verify the withdrawal after a reasonable interval, but in no event may such interval exceed 72 hours from time of withdrawal. Verification may be accomplished electronically from a remote site, if approved by the board.

(g) A drug regimen review, pursuant to a new medication order, will be conducted by a pharmacist either on-site or by electronic transmission within 24 hours of the new order.

(h) Another duly registered pharmacy may supply medications pursuant to a patient specific medication order provided:

(i) supplying pharmacy is licensed in this state;

(ii) supplying pharmacist is licensed in this state;

(iii) all pharmacy preparations of sterile products (including total parenteral nutrition and chemotherapy) shall be performed in accordance with board of pharmacy ~~[16.19.6.11]~~ 16.19.36 NMAC.

(3) The pharmacist-in-charge or designated pharmacist, intern or technician may prepackage drugs for emergency withdrawal.

C. A pharmacist shall be "on call" during all absences from the facility.

D. A hospital pharmacy shall have within the institutional facility it services sufficient floor space allocated to ensure that pharmaceutical services are provided in an environment which allows for the proper compounding, dispensing and storage of medications. The minimum required pharmacy floor space excluding office area is:

Average daily census including skilled beds	Specialty designation	1-25	26-50	51-100	101-200	201-500	>500
Minimum Square Feet	Adequate	Adequate	280	500	750	1000	1500
Min. [Sq. Ft.] square feet for Sterile Prep Area (in addition to above)	100	100	100	100	100	100	100

A hospital may petition the board for a variance to the required minimum square footage. The license application shall include an average daily inpatient census for the last year.

E. Specialty Designation:

(1) Adequate square footage will be decided by the board at the time of licensure. The yearly license application will be accompanied by photos and a drawing of the pharmacy area. The board may ask for more detailed information to make a determination.

(2) A hospital must petition the board for a specialty designation. The board may consider, but is not limited to the following:

- (a) size of facility;
- (b) type of patient population; or
- (c) number and types of drugs stored and dispensed from the pharmacy.

F. Hospitals having licensed outpatient pharmacies shall comply with retail pharmacy 16.19.6.10 NMAC.

G. The hospital pharmacy shall have the necessary equipment for the safe and appropriate storage, compounding, packaging, labeling, dispensing and preparation of drugs and parenteral products depending on the scope of pharmaceutical services provided.

- (1) Refrigerator.
- (2) Sink with hot and cold water.

H. Only one registered or certified pharmacy technician may be present in the pharmacy when the pharmacist is not in the facility, only to perform clerical tasks. A written log shall be maintained of technician activities while alone in the pharmacy

[8/16/1999; 16.19.7.1 NMAC – Rn, 16 NMAC 19.7.1, 3/30/2002; A, 6/9/2019]

16.19.7.11 DRUG DISTRIBUTION AND CONTROL:

A. In hospitals where there is not a pharmacy, pre-labeled, prepackaged medications shall be stored in and distributed from a drug storage area or automated medication management system, which is under the supervision of a pharmacist.

B. The pharmacist-in-charge shall have the responsibility for the procurement and storage of all drugs.

C. All medications, with the exception of those for emergency use, shall be issued for inpatients use pursuant to the review of the physician's order or direct copy thereof, prior to dispensing. If the pharmacy is closed when the order is written, the pharmacist shall review the order within 24 hours.

D. A medication profile for all inpatients and outpatients shall be maintained and used. The medication profile shall serve as the distribution record for inpatient medications. Dangerous drug distribution records, for inpatient use, must include the following information:

- (1) the patient's name and room (or bed) number;
- (2) the name, strength, quantity and dosage form of the drug distributed;
- (3) the name of the technician filling the drug order and pharmacist responsible for checking the technician's work; or
- (4) the name of the pharmacist or pharmacist intern filling the drug order;
- (5) the date filled; and
- (6) the date and amount of unwanted/ unused drug returned to the pharmacy stock;
- (7) records for schedule II controlled substances must be kept separate; and
- (8) schedule III-V must be kept separate or if stored with non-controlled records, readily retrievable.

E. Floor stock dangerous drug distribution records must include the following:

- (1) name, strength, dosage form, and quantity of the drug distributed;

- (2) date of filling;
- (3) a name of technician filling the drug order and the supervising pharmacist; or
- (4) the name of the pharmacist or pharmacist intern filling the drug order;
- (5) the destination location of the drug in the hospital; and
- (6) the date and quantity of unwanted/ unused drug returned to the pharmacy's stock;
- (7) schedule II controlled substance records must be kept separate from all other records; and
- (8) schedule IV controlled substance records must either be kept separate from other non-

controlled substances records or are readily retrievable.

F. Dangerous drug distribution records, inpatient and floor stock, and medication profiles may be stored electronically if such system is capable of producing a printout of all the required information and the information is retrievable within 72 hours upon demand. The pharmacist stating that it is a true and accurate record must certify the printout. Hospitals utilizing automated drug distribution must comply with Subsection M of 16.19.7.11 NMAC in lieu of the above. Hospital pharmacies are subject to all applicable state and federal record keeping requirements when a prescription from a licensed practitioner is filled.

G. A distribution system for controlled substances shall be maintained including perpetual inventory of all schedule II controlled substances. All schedule II controlled substances that are stored in the pharmacy will be kept in a locked storage area in the pharmacy.

H. Drug storage and preparation areas within the facility shall be the responsibility of the pharmacist-in-charge. All areas shall be inspected on a monthly basis and documented by a pharmacist, intern or technician.

I. All pharmacy preparations of sterile products shall be performed in accordance with the sterile products regulations, [~~16.19.6.11~~] 16.19.36 NMAC.

J. Floor stock drugs, including those issued from automated medication management systems, shall be limited to drugs for emergency use and routinely used items as listed in the pharmacy policy and procedure manual and approved by the pharmacy and therapeutics committee. Floor stock drugs shall be supplied in individual doses unless the bulk container cannot be individualized. Dangerous drug floor stock must be reviewed by the pharmacist or pharmacist intern on a routine basis to insure appropriate use.

K. Where such committees exist, the pharmacist-in-charge or designated pharmacist shall be a voting member of the pharmacy and therapeutics committee or its equivalent.

L. Medications dispensed in the emergency room will be dispensed only by a licensed pharmacist, a licensed pharmacist intern or a licensed practitioner and shall comply with the following:

(1) a record shall be kept of all medications dispensed from the emergency room of a hospital; the record shall include:

- (a) the date the drug was dispensed;
- (b) name and address of the patient;
- (c) name of the prescribing physician;
- (d) the name of the drug;
- (e) the strength of the drug;
- (f) the quantity of drug dispensed;
- (g) initials of the person recording the information if not a physician;

(2) a separate record shall be kept for schedule II controlled substances;

(3) the following will be recorded in the patient's medical chart:

- (a) the name of the drug(s) prescribed;
- (b) the strength of the drug;
- (c) the quantity of the drug dispensed;

(4) when medications are prescribed by the physician and dispensed to the patient in the emergency room of the hospital the dispensing label shall contain the following information:

- (a) the name of the patient;
- (b) the name of the prescribing physician;
- (c) name of the drug;
- (d) strength of the drug;
- (e) quantity of the drug;
- (f) name and address of the hospital;
- (g) date the drug is dispensed;
- (h) directions for use;
- (i) expiration date of medication.

M. Automated Pharmacy Systems.

(1) General Statement: Automated devices for storage and distribution of floor stock or patient profile drugs or both, shall be limited to licensed health care facilities and shall comply with all the following provisions. Written policies and procedures, approved by the appropriate health care facility committee, shall be in place to ensure safety, accuracy, security, and patient confidentiality. Personnel allowed access to an automated dispensing device shall have a confidential access code that records the identity and electronic signature of the person accessing the device.

(2) Security/Access: The control of access to the automated device must be controlled by the pharmacist-in-charge. Proper identification and access control, including electronic passwords or other coded identification, must be limited and authorized by the pharmacist-in-charge. The pharmacist-in-charge must be able to stop or change access at any time. The pharmacist-in-charge must maintain a current and retrievable list of all persons who have access and the limits of that access. Review of user access reports shall be conducted at least quarterly as established by policy and procedures to ensure that persons who are no longer employed at the facility do not have access to the system.

(3) Records: The records kept by the automated drug delivery system must comply with all state, federal, and board requirements. Records must be maintained by the pharmacy and be readily retrievable. Records may be retained in hard copy or an alternative data retention system may be used where current technology allows.

(4) Automated Drug Distribution: An automated medication management system shall be under the control of the pharmacist-in-charge. If used for storage and dispensing of doses scheduled for administration, there shall be a procedure by which orders for a drug are reviewed and approved by the pharmacist before the drug may be withdrawn from the automated dispensing device. There shall be written procedures for downtime in the event of system malfunction or otherwise inoperable. A downtime log shall be maintained and include:

- (a) date of transaction;
- (b) patient;
- (c) drug/dose;
- (d) quantity of transaction;
- (e) nurse signature;
- (f) beginning count;
- (g) ending count;
- (h) wasted amount;
- (i) witness signature, if needed; and
- (j) prescriber (for controlled substances only).

(5) Quality Assurance: The pharmacist-in-charge shall be responsible for developing and implementing a quality assurance program which monitors total system performance. Quality monitors shall include:

- (a) the proper loading/refilling of the device, including proof of delivery;
- (b) the proper removal, return or waste of drugs;
- (c) processes for recording, resolution, and reporting of discrepancies; and
- (d) processes for conducting periodic audits to assure compliance with policies and

procedures.

(6) Records: Transaction records: At the time of any event involving the contents of the automated device, 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 name, strength, and quantity of medication;
- (d) the name of the patient for whom the drug was ordered;
- (e) the name or identification code (electronic signature) of the person making the transaction;
- (f) the name of the attending, admitting or prescribing practitioner; and
- (g) the identity of the device accessed.

(7) Delivery Records: A delivery record shall be generated on demand for all drugs filled into an automated dispensing device which shall include:

- (a) date;
- (b) drug name;
- (c) dosage form

- (d) strength;
- (e) quantity;
- (f) identity of device; and
- (g) name or initials of the person filling the automated dispensing device.

(8) Filling: There shall be policies and procedures in place, utilizing either manual, bar coding or other electronic processing means of item identities as current technology allows, to ensure pharmacist verification of accuracy in the filling and refilling of the automated device. A delivery record of medications filled into an automated pharmacy system shall be maintained and shall include identification of the person filling the device.

(9) Labeling/Packaging: Drugs filled into automated dispensing devices shall be in manufacturers' sealed, original packaging or in repackaged containers in compliance with the requirements of the board regulations relating to packaging and labeling.

N. Outsourcing of Pharmaceutical Services: A hospital pharmacy may contract or enter into an agreement with another licensed pharmacy/pharmacist to provide pharmaceuticals and/or other pharmacist services under the following conditions:

- (1) the contract pharmacy is licensed by the board of pharmacy;
- (2) the pharmacist providing the services by the contracted pharmacy shall be licensed as a pharmacist in this state;
- (3) the contract is incorporated into the pharmacy's policy and procedure manual and complies with the requirements of 16.19.7 NMAC;
- (4) the contracted pharmacy/pharmacist must have complete access to the patient's profile in order to perform a drug regimen review;
- (5) the contracted pharmacy/pharmacist must have access to the licensed practitioners of the hospital;
- (6) records of all pharmaceuticals transferred from the contracted pharmacy to the hospital pharmacy comply with the requirements;
- (7) documentation of the services provided by the contracted pharmacy/pharmacist.

[8/16/1999; 16.19.7.11 NMAC - Rn, 16 NMAC 19.7.11, 3/30/2002; A, 1/31/2007; A, 6/9/2019]

16.19.7.16 [~~APPLICATION OF REGULATION: Pharmacies licensed by the board prior to adoption of this regulation shall comply with the facility floor space standards defined in "Subsection D of Section 9" by December 31, 2002. When these pharmacies change ownership, remodel the pharmacy or relocate the pharmacy after the effective date of this regulation, "Subsection D of Section 9" shall apply. All other portions of this regulation apply on the effective date.~~] **[RESERVED]**

[8/16/1999; 16.19.7.16 NMAC - Rn, 16 NMAC 19.7.16, 3/30/2002; Repealed, 6/9/2019]

16.19.7.17 INPATIENT HOSPITAL PHARMACY LIMITED DISPENSING, HOSPITALIZATION DISCHARGE:

A. In order to improve continuity of care by avoiding temporary disruption in a patient's prescribed medication regimen upon discharge from hospitalization, and to decrease medication waste (as in the case of a partially used multidose container, such as an inhaler), dispensing by a pharmacist in a hospital pharmacy not otherwise licensed as a retail pharmacy may occur under the conditions of this section.

B. A prescription or order is issued by a licensed practitioner of the hospital to be dispensed to the patient upon discharge. If not specified in the prescription or order, the pharmacist is responsible for obtaining and documenting any additional information needed for dispensing, including directions for use and quantity. The prescription or order may not be refilled, or transferred.

C. Naloxone for rescue use may be dispensed to the patient upon discharge pursuant to standing order, in accordance with Section 24-23-1 NMSA 1978.

D. The medication is not a controlled substance.

E. The dispensing label shall include all information as required in Paragraph (4) of Subsection (L) of 16.19.7.11 NMAC, and any other information required by state or federal law.

F. Responsibilities of pharmacist and pharmacist intern shall be fulfilled in accordance with 16.19.4.16 NMAC.

(1) Patient counseling shall be in person, whenever practicable, or by telephone.

(2) If the pharmacist is absent at the time of patient discharge, the patient shall be provided written information when appropriate on side effects, interactions, and precautions concerning the drug or device

provided. Written information may be printed or electronic, consistent with patient preference.

(3) The pharmacy phone number shall be made available to patients for consultation.

G. When the drug or device is not dispensed directly to the patient or patient's agent upon discharge, the pharmacist shall require the patient or patient's agent to sign a drug receipt record listing those prescriptions received from the pharmacy.

H. Records will be readily retrievable and available for inspection for three years unless longer retention is otherwise required by board regulation; including the prescription or order, dispensing and receipt records. If records are maintained electronically, the computer shall be capable of producing a printout of prescription or order information within a 72 hour period on demand, with certification by the pharmacist 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 prescription number, if applicable;

(2) the prescriber's name and license classification;

(3) full name and address of patient;

(4) date of issuance of prescription or order and the date filled;

(5) name, strength, dosage form, quantity dispensed;

(6) 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.

[16.19.7 NMAC - N, 6/9/2019]