This is an amendment to 16.19.7 NMAC, Section 8, 9, 10, 11, 12, 13 and 15 effective xx/xx/2025

Explanatory paragraph: Sections 1, 2, 3, 4, 6, 7, 14, 16 and 17 were not published as there are no changes

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 7 HOSPITAL PHARMACIES

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16.19.7.8 LEADERSHIP:

A. There shall be a pharmacist-in-charge of the hospital pharmacy. The pharmacist-in-charge may be employed part-time or full-time as the activity of service requires. When services are provided on a part-time basis, the pharmacist-in-charge or designated pharmacist shall visit the facility at least every 72 hours. Visitation schedules exceeding 72 hours must request Board approval.

B. The pharmacist-in-charge shall be assisted by an adequate number of competent and qualified personnel, which number shall be determined by the pharmacist-in-charge.

C. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

D. A pharmacy policy and procedure manual shall be prepared by the pharmacist-in-charge and readily available. The manual shall be reviewed annually for the purpose of establishing its consistency with current hospital practices and the process documented. A copy of this manual shall be submitted to the Board or its agent for review and approval at the time of the hospital license application. ~~Any subsequent changes shall be reviewed by the Board or its agent.~~

[8/16/1999; 16.19.7.8 NMAC - Rn, 16 NMAC 19.7.8, 3/30/2002; A, 4/30/2003; A, xx/xx/2025]

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 Subparagraph (b) of Paragraph (2) of Subsection (B) of 16.19.7.9 NMAC (record).~~

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

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

~~(f)~~ (e) 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)~~ (f) 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)~~ (g) 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 16.19.36 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. 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~~ initial license application will be accompanied by ~~photos and a drawing~~ blueprints of the pharmacy area. The board may ask for more detailed information, including photos, 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 or pharmacist intern (and no other individuals) may be present in the pharmacy when the pharmacist is not in the facility, the pharmacy technician may only ~~to~~ perform clerical tasks. Pharmacist interns may only perform clerical tasks or drug regimen reviews. A written log shall be maintained of technician and intern activities while alone in the pharmacy.

[8/16/1999; 16.19.7.9 NMAC - Rn, 16 NMAC 19.7.9, 3/30/2002; A, 4/30/2003; A, 1/31/2007; A, 06/9/2019; A, xx/xx/2025]

16.19.7.10 PHARMACY SERVICE UNIT:

A. A pharmacy service unit:

(1) is a separate entity from the central hospital pharmacy, within the same physical building;

(2) provides limited and/or specialized inpatient pharmacy services with a minimum of 100 square feet (not including space for sterile compounding);

(3) has the necessary space, references and equipment to perform the pharmacy service to be provided.

B. If controlled substances are stored in and/or dispensed from the Pharmacy Service Unit, a locked storage space must be provided and used to store all controlled substances.

C. The Pharmacy Service Unit shall be covered by the hospital pharmacy license.

D. A pharmacist shall be available to the Pharmacy Service Unit during operational hours.

E. A pharmacist shall control access to the Pharmacy Service Unit. Pharmacy technician(s) or intern(s) may be present in the Pharmacy Service Unit during operational hours when the pharmacist is present in the facility.

F. The addition of a Pharmacy Service Unit in a hospital will require submission of plans for remodeling/relocation to the board office for approval and inspection prior to authorization.

[8/16/1999; 16.19.7.10 NMAC - Rn, 16 NMAC 19.7.10, 3/30/2002; A, xx/xx/2025]

16.19.7.11 DRUG DISTRIBUTION AND CONTROL:

A. In hospitals where there is not a pharmacy, prelabeled, 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~~ patients shall be maintained and used. The medication profile shall serve as the distribution record for ~~in~~patient medications. Dangerous drug distribution records, for ~~in~~patient 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~~ III-V 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~~ including 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, 16.19.36 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~~ ensure 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 or designee. Proper identification and access control, including electronic passwords or other coded identification, must be limited and authorized by the pharmacist-in-charge or designee. The pharmacist-in-charge must ~~be able~~ have a mechanism to stop or change access at any time. The pharmacist-in-charge must ~~maintain a current and retrievable~~ be able to retrieve a current 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 outlines the services provided and 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 will be kept. ~~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, 06/9/2019; A, xx/xx/2025]

16.19.7.12 DRUG INFORMATION:

A. The pharmacist-in-charge is responsible for provision of drug information to the staff and patients of the healthcare facility. The pharmacist-in-charge shall be responsible for providing in-service education to the facility's professional staff. In-service activities shall be documented.

B. The pharmacist-in-charge is responsible for maintaining up-to-date reference materials or electronic access to reference publications commensurate with the scope of practice. The hospital pharmacy shall also have access to the current New Mexico Pharmacy Laws, Rules and Regulations. ~~At a minimum, these references will include the current editions of:~~

~~**(1)** a drug interactions text;~~

~~**(2)** an injectable drug text;~~

~~**(3)** a general drug information text; and~~

~~**(4)** New Mexico Pharmacy Law and Rules and Regulations and all available revisions.~~

C. The telephone number of a regional Poison and Drug Information Center shall be posted in all areas where medications are stored.

[8/16/1999; 16.19.7.12 NMAC - Rn, 16 NMAC 19.7.12, 3/30/2002; A, xx/xx/2025]

16.19.7.13 ASSURING RATIONAL DRUG THERAPY:

A. The pharmacist in conjunction with practitioners, nurses and other professional staff shall develop a procedure for the review and reporting of significant adverse drug reactions and medication errors. These events shall be reported to the prescribing practitioner and the appropriate hospital quality assurance committee such as the Pharmacy and Therapeutics Committee or its equivalent.

B. Clinical information about patients must be available and accessible to the pharmacist for use in daily practice activities.

C. The pharmacist shall review each medication order for safety and appropriateness and communicate with the prescriber when adjustments may be necessary. Suggested changes made to the prescriber must be documented.

D. A documented medication-use-measurement program, ~~developed~~ shall be in place to evaluate the medication-use-process ~~of~~ including prescribing, dispensing, administering and monitoring.

[8/16/1999; 16.19.7.13 NMAC - Rn, 16 NMAC 19.7.13, 3/30/2002; A, xx/xx/2025]

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16.19.7.15 IN-HOUSE CLINICS: In-house clinics owned and operated by the institution must meet regulations set forth in Part 10 "Limited Drug Clinics" and Part 4 "Pharmacists". The clinic may operate under the license of the hospital pharmacy and is not required to obtain a separate license or permit from the Board. The addition of an in-house clinic will require submission of plans for remodeling/relocation to the board office for approval and inspection prior to authorization.

[8/16/1999; 16.19.7.15 NMAC - Rn, 16 NMAC 19.7.15, 3/30/2002; A, xx/xx/2025]

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