## This is an amendment to 16.19.7 NMAC Sections 8 and 9, effective 04-30-2003.

## 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. <u>Visitation</u> 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.

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.

[08-16-99; 16.19.7.8 NMAC - Rn, 16 NMAC 19.7.8, 03-30-02; A, 04-30-03]

## **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 [a] <u>one</u> designated licensed nurse <u>per shift</u> may remove drugs from the pharmacy. The quantity of drugs [is limited to meet immediate therapeutic needs]. <u>shall not exceed the quantity needed to</u> <u>last until the pharmacist is in the facility:</u>

(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 (record).

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

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

[(e)] (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. <u>Verification may be accomplished electronically</u> from a remote site, if approved by the Board.

[(f)](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.

(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.

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**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:

Beds including Skilled	<del>1 - 50</del>	<del>51 - 100</del>	<del>101-200</del>	<del>201 - 500</del>	<u>&gt; 500</u>
Nursing Facility					
Minimum Square Feet	<del>280</del>	<del>500</del>	<del>750</del>	<del>1000</del>	<del>1500</del>
Min. Sq. Ft. Pharmacy	<del>380</del>	<del>600</del>	<del>850</del>	<del>1100</del>	<del>1600</del>
Compounding Sterile					
<b>Pharmaceuticals</b>					

Average daily census including skilled beds	<u>Specialty</u> <u>designatio</u> <u>n</u>	<u>1-25</u>	<u>26-</u> <u>50</u>	<u>51-</u> <u>100</u>	<u>101-</u> 200	<u>201-</u> <u>500</u>	<u>&gt;50</u> <u>0</u>
Minimum Square Feet	<u>Adequate</u>	<u>Adequat</u> <u>e</u>	<u>280</u>	<u>500</u>	<u>750</u>	<u>1000</u>	<u>1500</u>
Min. Sq. Ft. for Sterile Prep Area (in addition to above)	<u>100</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>100</u>	<u>100</u>

A hospital may petition the Board for a variance to the required minimum square footage. [The Board may approve or deny the petition at the Board's discretion. The Board may consider the following:

(1) size and scope of pharmacy services to be provided;

(2) size and type of patient population;

(3) number and types of drugs stored and dispensed from the pharmacy; and

(4) impact on the health and welfare of the institution's patients.]

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.

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

**[F]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 the technician activities while alone in the pharmacy.

[08-16-99; 16.19.7.9 NMAC - Rn, 16 NMAC 19.7.9, 03-30-02; A, 04-30-03]