TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 17 DANGEROUS DRUGS AND DANGEROUS DRUG RESEARCH

16.19.17.1 ISSUING AGENCY: Regulation and Licensing Department, Board of Pharmacy.
[02-15-1989...02-15-96; 16.19.17.1 NMAC - Rn, 16 NMAC 19.17.1, 03-30-02; A, 09-15-06]

16.19.17.2 SCOPE: All individuals or entities who sell, dispose of or possess any dangerous drug, including institutions of higher education, private organizations, or other applicants who do not possess a pharmacy license, and are not subject to licensure with any professional licensing board or the New Mexico department of health.
[02-15-96; 16.19.17.2 NMAC - Rn, 16 NMAC 19.17.2, 03-30-02; A, 09-15-06]

16.19.17.3 STATUTORY AUTHORITY: Chapter 26, Article 1 of the New Mexico Drug, Device and Cosmetic Act, Section 26-1-18 NMSA 1978, authorizes the board of pharmacy to promulgate regulations for the efficient enforcement of the act and to declare, by regulation, a substance a dangerous drug. Paragraph (6) of Subsection A of Section 61-11-6 NMSA 1978 authorizes the board to provide for the licensing of all places where dangerous drugs are stored, distributed, dispensed or administered and provide for the inspection of the facilities and activities. Paragraph (2) of Subsection A of Section 26-1-16 NMSA 1978 authorizes the board to license any person to sell, dispose of or possess any dangerous drug. Appropriate records of receipt and disposition must be kept.
[02-15-96; 16.19.17.3 NMAC - Rn, 16 NMAC 19.17.3, 03-30-02; A, 09-15-06]

16.19.17.4 DURATION: Permanent.
[02-15-96; 16.19.17.4 NMAC - Rn, 16 NMAC 19.17.4, 03-30-02]

16.19.17.5 EFFECTIVE DATE: February 15, 1996, unless a later date is cited at the end of a section.
[02-15-96; A, 04-30-98; 16.19.17.5 NMAC - Rn, 16 NMAC 19.17.5, 03-30-02; A, 07-15-2004]

16.19.17.6 OBJECTIVE: The objective of Part 17 of Chapter 19 is to provide notice of the board's designation of particular substances as dangerous drugs and for the licensure of dangerous drug researchers. A dangerous drug researcher will be allowed to possess dangerous drugs for the purpose of conducting research, including demonstrations or special projects, after receiving approval from the board.
[02-15-96; 16.19.17.6 NMAC - Rn, 16 NMAC 19.17.6, 03-30-02; A, 09-15-06]

16.19.17.7 DEFINITIONS:

A. "Board" means the New Mexico board of pharmacy.

B. "Dangerous Drug" as defined in the New Mexico Drug, Device and Cosmetic Act, Subsection F of Section 26-1-2 NMSA 1978.

(1) The following substance(s) has(have) been declared by the N.M. board of pharmacy as "Dangerous Drugs" in accordance with Section 26-1-18 NMSA 1978 of the Drug, Device and Cosmetic Act, Section 26-1-18 NMSA 1978 and the Uniform Licensing Act (Sections 61-1-1 to 61-1-31 NMSA 1978). The board of pharmacy shall by regulation declare a substance a "dangerous drug" when necessary and notification shall be sent to all registered pharmacies in the state within 60 days of the adoption of the regulation. Ephedrine, USP, as ephedrine hydrochloride or ephedrine sulfate or as any other salt form. Any compound, mixture, or preparation containing one-half percent or less of ephedrine or of any salt form of ephedrine is exempt from the above. These products are exempt because they are approved for sale over the counter (OTC) without a prescription under federal law, are labeled and marketed in a manner consistent with the pertinent OTC tentative final or final monograph, are manufactured and distributed for legitimate medical use in a manner that reduces or eliminates the likelihood for abuse, and are not marketed, advertised or labeled for an indication of stimulation, mental alertness, energy, weight loss, appetite control, or muscle enhancement. These approved OTC products shall be reported as required of a pseudoephedrine containing product as defined in Subsection B of 16.19.20.53 NMAC.

(2) A dangerous drug shall be dispensed only upon the prescription of a practitioner licensed by law to administer or prescribe such drug.

C. "Drug storage area" means the area restricted to the storage, dispensing and distribution of dangerous drugs.

D. "Research protocol" is the written documentation stating the objective, method, means of measurement, and utilization procedure of the dangerous drug.

[04-19-92; 16.19.17.7 NMAC - Rn, 16 NMAC 19.17.7, 03-30-02; A, 07-15-2004; A, 09-15-06; A, 11-28-17]

16.19.17.8 RESEARCH LICENSING REQUIREMENTS:

A. Authorized persons to be licensed: public agencies, institutions of higher education and private organizations, or individuals for the purpose of conducting research, demonstration or special projects with the use of a dangerous drug.

B. The person applying for licensure must fill out a license for dangerous drug research application prior to purchasing any dangerous drug. The applicant must provide information pertinent to the research including:

(1) name, address, and date of birth of persons who will be involved in handling of dangerous drugs, and if they have been convicted of a felony:

(2) drug protocol:

(a) formulary of dangerous drugs for research;

(b) how will the dangerous drug be utilized;

(c) how much of the dangerous drug will be used for each administered dose or experiment;

(d) how much drug will be purchased annually.

(3) policy and procedure manual including:

(a) drug security: storage area, list of individuals with access to dangerous drugs;

(b) drug procurement: invoices, receipts, and drug sources;

(c) drug usage: records or logs for accountability;

(d) drug waste/destruction: memorandum report describing accountability;

(e) drug storage area;

(f) research protocol: proprietary or trade secrets are confidential and not subject to public disclosure;

(4) qualifications of the applicant to conduct such research with dangerous drugs which may include:

(a) degrees;

(b) higher education;

(c) specialized training.

C. The board will review all applicants for licensure for consistency with the public's best interest.

[16.19.17.8 NMAC - N, 09-15-06; A, 11-28-17]

HISTORY OF 16.19.17 NMAC:

Pre-NMAC History: The material in this part was derived from that previously filed with the state records center and archives:

Regulation No. 17, Dangerous Drugs, filed 3-19-92.

History of Repealed Material: [RESERVED]

Other History:

Regulation No. 17, Dangerous Drugs (filed 3-19-92) renumbered, reformatted and replaced by 16 NMAC 19.17, Pharmacists - Dangerous Drugs, effective 02-15-96.

16 NMAC 19.17, Pharmacists - Dangerous Drugs (filed 02-02-96) renumbered and replaced by 16.19.17 NMAC, Dangerous Drugs, effective 03-30-2002.