TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 21 DRUG PRECURSORS

16.19.21.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM.
[02-14-1889...02-15-96; 16.19.21.1 NMAC - Rn, 16 NMAC 19.21.1, 03-30-02; A, 01-15-2005]

16.19.21.2 SCOPE: All individuals and entities that manufacture, possess, transfer, or transport drug precursors.
[02-15-96; 16.19.21.2 NMAC - Rn, 16 NMAC 19.21.2, 03-30-02]

16.19.21.3 STATUTORY AUTHORITY: Pursuant to 30-31B-6 of the Drug Precursor Act, 30-31B-1 through 30-31-B-18 NMSA 1978, the Board of Pharmacy may promulgate regulations and charge reasonable fees relating to the licensing and control of the manufacture, possession, transfer and transportation of drug precursors. Section 30-31B-4 NMSA 1978 authorizes the Board to add substances to the list of precursors enumerated in the Drug Precursor Act.
[02-15-96; 16.19.21.3 NMAC - Rn, 16 NMAC 19.21.3, 03-30-02]

16.19.21.4 DURATION: Permanent.
[02-15-96; 16.19.21.4 NMAC - Rn, 16 NMAC 19.21.4, 03-30-02]

16.19.21.5 EFFECTIVE DATE: February 15, 1996, unless a different date is cited at the end of a Section or Paragraph. This Part reformatted for inclusion into the New Mexico Administrative Code (NMAC) effective 2-15-96.
[02-15-96, A, 04-30-98; 16.19.21.5 NMAC - Rn, 16 NMAC 19.21.5, 03-30-02]

16.19.21.6 OBJECTIVE: The objective of Part 21 of Chapter 19 is to protect the public health and welfare of the citizens of New Mexico by establishing effective controls against unlawful diversion of drug precursors.
[02-15-96; 16.19.21.6 NMAC - Rn, 16 NMAC 19.21.6, 03-30-02]

16.19.21.7 DEFINITIONS: [RESERVED]
[02-15-96; 16.19.21.7 NMAC - Rn, 16 NMAC 19.21.7, 03-30-02]

16.19.21.8 PERSONS REQUIRED TO REGISTER:

A. The board shall license an applicant to manufacture, possess, transfer or transport drug precursors unless it determines that the issuance of that license would be inconsistent with the public interest. In determining the public interest, the board may consider the following factors:

(1) maintenance of effective controls against diversion of drug precursors into other than legitimate medical, scientific or industrial channels;

(2) compliance with applicable state and local law;

(3) any conviction of the applicant under federal or state laws relating to any controlled substance or drug precursor;

(4) past experience in the manufacturer, possession, transfer or transportation of drug precursors and the existence in the applicant's establishment of effective controls against diversion;

(5) furnishing by the applicant of false or fraudulent material in any application filed under the Drug Precursor Act or the Controlled Substances Act;

(6) suspension or revocation of the applicant's federal registration to manufacture, distribute or dispense controlled substances or drug precursors as authorized by federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

B. Licensing under this section does not entitle a licensee to manufacture, possess, transfer or transport drug precursors other than those allowed in the license.
[03-07-80...08-27-90; 16.19.21.8 NMAC - Rn, 16 NMAC 19.21.8, 03-30-02; A, 01-15-2005; A, 01-31-07]

16.19.21.9 REGISTRATION AND EXPIRATION DATE:

A. Any person who is required to be registered under this part and who is not registered may apply for registration at any time.

B. The license for persons required to register under this part shall be renewed bi-ennially before the last day of December.

[03-07-80...08-27-90; 16.19.21.9 NMAC - Rn, 16 NMAC 19.21.9, 03-30-02; A, 01-15-2005]

16.19.21.10 REGISTRATION FEE: The registration fee or annual renewal fee required by the Drug Precursor Act shall be$250.00 per year for a wholesaler, manufacturer, or distributor.

[03-07-80...08-27-90; 16.19.21.10 NMAC - Rn, 16 NMAC 19.21.10, 03-30-02; A, 01-15-2005; A, 01-31-07]

16.19.21.11 APPLICATION FORMS: Application forms may be obtained from the Board of Pharmacy.

[03-07-80...08-27-90; 16.19.21.11 NMAC - Rn, 16 NMAC 19.21.11, 03-30-02]

16.19.21.12 SEPARATE REGISTRATION OF EACH PRINCIPLE PLACE OF BUSINESS: Separate registration is required for each principle place of business or professional practice with the address indicated on the application if precursors are distributed from the different locations.

[03-07-80...08-27-90; 16.19.21.12 NMAC - Rn, 16 NMAC 19.21.12, 03-30-02]

16.19.21.13 INFORMATION REQUIRED: Each application shall include all information as required on the application form and shall be signed by the applicant.

[03-07-80...08-27-90; 16.19.21.13 NMAC - Rn, 16 NMAC 19.21.13, 03-30-02]

16.19.21.14 FACILITY INSPECTION: The board of pharmacy may direct the drug inspector to inspect the facilities prior to approval of any registration application filed under this part of any wholesaler, manufacturer, or distributor, for security provisions and other applicable standards as required by the Drug Precursor Act or regulations passed by the board. A fee of $150.00 must be submitted before such inspection of any wholesaler, manufacturer, or distributor.

[03-07-80...08-27-90; 16.19.21.14 NMAC - Rn, 16 NMAC 19.21.14, 03-30-02; A, 01-15-2005]

16.19.21.15 PROCEDURE SUMMARY: A scientific investigator or research applicant shall submit a summary of procedures indicating the nature, extent and duration of such research. This summary shall include, but is not limited to, the names of individuals engaged in the project, the name or names of the precursor substances to be used, safeguards to be used against diversion, the source of supply of substances, record keeping and forms to be used in receipt, use, and destruction of precursor substances.

[03-07-80...08-27-90; 16.19.21.15 NMAC - Rn, 16 NMAC 19.21.15, 03-30-02]

16.19.21.16 ANALYTICAL LABORATORIES:

A. Analytical laboratory applicants shall submit application on the form provided by the Board. All applicable questions on the application shall be filled in and signed by the person in charge of the facility.

B. Quantities of drug precursors in possession of analytical laboratories shall be limited to such quantities as required for reference standards, assays, or other analytical scientific purposes.

[03-07-80...08-27-90; 16.19.21.16 NMAC - Rn, 16 NMAC 19.21.16, 03-30-02]

16.19.21.17 EXEMPTION OF LAW ENFORCEMENT OFFICIALS: Registration is waived for the following persons:

A. Any officer or employee of the state or federal customs agency, the state police, or any enforcement officer of any political subdivision of the state, who is engaged in the enforcement of federal, state and local law relating to drug precursors and is duly authorized to possess drug precursors in the course of his official duties.

B. Any official exempted by this section may procure any drug precursor in the course of an inspection pursuant to any section of the Drug Precursor Act or in the course of any criminal investigation involving the person from whom the substance was procured.

C. Laboratory personnel, when acting in the scope of his official duties, are also exempt from registration under the Drug Precursor Act.

[03-07-80...08-27-90; 16.19.21.18 NMAC - Rn, 16 NMAC 19.21.18, 03-30-02]

16.19.21.18 TRANSFER AND TERMINATION OF REGISTRATION:

A. Registration shall terminate if and when a registrant dies, discontinues business or professional practice, has his professional license revoked or suspended, or changes his name or address as shown on the registration. In such instance, the registrant or his estate shall notify the Board of Pharmacy promptly of such fact and return certificate of registration to the Board.

B. Inventories and records of drug precursors shall be maintained separately from all other records or in such form that the information is readily retrievable from ordinary business records of the registrant.

C. In the event of a change in name or address, the registrant shall file an application in the same manner as an application for a new registration. No fee shall be required for such modification.

D. Registration under the Drug Precursor Act is not transferable.

[03-07-80...08-27-90; 16.19.21.18 NMAC - Rn, 16 NMAC 19.21.18, 03-30-02]

16.19.21.19 INVENTORY RECORDS: All registrants are required to keep procurement records in a readily retrievable manner for 3 years.

[03-07-80...08-27-90; 16.19.21.19 NMAC - Rn, 16 NMAC 19.21.19, 03-30-02; A, 01-15-2005]

16.19.21.20 ORDER FORMS (INVOICES) AS RECORDS: Order forms (invoices) for drug precursors shall be deemed proper records of receipt if the purchaser records on their copy the number of commercial or bulk containers furnished of each item, the date received and the name of person receiving the order.

[03-07-80...08-27-90; 16.19.21.20 NMAC - Rn, 16 NMAC 19.21.20, 03-30-02]

16.19.21.21 PROCUREMENT RECORDS: Procurement records, and all other records, must be kept at the registered location and must be available for inspection.

[03-07-80...08-27-90; 16.19.21.21 NMAC - Rn, 16 NMAC 19.21.21, 03-30-02]

16.19.21.22 REPORT OF LOSS OR THEFT OF A DRUG PRECURSOR: A significant loss or theft of a drug precursor shall be reported in writing to the Board of Pharmacy. "Significant loss" includes suspected diversions, in-transit losses or any other unexplained loss.

[03-07-80...08-27-90; 16.19.21.22 NMAC - Rn, 16 NMAC 19.21.22, 03-30-02]

16.19.21.23 DISTRIBUTION RECORDS: All wholesaler, manufacturer, or distributor registrants shall include the following in distribution records for drug precursors under this part:

A. purchaser's name, address and telephone number, and drug precursor registration number or other license number issued by the board in lieu of a drug precursor registration number;

B. quantity purchased;

C. date supplied;

D. suppliers name, address, telephone number, and drug precursor registration number or other license number issued by the board in lieu of a drug precursor registration number;

E. distribution records must be retained for three (3) years.

[03-07-80...08-27-90; 16.19.21.23 NMAC - Rn, 16 NMAC 19.21.23, 03-30-02; A, 01-15-2005; A, 09-30-2005; A, 01-31-07]

16.19.21.24 DISPOSITION OF DAMAGED, OUTDATED, OR UNWANTED DRUG PRECURSORS: Any registrant in possession of any drug precursor and desiring to dispose of such substance must abide by any applicable federal, state, local law or regulation for the destruction of such substance. This destruction must be witnessed by at least one law enforcement officer certified in the State of New Mexico. Appropriate records must be kept of the destruction.

[03-07-80...08-27-90; 16.19.21.24 NMAC - Rn, 16 NMAC 19.21.24, 03-30-02]

16.19.21.25 DISTRIBUTION UPON TRANSFER OR DISCONTINUANCE OF BUSINESS:

A. Upon transfer of a business from one owner to another, the owner may dispose of the drug precursors in the following manner:

(1) have the drug precursor destroyed as discussed in 16.19.21.24 NMAC;

(2) transfer the drug precursors to the new owner. All records required to be kept by the registrant-transferor with reference to the drug precursors being transferred shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

B. Upon discontinuance of business, if there are drug precursors which are not transferred to another registrant, these substances shall be handled as unwanted drug precursors under 16.19.21.24 NMAC.

[03-07-80...08-27-90; 16.19.21.25 NMAC - Rn, 16 NMAC 19.21.25, 03-30-02]

16.19.21.26 SECURITY REQUIREMENTS:

A. All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of drug precursors.

B. In evaluating the overall security system of a registrant or applicant, the following factors may be considered:

(1) the type of activity;

(2) the quantity of drug precursors;

(3) the location of premises and the relationship such location plays on security needs;

(4) the type of building construction of the facility and the general characteristic of the building;

(5) the adequacy of key control systems and/or lock control systems;

(6) the extent of unsupervised public access to the facility;

(7) the adequacy of supervision over employees having access to storage and distribution areas;

(8) the process for handling business guests, visitors, maintenance personnel, and non-employee service personnel;

(9) the adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of drug precursors in its' operation.

[03-07-80...08-27-90; 16.19.21.26 NMAC - Rn, 16 NMAC 19.21.26, 03-30-02]

16.19.21.27 HEARINGS, DENIAL OF REGISTRATION, REVOCATION OR SUSPENSION OF REGISTRATION: Proceedings to suspend or revoke a registration or to refuse renewal of a registration shall be held pursuant to the Uniform Licensing Act.

[03-07-80...08-27-90; 16.19.21.27 NMAC - Rn, 16 NMAC 19.21.27, 03-30-02]

16.19.21.28 ADMINISTRATIVE INSPECTION - DEFINED: Administrative inspection means: the inspection of any place where registrants are permitted to hold, manufacture, compound, process, sell, deliver, transport, or otherwise dispose of any drug precursors. When authorized by an administrative inspection warrant, the inspector may:

A. inspect and copy records required by the Drug Precursor Act;

B. inspect the restricted area and all pertinent equipment, all containers, substances, and labeling found at the controlled area;

C. make a physical inventory of the specific items or all drug precursors on hand at the premises;

D. collect samples, if applicable;

E. check records and information of distribution of substances by the registrant as they relate to total distribution;

F. examination of records, invoices, appropriate for verification of the records or otherwise bearing on the provisions of the Drug Precursor Act.

[03-07-80...08-27-90; 16.19.21.28 NMAC - Rn, 16 NMAC 19.21.28, 03-30-02]

16.19.21.29 VOLUNTARY CONSENT TO INSPECTION: The Board inspector will ask the registrant to voluntarily consent to the inspection. He will inform the registrant of his constitutional rights to an inspection warrant. However, if the registrant consents to inspection without warrant, the inspector will obtain a signed consent waiver statement from the registrant before proceeding with an accountability audit or inspection.

[03-07-80...08-27-90; 16.19.21.29 NMAC - Rn, 16 NMAC 19.21.29, 03-30-02]

16.19.21.30 WRITTEN CONSENT:

A. The written consent shall contain the following information:

(1) that the owner, or agent in charge of the premises has been informed of his constitutional rights not to have an administrative inspection made without an administrative inspection warrant;

(2) of his right to refuse to consent to such an inspection;

(3) of the possibility that anything of an incriminating nature which may be found may be seized and used against him in a Board hearing or a criminal prosecution;

(4) that he had been presented with a notice of inspection;

(5) that the consent given by him is voluntary and without threats of any kind; and

(6) that he may withdraw his consent at any time during the course of inspection.

B. Written consent shall be produced in duplicate and one copy shall be retained by the person being inspected and one copy shall be retained by the inspector for filing in the Board office.

[03-07-80...08-27-90; 16.19.21.30 NMAC - Rn, 16 NMAC 19.21.30, 03-30-02]

16.19.21.31 ADMINISTRATIVE WARRANT:

A. A copy of the administrative warrant need not be given to the registrant unless items are seized or confiscated.

B. To serve the warrant, all that is required, is to announce possession of it, the contents of the warrant need not e stated to the person upon whom the warrant is served.

[03-07-80...08-27-90; 16.19.21.31 NMAC - Rn, 16 NMAC 19.21.31, 03-30-02]

16.19.21.32 CONSENT: Unless the person in charge of the premises so consents in writing, these regulations shall not extend to financial data; pricing data; or sales data other than shipping dates.

[03-07-80...08-27-90; 16.19.21.32 NMAC - Rn, 16 NMAC 19.21.32, 03-30-02]

16.19.21.33 ADMINISTRATIVE WARRANT - NOT REQUIRED: An administrative warrant shall not be required for a new facility applying for initial registration under the Drug Precursor Act, or in any situation where a warrant is not constitutionally required.

[03-07-80...08-27-90; 16.19.21.33 NMAC - Rn, 16 NMAC 19.21.33, 03-30-02]

16.19.21.34 ADMINISTRATIVE WARRANT - REFUSAL: If a registrant or any person subject to the Drug Precursor Act refuses to permit execution of an administrative warrant or impedes the inspection in the execution of that warrant, he shall be advised that such refusal or action constitutes a violation of the Drug Precursor Act.

[03-07-80...08-27-90; 16.19.21.34 NMAC - Rn, 16 NMAC 19.21.34, 03-30-02]

16.19.21.35 CONTROLLED SUBSTANCE PRECURSORS: The following substances are designated as immediate precursors used in the manufacture of controlled substances:

A. phenyl acetone;
B. ephedrine;
C. phenyl-2-propanone;
D. norephedrine;
E. ethyl-1-methyl butyl diethyl malonate;
F. allyl-1-methyl butyl diethyl malonate;
G. hydroxyindole;
H. 3,4,5-trimethoxybenzyl cyanide;
I. 3,4,5-trimethoxybenzyl alcohol;
J. 3,4,5-trimethoxyphenylacetonitraile;
K. 3,4,5-trimethoxybenzoic acid amide;
L. 4-benzyloxyindole;
M. 4-chloro indole;
N. indole;
O. tryntophol;
P. 3-indole glyoxylic acid;
Q. 3-indole glyoxylic acid ethyl ester;
R. lysergic acid;
S. lysergic acid amide;

T. ergotamine tartrate;
U. 1-phenyl cyclohexylamine;
V. 1-piperidinocyclohexanecarbonitrile;
W. pseudoephedrine as a substance in a form not approved in 26-1-14 NMSA;
X. methylamine;
Y. methylformamide
Z. phenylacetic acid;
AA. anhydrous ammonia:
(1) a person shall not possess any amount of anhydrous ammonia;
(2) a person must store anhydrous ammonia in a container approved for the transport of anhydrous ammonia;
(3) the provisions of this section do not apply to a:
(a) person who is actively operating land used for agricultural purposes;
(b) retail distributor;
(c) wholesaler;
(d) manufacturer;
(e) warehouseman;
(f) common carrier; or
(g) person engaged in the regular course of conducting a lawful business;
BB. red phosphorous;
CC. iodine matrix, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine matrix in a single transaction;
DD. crystal iodine, a retail distributor registrant, pharmacy, hospital, clinic may not sell more than 2 ounces of iodine crystals in a single transaction.

[03-07-80…08-27-90; 16.19.21.35 NMAC - Rn, 16 NMAC 19.21.35, 03-30-02; A, 12-01-03; A, 01-15-2005; A, 01-31-07

HISTORY OF 16.19.21 NMAC:

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History of Repealed Material: [RESERVED]

Other History: 16 NMAC 19.21, Pharmacists - Drug Precursors, filed 02-02-96, reformatted and renumbered to 16.19.21 NMAC, Drug Precursors, effective 03-30-2002.