

TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 20 CONTROLLED SUBSTANCES

16.19.20.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, Albuquerque, NM.

[16.19.20.1 NMAC - Rp 16 NMAC 19.20.1, 07-15-02; A, 12-15-02; A, 03-07-11]

16.19.20.2 SCOPE: All persons or entities that manufacture, distribute, dispense, administer, prescribe, deliver, analyze, or conduct research using controlled substances.

[16.19.20.2 NMAC - Rp 16 NMAC 19.20.2, 07-15-02]

16.19.20.3 STATUTORY AUTHORITY: Section 30-31-11 of the Controlled Substances Act, "30-31-1 through 30-31-42 NMSA 1978, authorizes the Board of Pharmacy to promulgate regulations and charge reasonable fees for the registration and control of the manufacture, distribution and dispensing of controlled substances.

[16.19.20.3 NMAC - Rp 16 NMAC 19.20.3, 07-15-02]

16.19.20.4 DURATION: Permanent.

[16.19.20.4 NMAC - Rp 16 NMAC 19.20.4, 07-15-02]

16.19.20.5 EFFECTIVE DATE: July 15, 2002, unless a different date is cited at the end of a Section.

[16.19.20.5 NMAC - Rp 16 NMAC 19.20.5, 07-15-02]

16.19.20.6 OBJECTIVE: The objective of Part 20 of Chapter 19 is to protect the public health and welfare of the citizens of New Mexico by controlling and monitoring access to controlled substances and to give notice of the Board's designation of particular substances as controlled substances.

[16.19.20.6 NMAC - Rp 16 NMAC 19.20.6, 07-15-02]

16.19.20.7 DEFINITIONS: (Reserved)

[16.19.20.7 NMAC - Rp 16 NMAC 19.20.7, 07-15-02]

16.19.20.8 REGISTRATION REQUIREMENTS: Persons required to register:

A. manufacture - term includes repackagers;
B. distributors - term includes wholesale drug distributors;
C. dispensers - pharmacies, hospital pharmacies, clinics (both health and veterinarian);
D. practitioners - includes a physician, doctor of oriental medicine, dentist, physician assistant, certified nurse practitioner, clinical nurse specialist, certified nurse-midwife, veterinarian, pharmacist, pharmacist clinician, certified registered nurse anesthetists, psychologists, chiropractic examiner, euthanasia technicians or other person licensed or certified to prescribe and administer drugs that are subject to the Controlled Substances Act;

(1) Practitioners must register with the new mexico prescription monitoring program in conjunction with their controlled substance registration.

E. scientific investigators or researchers;
F. analytical laboratories and chemical analysis laboratories;
G. teaching institutes;
H. special projects and demonstrations which bear directly on misuse or abuse of controlled substances - may include public agencies, institutions of higher education and private organizations;
I. registration waiver: an individual licensed practitioner (e.g., intern, resident, staff physician, mid-level practitioner) who is an agent or employee of a hospital or clinic, licensed by the board, may, when acting in the usual course of employment or business, order controlled substances, for administration to the patients of the facility, under controlled substance registration of the hospital or clinic in which he or she is employed provided that:

(1) the ordering of controlled substances for administration, to the patients of the hospital or clinic, is in the usual course of professional practice and the hospital or clinic authorizes the practitioner to order controlled substances for the administration to its patients under its state controlled substance registration;

(2) the hospital or clinic has verified with the practitioner's licensing board that the practitioner is permitted to order controlled substances within the state;

- (3) the practitioner acts only within their scope of employment in that hospital or clinic;
 - (4) the hospital or clinic maintains a current list of practitioners given such authorization and includes the practitioner's full name, date of birth, professional classification and license number, and home and business addresses and phone numbers;
 - (5) the list is available at all times to board inspectors, the D.E.A., law enforcement and health professional licensing boards; and
 - (6) the hospital or clinic shall submit a current list of authorized practitioners with each hospital or clinic controlled substance renewal application.
- [16.19.20.8 NMAC - Rp 16 NMAC 19.20.8, 07-15-02; A, 12-15-02; A, 07-15-2004; A, 05-14-10]

16.19.20.9 REGISTRATION AND EXPIRATION DATES:

- A.** Any person who is required to be registered and who is not registered may apply for registration at any time.
- B.** In December 1982 all registrant renewal dates will be assigned to one of 12 groups which shall correspond to the months of the year. Thereafter, any person who first registers will also be assigned to one of the 12 groups.
- C.** Expiration date of the registration of all individuals or businesses within any group will be the last day of the month designated for that group. Renewal date will be within 30 days of the date shown on the registration permit and will expire on that date if not renewed by the registrant.
- D.** Renewal applications will be mailed to the address indicated on the application on file or as amended by change of address supplied by the registrant to the Board of Pharmacy.

[16.19.20.9 NMAC - Rp 16 NMAC 19.20.8(1), 07-15-02]

16.19.20.10 REGISTRATION FEE:

- A.** The registration fee or annual renewal fee required by the Controlled Substances Act shall be \$60.00 for registrants.
- B.** Research applicants registered as a practitioner shall not be required to register as a scientific investigator if he is registered as a practitioner. However, this does not exempt him from the regulations applicable to a scientific investigator.
- C.** Duplicate license - \$10.00

[16.19.20.10 NMAC - Rp 16 NMAC 19.20.9, 07-15-02]

16.19.20.11 APPLICATION FORMS: Application forms may be obtained from the Board of Pharmacy, Albuquerque, New Mexico.

[16.19.20.11 NMAC - Rp 16 NMAC 19.20.10, 07-15-02]

16.19.20.12 SCHEDULES: Applications shall designate the schedule of controlled substances and whether the application is for narcotic or non-narcotic in Schedules I through V.

[16.19.20.12 NMAC - Rp 16 NMAC 19.20.10(1), 07-15-02]

16.19.20.13 SEPARATE REGISTRATION OF EACH PRINCIPAL PLACE OF BUSINESS: Separate registration is required for each principal place of business or professional practice with the address indicated on the application if drugs are dispensed or distributed from the different locations. **NOTE:** This does not include warehouse storage areas; office used by agents for soliciting which contain no controlled substances other than samples, physicians office where controlled substances are prescribed but not administered or otherwise dispensed.

[16.19.20.13 NMAC - Rp 16 NMAC 19.20.10(2), 07-15-02]

16.19.20.14 INFORMATION REQUIRED:

- A.** The board shall register an applicant to manufacture or distribute controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board may consider the following factors from information listed on the application:
 - (1) maintenance of effective controls against diversion of controlled substances;
 - (2) compliance with applicable state and local law;
 - (3) any convictions of the applicant under any federal or state laws relating to any controlled substance;
 - (4) past experience in the manufacture or distribution of controlled substances, 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 Controlled Substances Act;

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

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

B. Each application shall include all information as required on the application form, including but not limited to a current DEA registration and/or professional license, and shall be signed by the applicant.

[16.19.20.14 NMAC - Rp 16 NMAC 19.20.10(3), 07-15-02]

16.19.20.15 FACILITY INSPECTION: The Board of Pharmacy may direct the drug inspector to inspect the facilities prior to approval of any application for security provision and other applicable standards as required by the Controlled Substances Act.

[16.19.20.15 NMAC - Rp 16 NMAC 19.20.10(4), 07-15-02]

16.19.20.16 PROCEDURE SUMMARY: A scientific investigator or research applicant shall submit a summary of procedures indicating the nature, extent and duration of such research. The summary shall also include the names of individuals engaged in the project (other than those exempt under the Controlled Substances Act) the name or names of the substances to be used in the research project, the adequacy of safeguards against diversion of the controlled substance(s) to be used, source of supply of controlled substance(s) if applicable, and evidence of FDA and DEA approval and registration if registered by the federal agencies.

[16.19.20.16 NMAC - Rp 16 NMAC 19.20.10(5), 07-15-02]

16.19.20.17 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 controlled substances in possession of analytical laboratories shall be limited to such quantities as required for reference standards, assays or other scientific purposes.

[16.19.20.17 NMAC - Rp 16 NMAC 19.20.10(6), 07-15-02]

16.19.20.18 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 any federal, state and local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

B. Any official exempted by this section may procure any controlled substance in the course of an inspection pursuant to Section 31 of the Controlled Substances 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 their official duties, are also exempt from registration under the Controlled Substances Act.

[16.19.20.18 NMAC - Rp 16 NMAC 19.20.11, 07-15-02]

16.19.20.19 MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION:

A. Modification of a registration to authorize additional controlled substances may be made by filing an application in the same number as an application for a new registration. No fee shall be required for such modification.

B. Registration shall terminate if and when a registrant dies, discontinues business or professional practice, has his professional license revoked or suspended, no longer possesses a DEA registration and/or has had his DEA registration revoked or suspended, or changes his name or address as shown on the registration. In such instances, the registrant or his estate shall notify the Board of Pharmacy promptly of such fact and return certificate of registration to the Board within 30 days.

C. Inventories and records of controlled substances listed in Schedules II, III, IV and V shall be maintained either separately from all other records or in such form that the information required is readily retrievable from ordinary business records of the registrant.

D. In the event of a change in name or address the person shall file an application in the same number as an application for modification of a registration. No fee shall be required for such modification.

E. Registration under the Controlled Substances Act shall not be transferable.
[16.19.20.19 NMAC - Rp 16 NMAC 19.20.12, 07-15-02]

16.19.20.20 INVENTORY RECORDS:

- A.** All registrants are required to keep inventory and procurement records.
- B.** All registrants shall comply with the following inventory requirements: Schedule I, II, III, IV and V Annual Inventory
- C.** The annual inventory date shall be May 1 for the initial inventory by the registrant or on the registrant's regular general physical inventory date, provided that date does not vary by more than 6 months before or after May 1. The registrant shall notify the Board of Pharmacy of the date on which the annual inventory will be taken, if different from May 1. The actual taking of the inventory should not vary more than four (4) days from the annual inventory date.
- D.** Controlled substances added to the Controlled Substances Act after date of enactment, which substance was, immediately prior to that date, not listed on any schedule, every registrant who possesses that substance shall take an inventory of all stock of the substance on hand and file this record with the other inventory records as required.
[16.19.20.20 NMAC - Rp 16 NMAC 19.20.13, 07-15-02]

16.19.20.21 INVENTORY RECORDS OF MANUFACTURERS AND REPACKAGERS: Manufacturers and repackagers inventory records shall contain the following information:

- A.** Finished form:
- (1) name of substance;
 - (2) each finished form of the substance (10 milligram tablet, etc.)
 - (3) the number of units or volume of each finished form in each commercial container (100 tablet bottle, etc.)
 - (4) the number of commercial containers of each such finished form.
- B.** Controlled substances not included above such as damaged, defective impure substances awaiting a disposal giving total quantity and the name of the substance. A statement of reason for the substance being included in this category.
[16.19.20.21 NMAC - Rp 16 NMAC 19.20.13(1), 07-15-02]

16.19.20.22 DISTRIBUTION INVENTORY RECORDS: Distributor inventory records shall contain the same information required of manufacturers.
[16.19.20.22 NMAC - Rp 16 NMAC 19.20.13(2), 07-15-02]

16.19.20.23 INVENTORY REQUIREMENTS - RESEARCH:

- A.** Research registrant shall include in his inventory the name of the substance, each finished form of the substance, the number of units or volume of each finished form in each commercial container (100 tablet bottle, etc.) and the number of commercial containers of each such finished form.
- B.** A commercial container which has been opened shall be the exact count or measure of substances listed in Schedule I or Schedule II. If the substance is listed in Schedule III, IV or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case the count must be exact.
[16.19.20.23 NMAC - Rp 16 NMAC 19.20.13(3), 07-15-02]

16.19.20.24 ANALYTICAL LABORATORIES: Analytical laboratories shall include in the inventory record the same information required of manufacturer's.
[16.19.20.24 NMAC - Rp 16 NMAC 19.20.13(4), 07-15-02]

16.19.20.25 CONTROLLED SUBSTANCES INVENTORIES AND RECORDS:

- A.** Pharmacies, hospitals, clinics and practitioners who dispense controlled substances shall maintain inventories and records of controlled substances listed in Schedules II and II-N separately from all of the other prescription records.
- B.** "Readily retrievable" means records kept in such a manner as to be easily separated out from all other records in a reasonable time or records are kept on which certain items are redlined, starred or in some manner are visually identifiable apart from other items appearing on the record.
[16.19.20.25 NMAC - Rp 16 NMAC 19.20.13(5), 07-15-02]

16.19.20.26 PROCUREMENT RECORDS: “Order Forms” refer to DEA form 222 required for distribution or procurement of a Schedule I or II controlled substance under the federal act. Order forms are issued in books of six (6) forms in triplicate to registrants by requisition from DEA Registration Branch, Department of Justice, P.O. Box 28083, Central Station, Washington, DC 20005.

[16.19.20.26 NMAC - Rp 16 NMAC 19.20.14, 07-15-02]

16.19.20.27 ORDER FORMS AS RECORDS: Order forms for Schedule I and II controlled substances shall be deemed proper record of receipt, if the purchaser records on Copy 3 of the order form the number of commercial or bulk containers furnished of each item and the date on which such containers are received by the purchaser.

[16.19.20.27 NMAC - Rp 16 NMAC 19.20.14(1), 07-15-02]

16.19.20.28 INVENTORY RECORDS: All Schedule I and II narcotic substance inventory records and procurement records will be kept separate from other records of the registrant.

[16.19.20.28 NMAC - Rp 16 NMAC 19.20.14(2), 07-15-02]

16.19.20.29 PROCUREMENT RECORDS: Procurement records, other than the inventory, may be kept at a central location, rather than at the registered location, if prior approval has been obtained under the federal regulations; provided such records are delivered, upon request of the Board, to the registered location within 48 hours of such request.

[16.19.20.29 NMAC - Rp 16 NMAC 19.20.14(3), 07-15-02]

16.19.20.30 DISPOSITION RECORDS: Practitioner’s disposition records shall include date of dispensing, name of patient, name and strength of substance and amount dispensed.

[16.19.20.30 NMAC - Rp 16 NMAC 19.20.15, 07-15-02]

16.19.20.31 PHARMACY AND HOSPITAL PRESCRIPTION AND DISPENSING RECORDS:

A. Prescriptions for Schedule II shall be maintained in a separate file.

B. In pharmacies without computerized prescription information, prescriptions for Schedules II, III, IV and V shall have the name of the dispensing pharmacist and the date filled inscribed on the face of the prescription. (Typewritten, printed or rubber stamp are acceptable.)

C. Prescriptions for Schedule III, IV and V shall be maintained either in a separate file only, or in such form that they are readily retrievable from other records of the pharmacy. “Readily retrievable” means that at the time of filing, the face of the prescription is stamped in red ink in the lower right hand corner with the letter “C” no less than 1” high, or the records comply with 16.19.6.22 NMAC “Computerized Prescription Information”.

D. Prescriptions so marked may then be filed with prescriptions for Schedule II substances, or in the usual consecutively numbered prescription file for non-controlled drugs.

E. Pharmacies employing automatic data processing systems or other electronic record keeping systems for prescriptions must comply with 16.19.6.22 NMAC “Computerized Prescription Information”.

F. Hospital floor stock records. A record of controlled substances administered from floor stock shall contain the following information:

- (1) name of patient;
- (2) date and time administered;
- (3) name of drug;
- (4) strength of drug;
- (5) amount administered;
- (6) name of prescribing physician;
- (7) name of person administering the controlled substance.

[16.19.20.31 NMAC - Rp 16 NMAC 19.20.15(1), 07-15-02; A, 01-31-07]

16.19.20.32 RESEARCH DISPOSITION RECORDS:

A. A registered person using any controlled substance under FDA regulations in research at a registered establishment which maintains records in accordance with FDA approved research requirements is not required to keep records if he notifies the DEA and the Board of Pharmacy of the name, address and all registration numbers of establishments maintaining such records.

B. A registered person using any controlled substance in preclinical research or in teaching at a

registered establishment which maintains records of such substances is not required to keep records if he notifies the DEA and the Board of Pharmacy of the name, address and all registration numbers of the establishments maintaining the records.

[16.19.20.32 NMAC - Rp 16 NMAC 19.20.15(2), 07-15-02]

16.19.20.33 MANUFACTURERS AND REPACKAGERS:

A. Disposition records shall be maintained on all controlled substances. Schedule I and II records shall be maintained separately from all other records.

B. Disposition records for Schedules III, IV and V shall be maintained either separately from all other records or in such form that the information required is readily retrievable from the ordinary business records of the registrant.

[16.19.20.33 NMAC - Rp 16 NMAC 19.20.15(3), 07-15-02]

16.19.20.34 WHOLESALE DISTRIBUTORS: Wholesale distributors disposition records shall contain the same information required of manufacturers.

[16.19.20.34 NMAC - Rp 16 NMAC 19.20.15(4), 07-15-02]

16.19.20.35 ANALYTICAL LABORATORIES RECORDS: Analytical laboratories records shall include:

A. name of substance;

B. the form or forms in which substance is received, imported or manufactured and the concentration of the substance;

C. quantity and strength received;

D. date of receipt;

E. name and DEA registry number of supplier;

F. adequate record of distribution.

[16.19.20.35 NMAC - Rp 16 NMAC 19.20.15(5), 07-15-02]

16.19.20.36 REPORT OF LOSS OR THEFT OF A CONTROLLED SUBSTANCE:

A. The registered supplier shall be responsible for reporting in-transit losses of controlled substances by a common carrier or contract carrier selected by the supplier upon discovery of such loss or theft. Registrant shall complete DEA Form 106 as required and furnish a copy to the Board of Pharmacy.

B. A significant loss or theft of a controlled substance shall be reported in writing to the Board of Pharmacy and DEA on Form 106 as required by federal regulations. "Significant loss" includes suspected diversions, in-transit losses or any other unexplained loss and must be reported to the Board of Pharmacy within five (5) days of becoming aware of that loss. DEA Form 106 may be obtained from the Board of Pharmacy or DEA.

[16.19.20.36 NMAC - Rp 16 NMAC 19.20.16, 07-15-02]

16.19.20.37 HOSPITALS, INSTITUTIONS AND CLINICS: Disposal of excess or undesirable controlled substances resulting from extemporaneous amounts of residue or wasted controlled substances. A registrant who needs to dispose of excess or undesirable controlled substances resulting from injections from ampules or less than the full ampule or other such circumstances shall keep a written memorandum report on the hospital narcotic records and periodically file a report on DEA Form 41 with DEA pursuant to the requirements of the Federal DEA Regulations 1307.21(c).

[16.19.20.37 NMAC - Rp 16 NMAC 19.20.16(1), 07-15-02]

16.19.20.38 DISPOSITION OF DAMAGED, OUTDATED OR UNWANTED CONTROLLED

SUBSTANCES: Any registrant in possession of any controlled substances and desiring or required to dispose of such substances(s) may contact the Regional Director of DEA for authority and instructions to dispose of such substance.

[16.19.20.38 NMAC -Rp 16 NMAC 19.20.17, 07-15-02]

16.19.20.39 EXEMPTION FOR PHARMACY REGISTRATION AS A DISTRIBUTOR, DISTRIBUTION BY A DISPENSER TO ANOTHER PRACTITIONER REGISTERED TO DISPENSE CONTROLLED SUBSTANCES: A registrant who is registered to dispense controlled substances may distribute a quantity of such substances to a registered practitioner for general dispensing to his patients if:

A. the distribution is recorded by the pharmacist indicating the number of units or volume of such

finished forms and/or commercial containers dispensed, the date and manner of disposition;

B. the same information is recorded as a procurement by the registrant receiving the substance;

C. if the substance is listed in Schedule I or II, an order form is used as required by the federal regulations;

D. the total number of dosage units of all controlled substances distributed by the pharmacy by this method during the 12 month period in which the practitioner is registered to dispense does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the 12 month period.

[16.19.20.39 NMAC - Rp 16 NMAC 19.20.18, 07-15-02]

16.19.20.40 DISTRIBUTION UPON TRANSFER OR DISCONTINUANCE OF BUSINESS:

A. Upon transfer of a business from one owner to another, the registrant may dispose of the controlled substances in his possession as follows:

(1) On the date of transfer of controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with 16.19.20.19 NMAC, Board of Pharmacy Regulations to Title 21, Section 1304.11-1304.14 of the Federal DEA Regulations. This inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with DEA or the Board of Pharmacy unless requested by either agency. Transfer of Schedule I or II substances require the use of Order Forms (Form DEA 222c).

(2) All records required to be kept by the registrant-transferor with reference to the controlled substances 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.

(3) All Schedule II substances must be transferred pursuant to order forms as required by the federal regulations. A copy of the inventory will constitute a record of receipt for the purchaser.

B. Upon discontinuance of business, if there are controlled substances which are not transferred to another registrant, these substances shall be handled as unwanted controlled substances under 16.19.20.37 NMAC. [16.19.20.40 NMAC - Rp 16 NMAC 19.20.19, 07-15-02]

16.19.20.41 PRESCRIPTIONS:

A. A prescription for a controlled substance may be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice, and who is registered under the Controlled Substances Act. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

B. A prescription may not be issued in order for a practitioner to obtain controlled substances for supplying the practitioner for the purpose of general dispensing to patients.

C. A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic dependent person for the sole purpose of continuing his dependence upon such drugs.

D. A prescription may not be issued for the dispensing of the narcotic drugs listed in any schedule to a narcotic drug-dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

[16.19.20.41 NMAC - Rp 16 NMAC 19.20.20, 07-15-02]

16.19.20.42 PRESCRIPTION REQUIREMENTS:

A. Prescriptions for controlled substances shall be dated and signed as of the date of issue, and shall contain the full name and address of the patient, the name, address and federal registration number of the prescribing practitioner. Prescriptions for controlled substances listed in schedule II shall be written in ink, indelible pencil, or typewritten and manually signed by the practitioner. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. Information on the prescription may be added or clarified by the pharmacist after consultation with the practitioner. A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions must be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually

signed. Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 the code of federal regulations.

An individual practitioner may sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the requirements of part 1306.08 of the code of federal regulations.

B. A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in Subsections C and D of 16.19.20.41 NMAC and Subsection E of 16.19.20.42 NMAC. The original prescription shall be maintained in accordance with 16.19.20.31 NMAC.

C. A prescription prepared in accordance with Subsection A of 16.19.20.41 NMAC written for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, or subcutaneous infusion may be transmitted by the practitioner or the practitioner's agent to the parenteral products pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this paragraph and it shall be maintained in accordance with 16.19.20.31 NMAC.

D. A prescription prepared in accordance with Subsection A of 16.19.20.41 NMAC written for a schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

E. A prescription prepared in accordance with Subsection A of 16.19.20.41 NMAC written for a schedule II narcotic substance for a patient enrolled in a hospice program certified by medicare under title XVIII or licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this sub-section and it shall be maintained in accordance with 16.19.20.31 NMAC.

F. A pharmacist may dispense directly a controlled substance listed in schedule III or IV, which is a prescription drug as determined under the New Mexico Drugs and Cosmetics Act, only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all information required for a prescription except the signature of the practitioner.

(1) A new telephone prescription for any schedule III or IV opiate shall not exceed a ten day supply, based on the directions for use, and cannot be refilled. Verbal refill authorizations and clarifications to existing prescriptions are exempt from this requirement.

G. A pharmacy employee must verify the identity of the patient or the patient's representative before a new prescription for a controlled substance listed in schedule II, III, or IV, is delivered. Acceptable identification means a state issued driver's license, including photo, or other government issued photo identification. The identification number of the government issued identification and the name imprinted on that identification must be recorded in a manner to be determined by a written policy developed by the pharmacist-in-charge. Exceptions are, a new controlled substance prescription filled for a patient known to the pharmacist or pharmacist intern, whose identification has already been documented in a manner determined by a written policy developed by the pharmacist-in-charge; a controlled substance prescription filled for home delivery; or a controlled substance prescription filled for and delivered to a licensed facility.

[16.19.20.42 NMAC - Rp 16 NMAC 19.20(1), 07-15-02; A, 01-15-08]

16.19.20.43 PRESCRIPTIONS NOT TO BE REFILLED: Prescriptions for Schedule II drugs may not be refilled.

[16.19.20.43 NMAC - Rp 16 NMAC 19.20.20(2), 07-15-02]

16.19.20.44 REFILL PROCEDURE: Each refilling of a Schedule III, IV or V controlled substance prescription shall be entered on the back of the prescription, indicating the amount dispensed, if less than the amount called for on the prescription, the date of refill and the initials of the pharmacist dispensing the substance.

[16.19.20.44 NMAC - Rp 16 NMAC 19.20.20(3), 07-15-02]

16.19.20.45 PRESCRIPTION REFILL REQUIREMENTS:

A. Prescriptions for Schedule III or IV substances shall not be filled or refilled more than six (6) months after the date of issue or be refilled more than five (5) times unless renewed by the practitioner and a new

prescription is placed in the pharmacy files.

(1) Controlled substance prescriptions dispensed directly to a patient shall not be refilled before 75% of the prescription days supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

(2) Controlled substance prescriptions delivered to a patient indirectly (as in mail order) to a patient shall not be refilled before 66% of a 90 day supply has passed or 50% of a 30 day supply has passed, unless the practitioner authorizes the early refill, which must be documented by the pharmacist.

B. Schedule V prescriptions may be refilled only as expressly authorized by the prescribing physician on the prescription. If no such authorization is given, the prescription may not be refilled.

[16.19.20.45 NMAC - Rp 16 NMAC 19.20.20(4), 07-15-02]

16.19.20.46 PRESCRIPTION - PARTIALLY REFILLED:

A. A Schedule II prescription may be partially filled if the amount is recorded on the prescription. The remaining portion may be filled within 72 hours of the partial filling. Pharmacist must notify the prescribing physician if remaining portion cannot be filled within a 72 hour period.

B. Partial filling of a prescription for Schedule III or IV shall be recorded in the same manner as a refill, providing the total quantity of partial filling does not exceed the total quantity prescribed and no dispensing occurs after six (6) months from date of prescription.

C. A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, to include individual dosage units.

(1) If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient".

(2) A prescription that is partially filled and does not contain the notation "terminally ill" or LTCF patient" shall be deemed to have been filled in violation of this regulation. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist.

(3) The total quantity of Schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

[16.19.20.46 NMAC - Rp 16 NMAC 19.20.20(5), 07-15-02]

16.19.20.47 EMERGENCY DISPENSING:

A. Emergency dispensing of Schedule II controlled substances. "Emergency situation" means the prescribing physician determines:

(1) that immediate administration of a controlled substance is necessary for proper treatment of the intended patient;

(2) that no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and

(3) that it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance prior to the dispensing.

B. A pharmacy may dispense a Schedule II controlled substance in the above instance only if he receives oral authorization of a practitioner or authorization via facsimile machine and provided:

(1) the quantity prescribed is limited to the amount needed to treat the patient during the emergency period;

(2) the pharmacist shall reduce the prescription to a written form and it contains all information required of a Schedule II controlled substance prescription except the signature of the prescribing practitioner;

(3) the prescribing physician, within 7 days after authorization of the emergency dispensing, shall furnish a written, signed prescription to the pharmacist. The signed prescription shall have written on the face "AUTHORIZATION FOR EMERGENCY DISPENSING" and the date of the oral order or facsimile order;

(4) the signed prescription shall be attached to the oral emergency prescription order or the facsimile emergency prescription order and be filed as other Schedule II prescriptions.

C. In the event the prescribing physician fails to deliver a signed written prescription to the pharmacist, within the 7 days period, the pharmacist shall notify the nearest DEA office, and the Board of

Pharmacy.

[16.19.20.47 NMAC - Rp 16 NMAC 19.20.20(6), 07-15-02]

16.19.20.48 SECURITY REQUIREMENTS:

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

B. In evaluating the overall security system of a registrant or applicant, the following factors may be considered, where applicable to the need for strict compliance with security requirements:

- (1) the type of activity;
- (2) the type and form of controlled substances handled;
- (3) the quantity of controlled substances handled;
- (4) the location of the premises and relationship such location bears on security needs;
- (5) the type of building construction of the facility and the general characteristics of the building;
- (6) the type of vault, safe, and secure enclosures or other storage system used;
- (7) the type of closures on vaults, safes, and secure enclosures;
- (8) the adequacy of key control systems and/or lock control system;
- (9) the extent of unsupervised public access to the facility;
- (10) the adequacy of supervision over employees having access to storage or distribution areas;
- (11) the procedures for handling business guests, visitors, maintenance personnel and non-employee service personnel;
- (12) the adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled substances in its' operation.

[16.19.20.48 NMAC - Rp 16 NMAC 19.20.21, 07-15-02]

16.19.20.49 MANUFACTURERS, REPACKAGERS AND WHOLESALE DISTRIBUTORS: Security requirements which meet the federal DEA provision, shall be deemed adequate under New Mexico Controlled Substances Act.

[16.19.20.49 NMAC - Rp 16 NMAC 19.20.21(1), 07-15-02]

16.19.20.50 PHARMACIES, HOSPITALS, EMPLOYING STAFF PHARMACISTS: Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet. Controlled substances listed in Schedule II, III, IV and V shall be stored either in securely locked, substantially constructed cabinets or dispersed throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the substances.

[16.19.20.50 NMAC - Rp 16 NMAC 19.20.21(2), 07-15-02]

16.19.20.51 HOSPITALS SERVED BY CONSULTANT OR PART-TIME PHARMACISTS, CLINICS AND PHYSICIANS: Controlled substances listed in Schedule I through V shall be stored in a securely locked, substantially constructed cabinet.

[16.19.20.51 NMAC - Rp 16 NMAC 19.20.21(3), 07-15-02]

16.19.20.52 RESEARCH REGISTRANTS AND CHEMICAL ANALYSIS LABORATORIES:

Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet. Schedules III, IV and V substances shall be stored either in a securely locked, substantially constructed cabinet or dispersed in with the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the substances.

[16.19.20.52 NMAC - Rp 16 NMAC 19.20.21(4), 07-15-02]

16.19.20.53 DISPENSING WITHOUT PRESCRIPTION:

A. A controlled substance listed in Schedule V and a substance listed in Schedules II, III, or IV *which is not a prescription drug* as determined by FDA and the Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription provided:

- (1) such dispensing is made by a pharmacist or registered pharmacist intern and not by a non-pharmacist employee;
- (2) not more than eight (8) ounces of any controlled substance containing opium, nor more than 48 dosage units is dispensed at retail to the same person in any given 48 hour period;
- (3) not more than four (4) ounces of any other controlled substance or more than 24 dosage units may be dispensed

at retail to the same person in any given 48 hour period;

(4) the purchaser is at least 18 years of age;

(5) the pharmacist requires every purchaser of such substance, not known to him to furnish suitable identification (including proof of age where appropriate);

(6) a bound record book for dispensing such substances is maintained requiring the signature and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance; the book shall contain a statement on each page where purchaser is required to sign, stating no purpose of such substance has been made within the given 48 hour period at another pharmacy and the purchaser shall be made aware of such statement before signing the record.

B. Exempt pseudoephedrine product.

(1) Any pseudoephedrine containing product listed as a Schedule V Controlled Substance in Paragraph (2) of Subsection B of 16.19.20.69 NMAC shall be dispensed, sold or distributed only by a licensed pharmacist, pharmacist intern, or a registered pharmacy technician.

(2) Unless pursuant to a valid prescription, a person purchasing, receiving or otherwise acquiring the compound, mixture or preparation shall:

(a) produce a driver's license or other government-issued photo identification showing the date of birth of the persons;

(b) sign a log after reading the purchaser statement for pseudoephedrine receipt or other program or mechanism indicating the date and time of the transaction, name of the person, address, driver's license number or government issued identification number, name of the pharmacist, pharmacist intern or pharmacy technician conducting the transaction, the product sold and the total quantity, in grams or milligrams, of pseudoephedrine purchased; this log will be only for exempt pseudoephedrine products and shall be kept separate from all other records; the log is to be produced in a way that a customer's personal information is not available to other purchasers;

(c) be limited to no more than 3.6 grams per day or more than a total of 9 grams of a product, mixture or preparation containing pseudoephedrine within a thirty-day period.

(3) Pseudoephedrine purchaser statement must state in addition to any federal requirements "I have not purchased more than 3.6 grams today or more than a total of 9 grams of pseudoephedrine as a single entity or in a combination with other medications in the last 30 days. Entering false statements or misrepresentations in this logbook may subject me to criminal penalties."

(4) Prices charged for compounds, mixtures, and preparations that contain pseudoephedrine shall be monitored. The board may adopt rules to prevent unwarranted price increases as a result of compliance with this section.

[16.19.20.53 NMAC - Rp 16 NMAC 19.20.22, 07-15-02; A, 06-30-06]