

COMAR 10.19.03 Controlled Dangerous Substances

.01 Scope and Purpose.

A. The Secretary of the Department of Health and Mental Hygiene recognizes that the public interest requires control over the use of controlled dangerous substances in the legitimate manufacture, distribution, and dispensing of controlled dangerous substances. The Secretary is adopting some sections of the Code of Federal Regulations, and these sections are identified by the federal citation in parentheses after the heading.

B. This chapter applies to every registrant who manufactures, distributes, or dispenses any controlled dangerous substances within the State of Maryland, unless exempted from registration by Criminal Law Article, §5-301(d), Annotated Code of Maryland, or 21 CFR §§1301.22 — 1301.24.

C. In the event of conflict between a provision of the Code of Federal Regulations referenced under §B of this regulation and a provision of this chapter, the registrant shall comply with the more stringent provision.

.02 Definitions.

A. As used in this chapter, unless otherwise provided, those definitions appearing in Criminal Law Article, §5-101, Annotated Code of Maryland, shall apply.

B. In this chapter, the following terms have the meanings indicated.

C. Terms Defined.

(1) "Act" means the Maryland Controlled Dangerous Substances Act, Criminal Law Article, §§5-101—5-1101, Annotated Code of Maryland.

(2) Commercial Container.

(a) "Commercial container" means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user.

(b) "Commercial container" includes any box or package in which a receptacle is held for distribution or dispensing to an ultimate user.

(c) "Commercial container" does not include any package liner, package insert, or other material kept with or within a commercial container, or any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled dangerous substances.

(3) Controlled Premises.

(a) "Controlled premises" means places where original or other records or documents required under the Act are kept or required to be kept.

(b) "Controlled premises" includes factories, warehouses, other establishments, and conveyances, where persons registered under the Act or exempt from registration under the Act may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled dangerous substances.

- (4) "Department" means the Department of Health and Mental Hygiene of the State.
- (5) "Division of Drug Control" means a division within the Department of Health and Mental Hygiene.
- (6) "Federal Act" means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substance Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).
- (7) Individual Practitioner.
- (a) "Individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which the individual practitioner practices, to dispense a controlled dangerous substance in the course of professional practice.
- (b) "Individual practitioner" does not include a pharmacist, a pharmacy, or an institutional practitioner.
- (8) "Inspector" means an officer or employee of the Department authorized by the Secretary to make inspections under the Act.
- (9) Institutional Practitioner.
- (a) "Institutional practitioner" means a hospital or other person other than an individual licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a controlled dangerous substance in the course of professional practice.
- (b) "Institutional practitioner" does not include a pharmacy.
- (10) "Labeling" means all labels and other written, printed, or graphic matter on any controlled substance or any of its commercial containers or wrappers accompanying controlled dangerous substances.
- (11) Manufacture.
- (a) "Manufacture" means the:
- (i) Producing, preparation, propagation, compounding, or processing of a drug or other substance;
- (ii) Packaging or repackaging of the substance; or
- (iii) Labeling or relabeling of the commercial container of the substance.
- (b) "Manufacture" does not include the activities of a practitioner who, as an incident to the practitioner's administration or dispensing the substance in the course of the practitioner's professional practice, prepares, compounds, packages, or labels the substance.
- (12) "Manufacturer" means a person who manufactures a drug or other substance under:
- (a) A registration as a manufacturer; or
- (b) Authority of registration as a researcher or chemical analyst.
- (13) Pharmacist.

(a) "Pharmacist" means any pharmacist licensed in the State to dispense controlled dangerous substances.

(b) "Pharmacist" includes any other individual, for example, a pharmacist intern, authorized by a state to dispense controlled dangerous substances under the supervision of a pharmacist licensed by that state.

(14) Prescription.

(a) "Prescription" means an order for medication that is dispensed to or for an ultimate user.

(b) "Prescription" does not include an order for medication which is dispensed for immediate administration to the ultimate user, such as an order to dispense a drug to a bed patient for immediate administration in a hospital.

(15) "Registration" means initial registration or subsequent reregistration.

(16) "Secretary" means the Secretary of Health and Mental Hygiene.

.03 Registration; Registration Certificate.

A. Requirement. A person shall register with the Department and obtain and maintain a registration certificate before the person:

(1) Manufactures, distributes, or dispenses controlled dangerous substances;

(2) Conducts research or instructional activities with controlled dangerous substances listed in Schedules II through V of Criminal Law Article, §§5-403—5-406, Annotated Code of Maryland;

(3) Conducts research or instructional activities with a controlled dangerous substance listed in Schedule I of Criminal Law Article, §5-402, Annotated Code of Maryland; or

(4) Conducts a chemical analysis with controlled dangerous substances listed in any schedule.

B. Application.

(1) A person required to obtain and maintain a registration certificate as set forth under this chapter shall:

(a) Obtain, complete, and submit an application for a registration certificate on a form provided by the Department; and

(b) Pay the appropriate fee as set in §C of this regulation, unless the applicant is eligible for a fee exemption.

(2) The application and any accompanying document or statement required for registration by the Secretary shall be signed by the:

(a) Applicant, if an individual;

(b) General partner, if the applicant is a partnership; or

(c) Officer responsible for the applicant, if the applicant is a corporation or other entity.

(3) If the information requested on the application is not applicable to the applicant, the applicant shall indicate this on the form.

(4) The Secretary may require additional documentation pertinent to the registration to:

(a) Clarify application information; or

(b) Determine if the applicant meets the requirements of this chapter.

(5) A person shall submit an application and fee for each separate place of business, professional practice, or location for which registration is required.

(6) The registration certificate shall be readily available to any agent or representative of the Secretary within the registered location.

C. Fees.

(1) A person required to obtain and maintain a registration certificate as set forth under this chapter shall pay the appropriate fees as set in this regulation. Fees include the following:

(a) Registration every 2 years—\$120;

(b) Amend an unexpired registration certificate—\$50; and

(c) Replace a lost registration certificate—\$30.

(2) Persons Exempt from Fee.

(a) The following persons are exempt from payment of a fee for registration or renewal of registration:

(i) A hospital, clinic, institution, facility, or unit operated by the State or by the United States;

(ii) An agency, excluding State employees, for which the State is responsible for payment of the fee, provided that the exemption is approved by the Secretary; and

(iii) A person included in 21 CFR §§1301.21—1301.24.

(b) A person exempt from payment of a registration fee is required to obtain and maintain a registration certificate.

(3) Payment of Prorated Fees.

(a) A registrant applying for a registration certificate shall pay a prorated registration fee when a registration certificate is issued for less than 24 months.

(b) The prorated fee shall be based on the total number of full plus partial months for which the registration certificate is issued.

(4) Refunds and Credits. The Secretary may not issue a refund or credit or return any registration fees to a registrant, including if a registrant:

(a) Withdraws a registration application; or

(b) Voluntarily or involuntarily ceases to manufacture, distribute, or dispense a controlled dangerous substance before a registration certificate expires.

(5) Failure to Pay Fees. The Secretary may not issue a new or a renewed registration certificate until all required fees are paid.

D. Issuance. The Secretary may issue a registration certificate that:

(1) Is valid for not more than 2 years; and

(2) Shall be renewed before its expiration date if the registrant intends to operate as described in §A of this regulation.

E. Expiration and Renewal.

(1) A registration certificate expires on the date shown on the certificate.

(2) The Secretary shall mail a renewal application or a notice to renew to a registrant not less than 30 days before the expiration date shown on the certificate.

F. Assignment, Transfer, or Termination.

(1) A registration certificate is not transferable.

(2) A registration certificate becomes void when the registrant:

(a) Dies;

(b) Discontinues business or professional practice in the State; or

(c) Changes ownership, including when:

(i) Partners are added or deleted from the partnership;

(ii) There is a change in the president or chief executive officer of the corporation; or

(iii) There is a change in the ownership of 10 percent or more of the outstanding shares in the corporation.

(3) A registrant who discontinues business or professional practice in the State shall:

(a) Notify the Secretary in writing;

(b) Surrender the registrant's current registration certificate; and

(c) Legally transfer or dispose of any controlled dangerous substances relative to the registrant's operation.

(4) Change of Ownership.

(a) A registrant who changes ownership of the business or professional practice as stated in §C(2)(c) of this regulation, shall:

(i) Notify the Secretary in writing;

(ii) Submit a registration application to change the current registration and a \$144 2-year registration fee at least 30 days before the change in the ownership of the registrant's business or professional practice occurs; and

(iii) Surrender the registrant's current registration certificate after the ownership change is finalized.

(b) After a change in ownership, the Secretary may inspect the business or professional practice of the new owners as provided in §G of this regulation.

(5) Change of Location. A registrant shall submit an application to amend a current registration certificate along with a \$50 fee at least 30 days before there is a change in the location of the registrant's place of business or professional practice from the location which is stated on the registration certificate to a new location within the State.

G. Inspection. After an application for registration has been filed, the Secretary may:

(1) Inspect the place of business or professional practice described in the application; and

(2) Investigate the applicant to determine whether the applicant meets the requirements of this chapter.

04 Labeling and Packaging Requirements for Controlled Dangerous Substances. (Title 21, Code of Federal Regulations 1302.01).

A. Requirements governing the labeling and packaging of controlled dangerous substances pursuant to Criminal Law Article, §§5-202 and 5-604, Annotated Code of Maryland, are set forth generally by those sections and specifically by the sections of this regulation.

B. Symbol Required—Exceptions (21 CFR §1302.03).

(1) Each commercial container of a controlled dangerous substance (except for a controlled dangerous substance excepted by the Administrator pursuant to Title 21, Code of Federal Regulations, §1308.31, shall have printed on the label the symbol designating the schedule in which this controlled dangerous substance is listed. Each commercial container, if it has no label, shall bear a label complying with the requirement of this part.

(2) Each manufacturer shall print upon the labeling of each controlled dangerous substance distributed by the manufacturer the symbol designating the schedule in which this controlled dangerous substance is listed.

(3) Schedules.

(a) The following symbols shall designate the schedule corresponding to it:

Schedule	Symbol
Schedule I	CI or C-I
Schedule II	CII or C-II

Schedule III	CIII or C-III
Schedule IV	CIV or C-IV
Schedule V	CV or C-V

(b) The word "schedule" need not be used. A distinction need not be made between narcotic and non-narcotic substances.

(4) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through this carton or wrapper.

(5) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.

(6) The symbol is not required on a commercial container containing, or on the labeling of, a controlled dangerous substance being used in clinical research involving blind and double blind studies.

C. Location and Size of Symbol on Label (21 CFR §1302.04).

(1) The symbol shall be prominently located on:

(a) The label or the labeling of the commercial container;

(b) The panel of the commercial container normally displayed to dispensers of any controlled substance; or

(c) Both.

(2) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled dangerous substance upon inspection, without removal from the dispenser's shelf.

(3) The symbol shall be prominently located on all labeling other than labels covered by this section. In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled dangerous substance upon inspection of the labeling.

D. Effective Dates of Labeling Requirements (21 CFR §1302.05).

(1) All labels on commercial containers of, and all labeling of, a controlled substance which either is transferred to another schedule or is added to any schedule, shall comply with the requirements of §B of this regulation, on or before the effective date established in the final order for the transfer or addition.

(2) In the case of any controlled dangerous substance, the Secretary may require compliance with the requirements of §B within a period of time shorter than required by this regulation if the Secretary finds that public health or safety necessitates an earlier effective date.

(3) Until compliance is required under this regulation, the label on commercial containers containing, and the labeling of, any controlled dangerous substance, shall comply with any requirements under federal law as to labels of these substances existing before the effective date prescribed in this regulation.

E. Sealing of Controlled Dangerous Substances (21 CFR §1302.06). On each bottle, multiple dose vial, or other commercial container of any controlled dangerous substance, there shall be securely affixed to the

stopper, cap, lid, covering, or wrapper of that container a seal to disclose upon inspection any tampering or opening of the container.

F. Labeling and Packaging Requirements for Imported and Exported Substances (21 CFR §1302.07).

(1) The symbol requirements of §§B—D of this regulation apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of or the customs territory of the United States.

(2) The symbol requirements of §§B—D of this regulation do not apply to any commercial containers containing, or any labeling of, a controlled dangerous substance intended to export from the jurisdiction of the United States.

(3) The sealing requirements of §E of this regulation apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of or the customs territory of the United States.

.06 Order Forms.

The Maryland Act directs that Controlled Dangerous Substances in Schedule I and II shall be distributed by a registrant, pursuant to an order form, and that compliance with the provisions of the federal law respecting order forms for these schedules is compliance with the Maryland Act. For administrative interpretations, the regulations effective pertaining to the federal law respecting order forms are hereby incorporated into these regulations in their entirety (Title 21, Part 1305, §§1305.01 through 1305.16).

.07 Prescriptions.

A. Provisions governing the issuance, filling, and filing of prescriptions pursuant to Criminal Law Article, §§5-501—5-505, Annotated Code of Maryland, are set forth generally in those sections and specifically by the sections of this regulation.

B. Persons Entitled to Issue Prescriptions (21 CFR §1306.03).

(1) A prescription for a controlled dangerous substance may be issued only by an individual practitioner who is:

(a) Authorized to prescribe controlled dangerous substances in the State of Maryland, in which the practitioner is licensed to practice the practitioner's profession; and

(b) Either registered or exempted from registration pursuant to 21 CFR §1301.22(c) and 21 CFR §1301.23.

(2) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

C. Purpose of Issue of Prescription (21 CFR §1306.04).

(1) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the individual practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of

professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Maryland Controlled Dangerous Substances Act Criminal Law Article, §§5-501—5-505, Annotated Code of Maryland, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.

(2) A prescription may not be issued in order for an individual practitioner to obtain controlled dangerous substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for detoxification treatment or maintenance treatment.

D. Manner of Issuance of Prescriptions (21 CFR §1306.05).

(1) All prescriptions for controlled dangerous 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. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (for example, J.H. Smith or John H. Smith). When an oral order is not permitted, prescriptions shall be written with ink, indelible pencil, typewriter, or computer and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(2) An individual practitioner exempted from registration under 21 CFR §1301.22(c) shall include on all prescriptions issued by the individual practitioner the registration number of the hospital or other institution and the special internal code number assigned to the individual practitioner by the hospital or other institution, as provided in 21 CFR §1301.22(c), instead of the registration number of the practitioner required by this regulation. Each written prescription shall have the name of the individual practitioner stamped, typed, or handprinted on it, as well as the signature of the individual practitioner.

(3) An official exempted from registration under 21 CFR §1301.23 shall include on all prescriptions issued by the practitioner the branch of service or agency (for example—"U.S. Army" or "Public Health Service") and the practitioner's service identification number, instead of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is the practitioner's Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

E. Persons Entitled to Fill Prescriptions. A prescription for controlled dangerous substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

F. Administering or Dispensing of Narcotic Drugs (21 CFR §1306.07).

(1) The administering or dispensing directly, but not prescribing, of narcotic drugs listed in any schedule to a narcotic drug dependent individual for "detoxification treatment" or "maintenance treatment" as defined in 21 U.S.C. §802 shall be deemed to be within the meaning of the term "in the course of his professional practice of research" as provided in 21 U.S.C. §828(e) and 21 U.S.C. §802(21), if the practitioner is separately registered with the United States Attorney General as required by 21 U.S.C. §823(g) and complies with the regulatory standards for treatment qualification, security, records, and unsupervised use of drugs pursuant to the federal Act.

(2) A physician who is not specifically registered to conduct a narcotic treatment program may administer, but may not prescribe, narcotic drugs to an individual for the purpose of relieving acute withdrawal symptoms if necessary while arrangements are being made for referral for treatment. More than one day's medication may not be administered to the individual, or for the individual's use, at one time. This emergency treatment may not be carried out for more than 3 days and may not be renewed or extended.

(3) A physician or authorized hospital staff may administer or dispense narcotic drugs:

(a) In a hospital to maintain or detoxify an individual as an incidental adjunct to medical or surgical treatment of conditions other than addiction; or

(b) To an individual with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

.08 Controlled Substances Listed in Schedule II.

A. Requirement of Prescription—Schedule II (21 CFR §1306.11).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in §A(4) of this regulation. Except as noted in §A(5)—(7) of this regulation, a prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review before the actual dispensing of a controlled substance.

(2) An individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule II in the course of the individual practitioner's professional practice without a prescription, subject to Regulation .07 of this chapter.

(3) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(4) In the case of an emergency situation, as cited in 21 CFR §1306.11(d), a pharmacist may dispense a controlled dangerous substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, if all of the following requirements are met:

(a) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Regulation .07 of this chapter, except for the signature of the prescribing individual practitioner;

(c) If the prescribing individual practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using the prescribing individual practitioner's telephone number as listed in the telephone directory or other good faith efforts to insure the individual practitioner's identity;

(d) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall have a written prescription for the emergency quantity prescribed delivered to the dispensing pharmacist. In addition to conforming to the requirements of Regulation .07 of this chapter, the prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if it is delivered by mail, it shall be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify in writing the Department of Health and Mental Hygiene if the prescribing individual practitioner fails to deliver a written prescription to the pharmacist; failure of the pharmacist to do so shall void the authority conferred by this section to dispense without a written prescription of a prescribing individual practitioner.

(5) A prescription prepared in accordance with 21 CFR §1306.05 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile equipment. The facsimile received by facsimile equipment serves as the original written prescription for purposes of §A(5) of this regulation and the facsimile received by facsimile equipment shall be maintained in accordance with 21 CFR §1304.04(h).

(6) A prescription prepared in accordance with 21 CFR §1306.05 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 equipment. The facsimile received by facsimile equipment serves as the original written prescription for purposes of §A(6) of this regulation and the facsimile received by facsimile equipment shall be maintained in accordance with 21 CFR §1304.04(h).

(7) A prescription prepared in accordance with 21 CFR §1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified or paid for by Medicare, or both, under Title XVIII or a hospice program which is licensed by the State, may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile equipment. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The facsimile received by the facsimile equipment serves as the original written prescription for purposes of §A(7) of this regulation and the facsimile received by facsimile equipment shall be maintained in accordance with 21 CFR §1304.04(h).

(8) A prescription for a Schedule II controlled dangerous substance shall be dispensed within 120 days of the date of issue.

B. Refilling of Prescription—Schedule II (21 CFR §1306.12). The refilling of a prescription for a controlled dangerous substance listed in Schedule II is prohibited.

C. Partial Filling of Prescriptions—Schedule II (21 CFR §1306.13).

(1) The partial filling of a prescription for a controlled dangerous substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription, and the pharmacist makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

(2) Long-Term Care Facility or Terminal Illness Patient.

(a) A prescription for a Schedule II controlled dangerous 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. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner before partially filling the prescription.

(b) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled dangerous substance is for a terminally ill patient.

(c) The pharmacist shall record on the prescription whether the patient is a "terminally ill" or "LTCF" patient.

(d) A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" is considered to have been filled in violation of Criminal Law Article, §§5-101—5-1101, Annotated Code of Maryland.

(e) For each partial filling, the dispensing pharmacist shall record on the back of the prescription or on another appropriate record, uniformly maintained and readily retrievable, the:

(i) Date of the partial filling;

(ii) Quantity dispensed;

(iii) Remaining quantity authorized to be dispensed; and

(iv) Identification of the dispensing pharmacist.

(f) Before any subsequent partial filling, the pharmacist shall determine if the additional partial filling is necessary. The total quantity of Schedule II controlled dangerous substances dispensed in all partial fillings may not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness are valid for a period not to exceed 60 days from the issue date, unless sooner terminated by the discontinuance of medication.

(g) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit output (display or printout) of the:

(i) Original prescription number;

(ii) Date of issue;

(iii) Identification of prescribing individual practitioner;

(iv) Identification of patient;

(v) Address of the LTCF or address of the hospital or residence of the patient;

(vi) Identification of medication authorized, including dosage, form, strength, and quantity;

(vii) Listing of the partial fillings that have been dispensed under each prescription;

(viii) Information required in §C(2)(a)—(f) of this regulation; and

(ix) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.

(h) Retrieval of partially filled Schedule II prescription information is the same as required by 21 CFR §1306.22(b)(4) and (5) for Schedule III and IV prescription refill information.

D. Labeling of Substances (21 CFR §1306.14).

(1) The pharmacist filling a written or emergency oral prescription for a controlled dangerous substance listed in Schedule II shall affix to the package a label showing the date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in this prescription or required by law. It is further provided that the label of a drug listed in Schedules II, III, IV, and V of Criminal Law Article, §§5-403—5-406, Annotated Code of Maryland, shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient. When the size of the label space requires a reduction in type, the reduction shall be made to a size no smaller than necessary and in no event to a size smaller than six-point type.

(2) The requirements of §D(1) of this regulation, do not apply when a controlled dangerous substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, provided that:

(a) Not more than a 7-day supply of the controlled dangerous substance listed in Schedule II is dispensed at one time;

(b) The controlled dangerous substance listed in Schedule II is not listed in the possession of the ultimate user before the administration;

(c) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled dangerous substance listed in Schedule II; and

(d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

(3) When dispensed to or for a patient, the label of a drug listed in Schedules II, III, IV, or V shall contain a clear and concise warning that it is a crime to transfer the drug to any person other than the patient.

E. Filing of Prescriptions (21 CFR §1306.14). All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirement of Regulation .05.

.09 Controlled Substances Listed in Schedules III, IV, and V.

A. Requirement of Prescriptions Listed in Schedules III, IV, and V (21 CFR §1306.21).

(1) A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment 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 a prescribing individual practitioner and immediately reduced to writing by the pharmacist containing all information required in Regulation .07 of this chapter, except the signature of the prescribing individual practitioner.

(2) An individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedules III, IV, or V in the course of the individual practitioner's professional practice without a prescription, subject to Regulation .07 of this chapter.

(3) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule III, IV, or V only pursuant to:

(a) A written prescription signed by a prescribing individual practitioner;

(b) A facsimile received by facsimile equipment of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist;

(c) An oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the pharmacist (containing all information required in Regulation .07 of this chapter, except for the signature of the prescribing individual practitioner); or

(d) An order for medication made by an individual practitioner, which is dispensed for immediate administration to the ultimate user, subject to Regulation .07 of this chapter.

B. Refilling of Prescriptions (21 CFR §1306.22).

(1) Unless otherwise instructed by the prescribing individual practitioner, a prescription for a controlled dangerous substance listed in Schedule III, IV, or V, may not be initially filled more than 120 days after the date on which the prescription was issued. If the prescribing individual practitioner instructs that the prescription be filled more than 120 days after the prescription was issued, a prescription for a controlled dangerous substance listed in Schedule III, IV, or V may not be initially filled more than 6 months after the date on which the prescription was issued. A prescription for a controlled dangerous substance listed in Schedule III, IV, or V may not be refilled more than 6 months after the date on which the prescription was issued. A prescription authorized to be refilled may not be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription, or on another appropriate uniformly maintained, readily retrievable record, such as medication records (prior approval of the Department required), which indicates by the number of the prescription the name and dosage form of the controlled dangerous substance, the date of each refilling, the quantity dispensed, the identity or initials of the dispensing pharmacist in each refilling, and the total number of refills for that prescription, initialed, and dated by the pharmacist as of the date of dispensing. Each refilling of a prescription shall state the amount dispensed. If the pharmacist merely initials and dates the back of the prescription, the pharmacist shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled dangerous substances listed in Schedule III, IV, or V, beyond the five refill 6-month limitation, may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in §A of this regulation, which shall be a new and separate prescription.

(2) Instead of the procedures in §B(1) of this regulation, and subject to the requirements in 21 CFR §1306.22, an automated data process system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V.

C. Partial Filling of Prescriptions (21 CFR §1306.23). The partial filling of a prescription for a controlled dangerous substance listed in Schedule III, IV, or V is permissible, provided that:

(1) Each partial filling is recorded in the same manner as a refilling;

(2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and

(3) No dispensing occurs after 6 months after the date on which the prescription was issued.

D. Labeling of Substances (21 CFR §1306.24).

(1) The pharmacist filling a prescription for a controlled dangerous substance listed in Schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in this prescription or as required by law.

(2) The requirements of §D(1) of this regulation do not apply when a controlled dangerous substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized, if:

(a) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled dangerous substance listed in Schedule III, IV, or V is dispensed at one time;

(b) The controlled dangerous substance listed in Schedule III, IV, or V is not in the possession of the ultimate user before administration;

(c) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled dangerous substance listed in Schedule III, IV, or V; and

(d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

E. Filing Prescription (21 CFR §1306.24). All prescriptions for controlled dangerous substances listed in Schedules III, IV, and V shall be kept in accordance with Regulation .05A of this chapter.

F. Dispensing without Prescription (21 CFR §1306.26). Unless prohibited by local or federal law, a controlled dangerous substance listed in Schedule V (Criminal Law Article, §5-406, Annotated Code of Maryland), which is not a prescription drug as determined by federal or State law, may be dispensed by a pharmacist without a prescription to a purchaser at retail according to the requirements stated in Criminal Law Article, §5-505, Annotated Code of Maryland.

.10 Miscellaneous (21 CFR §1307).

A. Distribution by Dispenser to Another Practitioner (21 CFR §1307.11).

(1) A practitioner who is registered to dispense a controlled dangerous substance may distribute (without being registered to distribute) a quantity of the substance to another practitioner for the purpose of general dispensing by the practitioner to the practitioner's patients, if:

(a) The practitioner to whom the controlled dangerous substance is to be distributed is registered under the Act to dispense that controlled dangerous substance;

(b) The distribution is recorded by the distributing practitioner in accordance with 21 CFR §1304.22(c), and by the receiving practitioner in accordance with 21 CFR §1304.22(c);

(c) The substance is listed in Schedule I or II, an order form is used as required in Criminal Law Article, §5-303(d), Annotated Code of Maryland; and

(d) The total number of dosage units of all controlled dangerous substances distributed by the practitioner pursuant to this section and 21 CFR §1301.25 during each calendar year in which the practitioner is

registered to dispense does not exceed 5 percent of the total number of dosage units of all controlled dangerous substances distributed and dispensed by the practitioner during the same calendar year.

(2) If, at any time during any calendar year during which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled dangerous substances which will be distributed by the practitioner pursuant to this regulation will exceed 5 percent of the total number of dosage units of all controlled dangerous substances distributed and dispensed by the practitioner during that calendar year, the practitioner shall obtain a registration to distribute controlled dangerous substances.

B. Distribution to Supplier (21 CFR §1307.12).

(1) Any person lawfully in possession of a controlled dangerous substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom the person obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier or manufacturer. In the case of returning a controlled dangerous substance listed in Schedule I or II, an order form shall be used in the manner prescribed in 21 CFR §1305, and be maintained as the written record of the transaction. Any person not required to register pursuant to §§302C or 1007(b)(1) of the Federal Act (21 U.S.C. §822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this regulation.

(2) Distributions referred to in §B(1) of this regulation may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned, provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

C. Distribution upon Discontinuance or Transfer of Business 21 CFR §1307.21.

(1) A registrant desiring to discontinue business activities altogether, who has controlled dangerous substances in the registrant's possession, may have these substances destroyed in accordance with §D of this regulation. A registrant shall return the State certificate of registration to the Division of Drug Control.

(2) A registrant desiring to discontinue business activities altogether, or with respect to controlled dangerous substances (by transferring those business activities to another person), shall submit in person or by registered or certified mail, return receipt requested, to the Secretary of the Department of Health and Mental Hygiene, Attention: Division of Drug Control, at least 14 days before the date of the proposed transfer (unless the Secretary waives this time limitation in individual instances), the following information:

(a) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);

(b) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);

(c) Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed);

(d) The date on which the transfer of controlled dangerous substances will occur.

(3) Unless the registrant-transferor is informed by the Secretary, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled dangerous substances in the registrant-transferor's possession to the registrant-transferee in accordance with the following procedures:

(a) On the date of transfer of the controlled dangerous substances, a complete inventory of all controlled dangerous substances being transferred shall be taken in accordance with 21 CFR §1304.11. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It is not necessary to file a copy of the inventory with the Department unless requested by the Secretary. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with 21 CFR §1305.

(b) On the date of transfer of the controlled dangerous substances, all records required to be kept by the registrant-transferor with reference to the controlled dangerous substances being transferred, under 21 CFR §1304, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records before the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

(c) In the case of registrants required to make reports pursuant to 21 CFR §1304, a report marked "Final" shall be prepared and submitted by the registrant-transferor showing the disposition of all the controlled dangerous substances for which a report is required. An additional report is not required from the registrant-transferor, if no further transactions involving controlled dangerous substances are consummated by the registrant-transferor. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant, and the substances transferred to the registrant-transferee shall be reported as receipts in the registrant-transferee's initial report.

D. Procedure for Disposing of Legally Obtained Controlled Dangerous Substances (21 CFR §1307.21).

(1) Any registrant in possession of legally obtained controlled dangerous substances and desiring or required to dispose of any of these substances may ask the Division of Drug Control of the Department of Health and Mental Hygiene for authority and instructions to dispose of this substance. This does not eliminate the requirement on registrants under federal regulations to report destruction of controlled dangerous substances.

(2) The request should be made as follows:

(a) If the registrant is required to make reports pursuant to 21 CFR §1304, the registrant shall list the controlled dangerous substance or substances which the registrant desires to dispose of and submit one copy of the request to the Division of Drug Control of the Department of Health and Mental Hygiene.

(b) If the person is a registrant not required to make reports pursuant to 21 CFR §1304, the person shall list the controlled dangerous substance or substances which the person desires to dispose of on a form required by the Department, and submit a copy of that report to the Division of Drug Control of the Department of Health and Mental Hygiene.

(3) The division of Drug Control shall authorize and instruct the registrant to dispose of the controlled dangerous substance in one of the following manners, provided complete records of the disposition are maintained by the registrant:

(a) By transfer to a person registered under the Act and authorized to possess the substance;

(b) By destruction in the presence of an agent of the Division of Drug Control or other authorized person;

(c) By forwarding to the District Office of the Drug Enforcement Administration pursuant to the procedures of that agency;

(d) In a facility registered to administer only, two members of the professional staff (administrator, nurse, pharmacist) may destroy controlled drugs on the premises; a record of the disposal shall be recorded on a form to be supplied by the Division of Drug Control, a copy of which is to be forwarded to the Division within 10 days of destruction;

(e) Aforementioned procedures do not preclude release of medication to discharged patients if so ordered in writing by the attending physician;

(f) Unused controlled dangerous substances dispensed by registered hospital pharmacies for administration to in-patients shall be returned to the pharmacy for appropriate disposition;

(g) By other means that the Secretary may determine to assure that the substance does not become available to unauthorized persons.

(4) If a registrant is required regularly to dispose of controlled dangerous substances, the Special Agent in Charge of the Federal Drug Enforcement Administration may authorize the registrant to dispose of these substances, in accordance with 21 CFR §1307.21(b), without prior approval of the Drug Enforcement Administration in each instance, on the condition that the registrant keep records of these disposals and file periodic reports with the Special Agent in Charge summarizing the disposals made by the registrant. In granting authority, the Special Agent in Charge may place conditions that the Special Agent in Charge deems proper on the disposal of controlled dangerous substances, including the method of disposal and the frequency and detail of reports.

E. Disposal of Controlled Dangerous Substances by the Federal Drug Enforcement Administration (21 CFR §1307.22). Any controlled dangerous substances delivered to the Federal Drug Enforcement Administration under 21 CFR §1307.21, or forfeited pursuant to §511 of the Federal Act (21 U.S.C. 881), may be delivered to any department, bureau, or other agency of the United States or of any state upon proper application addressed to the Administrator of the Drug Enforcement Administration, Department of Justice, Washington, D.C. The application shall show the name, address, and official title of the person or agency to whom the controlled dangerous substances are to be delivered, including the name and quantity of the substances desired and the purpose for which intended. The delivery of these controlled dangerous substances shall be ordered by the Administrator, if, in the Administrator's opinion, there exists a medical or scientific need for it.

F. Native American Church (21 CFR §1307.31).

(1) The listing of peyote as a controlled dangerous substance in Schedule I under Criminal Law Article, §5-402, Annotated Code of Maryland, does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the Native American Church using peyote in this manner are exempt from registration.

(2) A person who manufactures peyote for, or distributes peyote to, the Native American Church is required to obtain registration every 2 years and to comply with all other requirements of law.

.11 Administrative Functions, Practices, and Procedures.

A. Administrative Inspections.

(1) Procedures regarding administrative inspections and warrants pursuant to Criminal Law Article, §§5-305, 5-804, and 5-805, Annotated Code of Maryland, are governed generally by those sections of the Annotated Code and specifically by this regulation.

(2) Authority to Make Inspections. In carrying out the Secretary's functions under the Act, the Secretary, through the Department's inspectors, is authorized in accordance with Criminal Law Article, §§5-804—5-805, Annotated Code of Maryland, to enter controlled premises and conduct administrative inspections for the purpose of all of the following:

(a) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made under the Act and the regulations promulgated under the Act, including inventory and other records required to be kept pursuant to Regulation .05, order form records required to be kept pursuant to Regulation .06, prescription and distribution records required to be kept pursuant to Regulation .07, shipping records identifying the name of each carrier used and the date and quantity of each shipment, and storage records identifying the name of each warehouse used and the date and quantity of each storage;

(b) Making a physical inventory of all controlled substances on hand at the premises;

(c) Collecting samples of controlled dangerous substances or precursors (if samples are collected during an inspection, the inspector shall issue a receipt for these samples to the owner, operator, or agent in charge of the premises);

(d) Checking of records and information on distribution of controlled dangerous substances by the registrant as they relate to total distribution of the registrant (i.e., has the distribution in controlled dangerous substances increased markedly within the past year, and if so, why);

(e) Except as provided in Criminal Law Article, §5-805(f), Annotated Code of Maryland, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to above or otherwise bearing on the provisions of the Act and the Regulations under it.

(3) Entry.

(a) An inspection shall be carried out by an inspector.

(b) An inspector shall have the right to enter the premises and conduct inspections at reasonable times and in a reasonable manner, upon the following conditions:

(i) Stating the inspector's purpose; and

(ii) Presenting to the owner, operator, or agent in charge of the premises to be inspected, appropriate credentials and written notice of the inspector's inspection authority under Criminal Law Article, §5-305, 5-804, or 5-805, Annotated Code of Maryland.

(4) Consent to Inspection of Financial Data; Sales Data other than Shipment Data; or Pricing Data.

(a) If inspection is desired of financing, sales, or pricing data, written consent shall first be obtained from the owner, operator, or agent in charge of the premises to be inspected.

(b) This written consent shall contain the following information:

(i) That the owner, operator, or agent in charge has the right to refuse to consent to an inspection of these items;

- (ii) That anything of an incriminating nature which may be found may be seized and used against the owner, operator, or agent in charge in a criminal prosecution;
 - (iii) That the owner, operator, or agent in charge has been presented with a notice of inspection;
 - (iv) That the consent is given by the owner, operator, or agent in charge voluntarily and without threats of any kind; and
 - (v) That the owner, operator, or agent in charge may withdraw the owner's, operator's, or agent in charge's consent at any time during the course of inspection.
- (c) The written consent shall be produced in duplicate and be distributed as follows:
- (i) The original will be retained by the inspector; and
 - (ii) The duplicate will be given to the person inspected.

(5) Administrative Probable Cause. If the judge or magistrate is satisfied that "administrative probable cause", as defined in Criminal Law Article, §5-804(a), Annotated Code of Maryland, exists, the judge or magistrate shall issue an administrative warrant. Administrative probable cause does not mean criminal probable cause as defined by federal statute or case law.

(6) Execution of Warrants. An administrative inspection warrant shall be executed and returned as required by, and any inventory or seizure made shall comply with the requirements of Criminal Law Article, §5-804(d), Annotated Code of Maryland.

(7) Refusal to Allow Inspection with an Administrative Warrant. If a registrant or any person subject to the Act refuses to permit execution of an administrative warrant, or impedes the inspector in the execution of that warrant, the registrant or person shall be advised that this refusal or action constitutes a violation of Criminal Law Article, §5-902(a)(3), Annotated Code of Maryland.

B. Enforcement Proceedings.

(1) Authority for Enforcement Proceeding. A hearing may be ordered or granted by the Secretary, at the Secretary's discretion, to permit any person against whom criminal or civil action is contemplated under the Controlled Dangerous Substances Act an opportunity to present the individual's views and the individual's proposals for bringing the individual's alleged violations into compliance with the law. The hearing will also permit the individual to show cause why prosecution should not be instituted, or to present the individual's views on the contemplated proceeding.

(2) The rules of procedure for hearings before the Secretary of the Department of Health and Mental Hygiene shall be governed by COMAR 10.01.03 and State Government Article, §§10-201—10-226, Annotated Code of Maryland.

C. Administrative Hearings. Procedures for administrative hearings shall be governed by the rules set forth in Criminal Law Article, §5-308, Annotated Code of Maryland, if applicable; Health-General Article, §2-207, and State Government Article, §§10-201—10-226, Annotated Code of Maryland; and COMAR 10.01.03.

.12 Physical Security Controls for Registrants.

A. General.

(1) All applicants and registrants shall provide effective controls and procedures to guard against theft and unlawful diversion of controlled substances. In order to determine whether a registrant or applicant has provided protective controls against theft and unlawful diversion, the Department shall use the security requirements set forth in §B of this regulation and 21 CFR §§1307.71—1301.77 as standards for physical security controls and operating procedures necessary to prevent theft and unlawful diversion.

(2) Substantial Compliance. Substantial compliance with the standards set forth in §B of this regulation and 21 CFR §§1301.71—1301.77 may be deemed sufficient by the Department after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall systems of a registrant or applicant, the Department may consider any or all of the following factors as relevant to the need for strict compliance with security requirements of §B of this regulation and 21 CFR §§1301.71—1301.77:

- (a) The type of activity conducted (e.g. packaging, labeling, cooperative buying);
- (b) The type and form of controlled drug substances handled (e.g. bulk liquids, powders);
- (c) The quantity of controlled drug substances handled;
- (d) The location of the prescription department as it may be affected by security problems;
- (e) The type of vault, safe, and secure enclosures or other storage system used for controlled dangerous substances;
- (f) The type of locking mechanisms on areas to be secured;
- (g) The adequacy of control over access to locked enclosures containing controlled dangerous substances;
- (h) The extent of unsupervised public access to the prescription department;
- (i) The adequacy of supervision over employees having access to the prescription department;
- (j) The procedures for handling business agents, visitors, maintenance personnel, and nonemployee maintenance personnel, who may have need to enter the prescription department area at a pharmacy;
- (k) The adequacy of the registrant's system for monitoring the receipt, distribution, dispensing, and disposition of controlled drug substances in its operations; or
- (l) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources.

(3) Any registrant desiring to determine whether a proposed security system substantially complies with the requirements set forth in §B of this regulation may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the Department of Health and Mental Hygiene, Division of Drug Control.

B. Security Controls for Registrants.

(1) Controlled drug substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(2) Controlled dangerous substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners (as defined in

Regulation .07B(2) may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled dangerous substances.

(3) The registrant may not knowingly employ as an agent or employee any person who has had an application for registration currently denied or has had a registration revoked, at any time, if this agent or employee will have access to controlled substances.

(4) The registrant shall notify the regional office of the Drug Enforcement Administration, and the Department of Health and Mental Hygiene, Division of Drug Control, of the theft or significant loss of any controlled drug substances upon discovery of a loss or theft. The registrant shall also complete DEA form 106 regarding a loss or theft.

(5) Only practitioners, duly registered pharmacists, pharmacy students, or other duly authorized personnel are allowed to participate in the handling or dispensing of controlled dangerous substances.

(6) Each pharmacy handling controlled dangerous substances shall have a specific area with clearly designated boundaries as the prescription department area. Only duly registered pharmacists, pharmacy students, or other personnel specifically authorized by the registrant shall be allowed to enter the area designated as the prescription department area.

C. This regulation shall also apply to nonpractitioners authorized to conduct research or chemical analysis under other registration.