

**DISTRICT OF COLUMBIA
MUNICIPAL
REGULATIONS FOR
PHARMACY FACILITIES,
MANUFACTURERS,
DISTRIBUTERS**

**TITLE 22.
CHAPTERS 4, 10, 11, 12, 13, 15, 19**

**DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 4. DRUG MANUFACTURE AND DISTRIBUTION**

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400. GENERAL PROVISIONS

- 400.1 This chapter sets forth the procedures governing the licensure, registration and operation of drug manufacturers, distributors or wholesalers.
- 400.2 The rules in this chapter shall not apply to the distribution and sale of blood and blood products.
- 400.3 All in-state drug manufacturers, distributors, or wholesalers shall be licensed pursuant to Section 401 of this chapter. All out-of-state drug manufacturers, distributors, or wholesalers shall be registered pursuant to Section 404 of this chapter.

401. APPLICATION FOR IN STATE LICENSURE

- 401.1 No person, with the exception of an out-of state drug manufacturer, distributor, or wholesaler, duly registered under Sections 404 and 405, may engage in the manufacture, distribution, or wholesale of any drug until the application for licensure has been approved and a license issued by the Director.
- 401.2 Applications for licensure shall be made on a form prescribed by the Director and shall be accompanied by the required fee.
- 401.3 The application shall include the following information:
- (a) The name and all trade or business names of the applicant and the address and telephone number of the place of business for which the applicant seeks a license;
 - (b) The name, address, and telephone number of contact personnel for all facilities used by the applicant for the storage, handling, and distribution of drugs;
 - (c) The type of ownership or operation (i.e., partnership, corporation, joint venture, or sole proprietorship);
 - (d) If the applicant is a corporation, the name and address of each officer or director of the corporation and each stockholder who owns 10% or more of any 1 class of stock in the corporation or who owns 10% or more of the total stock of the corporation, and the name of the state of incorporation if other than the District of Columbia;
 - (e) If the applicant is a partnership or joint venture, the name and address of each partner or joint venturer. If a partner or joint venturer is a corporation, any information required pursuant to paragraphs (c) and (l) of this Section shall be produced by the partner or joint venturer;
 - (f) If the applicant is a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
 - (g) A description of the manufacturing, wholesaling or distribution activity for which the applicant seeks a license;

- (h) A list of all drugs that the applicant proposes to manufacture, distribute, or wholesale in the District of Columbia;
- (i) Proof of current approval by the United States Food and Drug Administration for registration of producers of drugs and medical devices pursuant to Section 360 of the Federal Food, Drug and Cosmetic Act, approved June 25, 1938 (52 Stat. 1040; 21 U.S.C. 360);
- (j) Proof of current registration with the Director and the United States Drug Enforcement Administration (DEA) if the applicant proposes to manufacture, distribute, or wholesale a controlled substance as defined in Section 802 of the Drug Abuse Prevention and Control Act, approved October 27, 1970 (84 Stat. 1242; 21 U.S.C. 802);
- (k) A valid certificate of occupancy; and
- (l) A certificate of good standing from the Director if the applicant is incorporated in the District of Columbia.

401.4 The Director shall consider the following factors in determining eligibility for licensure:

- (a) Any conviction of the applicant under any Federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
- (b) Any felony convictions of the applicant under Federal, state or local laws;
- (c) The applicant's past experience in the manufacture, distribution, or wholesale of drugs, including controlled substances;
- (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
- (e) Suspension or revocation by Federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(f) Compliance with licensing requirements under previously granted licenses, if any;

(g) Compliance with requirements to maintain and make available to District officials those records required under this chapter; and

(h) Any other factors or qualification the District considers relevant to and consistent with the public health and safety.

401.5 The Director shall require a separate license for each facility directly or indirectly owned or operated by the same business.

401.6 The Director shall have the right to deny a license to an applicant if it is determined that granting of such a license would not be consistent with the public health, safety and welfare.

401.7 The license must be posted in a conspicuous place in the facility to which it is issued.

402. RENEWAL OF LICENSE

402.1 The Director shall mail a renewal notice to a licensee by first class mail to the licensee's last known address on file with the Director at least forty-five (45) calendar days prior to the expiration of the license. The notice shall specify the expiration date.

402.2 The failure of a licensee to receive the renewal notice required by this section does not relieve the licensee of the responsibility of renewing the license by the expiration of the existing license.

402.3 If the Director does not receive the application for renewal of a license prior to the date of expiration on the license, the license shall lapse. The license may be reinstated within thirty (30) calendar days of its expiration, upon receipt of a completed renewal application.

402.4 The appropriate renewal fee shall accompany the application for renewal.

402.5 Any information the Director deems appropriate or necessary to renew the license since the initial application shall be mailed with the renewal notice.

403. CONDITIONAL LICENSE

403.1 The Director may issue a license with specific conditions that are stated on the

license.

403.2 The expiration license date, if any, of each condition shall be specified on the license.

403.3 The Director may revoke the license, if the Director determines that any of the conditions have been violated.

404. APPLICATION FOR OUT-OF-STATE REGISTRATION

404.1 An out-of-state drug manufacturer, distributor, or wholesaler who conducts distribution activities within the District of Columbia shall be required to register with the Director.

404.2 No person required to be registered shall conduct distribution activities within the District of Columbia until the application for registration is issued and a Certificate of Registration is issued by the Director.

404.3 Applications for registration shall be made on a form prescribed by the Director and shall be accompanied by the required fee.

404.4 The registrants shall submit the following information:

(a) Completed registration form provided by the Director;

(b) A certificate of good standing in the state where incorporated or where the principal place of business is located;

(c) Proof of current approval by the United States Food and Drug Administration for registration of producers of drugs and medical devices pursuant to Section 360 of the Federal Food, Drug and Cosmetic Act, approved June 25, 1938 (52 Stat. 1040; 21 U.S.C. 360);
and

(d) Proof of current registration with the United States Drug Enforcement Administration for controlled substances, where applicable.

404.5 The Director shall require a separate registration for each facility directly or indirectly owned or operated by the same business.

404.6 The Director may require a registrant to submit documentation or written statements in support of an application. The Director may deny an application if the registrant fails to provide the requested information within fifteen (15)

business days of receipt of the Director's request.

405. RENEWAL OF REGISTRATION FOR-OUT-OF-STATE DRUG MANUFACTURERS, DISTRIBUTORS, REPACKAGERS, AND WHOLESALERS

405.1 The Director shall mail a renewal notice to an out-of-state registrant by first class mail to the registrant's last known address on file with the Director at least forty-five (45) calendar days prior to the expiration of the registration.

405.2 The failure of a registrant to receive the renewal notice required by this section does not relieve the registrant of the responsibility of renewing the registration in a timely manner.

405.3 The appropriate renewal fee shall accompany the application for renewal.

405.4 A registration shall lapse if the application for renewal of the registration is not received prior to the date of expiration on the registration. The registration may be reinstated within thirty (30) calendar days of its expiration, upon receipt of a completed renewal application. If the registration lapses, the fee to reinstate the registration shall accompany the application for registration.

406. EXEMPTIONS

406.1 The following shall be exempt from licensure and registration:
(a) Manufacturers' representatives that distribute drug samples;

(b) Distributors' representatives that distribute drug samples;

(c) Group purchasing organizations established to maintain and to operate for the purchase of drugs for distribution exclusively to its members;

(d) Intracompany distribution of products, namely to retail stores that are under common ownership or within the same corporate structure; and

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for "emergency medical reasons" which includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

407. PERSONNEL

- 407.1 A pharmacist licensed in the District of Columbia or an individual approved by the Director as having scientific or technical training or experience to perform the duties required to ensure that the licensed activity is conducted in a manner that will protect the public health and safety shall supervise all personnel engaged in the manufacturing activities.
- 407.2 Each person employed in any drug wholesale distribution activity shall have education, training, and experience to ensure an acceptable level of proficiency to perform assigned functions and provide assurance that the drug product quality, safety and security will be maintained at all times.
- 407.3 Licensees shall establish and maintain a list of officers, directors, managers and other personnel in charge of manufacturing, wholesale drug distribution, storage, and handling. The list shall include a description of their duties and a summary of their qualifications.

408. SECURITY

- 408.1 All facilities used for manufacturing and wholesale drug distribution shall be secure from unauthorized entry.
- (a) Access from outside the premises shall be kept to a minimum and be well-controlled.
- (b) The outside perimeter of the premises shall be well-lighted.
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- 408.2 All facilities shall be equipped with an alarm system to detect entry after hours.
- 408.3 All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

409. WRITTEN POLICIES AND PROCEDURES

- 409.1 Licensees shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory and distribution of drugs. Written policies shall include the following:

(a) Procedures for identifying, recording, and reporting losses and thefts;

(b) Procedures for identifying, recording, and reporting losses and thefts;

(c) Procedures whereby the oldest approved stock of a drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate;

(d) Procedures to be followed for handling recalls and withdrawals of drugs. Such procedures shall ensure that all drugs included on the recall and/or withdrawal, are returned for proper disposition due to:

(1) An action initiated at the request of the Food and Drug Administration or other Federal, state, or local law enforcement or other government agency, including the Director;

(2) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(3) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(e) Procedures to ensure that licensees prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(f) Procedures to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

410. SALVAGING AND REPROCESSING

410.1 All facilities licensed pursuant to this chapter shall be in compliance with applicable provisions of Federal, state or local laws or regulations relating to drug product salvaging or reprocessing.

411. EXAMINATION OF MATERIALS

411.1 Manufacturers, distributors and wholesalers upon receipt, of each incoming

shipping container shall carefully inspect all shipments of drugs to determine their identity and to prevent the acceptance of contaminated drugs unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

- 411.2 Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

411. EXAMINATION OF MATERIALS

- 411.1 Manufacturers, distributors and wholesalers upon receipt, of each incoming shipping container shall carefully inspect all shipments of drugs to determine their identity and to prevent the acceptance of contaminated drugs unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

- 411.2 Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

412. LABELING, HANDLING, STORAGE, AND RECORDKEEPING STANDARDS

- 412.1 Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to their supplier.
- 412.2 Any drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to their supplier.
- 412.3 If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug supplier shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

- 412.4 All facilities at which drugs are stored, warehoused, handled, held, offered, marketed or displayed shall meet the following minimum requirements:
- (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, adulterated, or that are in sealed, secondary containers that have been opened;
 - (d) Be maintained in a clean and orderly condition; and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- 412.5 All drugs shall be stored at appropriate temperatures and under conditions in accordance with requirements, if any, in the labeling of such drugs, or according with the requirements in the current edition of an official compendium.
- (a) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected; and
 - (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.
- 412.6 Manufacturers, wholesaler, and distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records shall include the following information:
- (a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
 - (b) The identity and quantity of the drugs received and distributed or disposed of; and
 - (c) The dates of receipt and distribution or other disposition of the drugs.

- 412.7 Inventories and records shall be made available for inspection and photocopying by the Director for a period of two (2) years following disposition of drugs.
- 412.8 Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for inspection during the retention period. Records kept at a central location apart from the inspection site and are not electronically retrievable shall be made available for inspection within two (2) business days of a request by the Director.

413. INSPECTIONS

- 413.1 The Director shall conduct an on-site inspection of an applicant's facility before a license is granted.
- 413.2 Applicants and licensees shall permit the Director or any authorized District official to enter and inspect their premises and delivery vehicles, and audit their records and operating procedures at any reasonable hour and in a reasonable manner.
- 413.3 Applicants and licensees shall permit the Director to have access to all records, policies and procedures, contracts, and any other information that the Director deems necessary to determine if the facility is in compliance with the Act, rules issued pursuant to the Act, or any other District law or Federal law applicable to the manufacture, distribution, or wholesale of drugs.
- 413.4 The Director shall send a written report of the findings of the inspection to the applicant or licensee no later than fifteen (15) working days after the conclusion of the inspection.
- 413.5 If the report states that there are deficiencies, the applicant or licensee shall correct them within the time period required by the Director.
- 413.6 The Director may request written proof of correction of all deficiencies and may conduct a follow-up inspection to determine correction of the deficiencies after the applicant or licensee notifies the Director that the deficiencies have been corrected.
- 413.7 The Director may deny or revoke a license if the deficiencies have not been corrected within the time period specified by the Director pursuant to Section 414 of this chapter. The applicant may reapply for a license after the deficiencies are corrected by submitting a new application and fee in accordance with this chapter.

414. SUSPENSION, DENIAL, REVOCATION OF LICENSE

- 414.1 The Director shall take action to deny, suspend, or revoke a license, or convert the license to a conditional license, subject to the right of a hearing as provided, by this chapter.
- 414.2 Grounds for suspension, revocation, denial or refusal to renew a license include but are not limited to the following:
- (a) Violation or noncompliance with the Act, rules issued pursuant to the Act, or any other applicable Federal or District law;
 - (b) Refusal to allow the Director or a duly authorized agent access to the facility for the purpose of determining compliance with the Act, or rules issued pursuant to the Act;
 - (c) Willful submission by the licensee of false or misleading information to the Director in connection with an application for licensure;
 - (d) Failure of the licensee to meet and maintain the standards required by the Act, or rules issued pursuant to the Act;
 - (e) Failure to comply with the terms of a plan to correct deficiencies submitted to the Director or other agreement with the Director; or
 - (f) Failure of the licensee to obey any lawful order of the Director issued pursuant to this chapter.
- 414.3 The Director shall revoke any license issued pursuant to the Act upon conviction of the licensee of a criminal violation of the Act, rules issued pursuant to the Act, or any applicable District or Federal law.
- 414.4 Once a license has been revoked or suspended, the licensee cannot distribute drugs in the District.
- 414.5 Upon service of the order of the Director suspending or revoking licensure, the licensee shall immediately deliver the certificate of licensure to the Director.
- 414.6 Upon suspension or revocation of a license, all controlled substances in the possession of the licensee shall be placed under seal.

414.7 No disposition may be made of controlled substances under seal unless the time for filing an appeal has elapsed or until all appellate remedies have been exhausted, unless a court orders the sale of perishable substances and the proceeds of the sale are deposited with the court.

414.8 The Director shall promptly notify the United States Drug Enforcement Administration of all orders suspending or revoking licensure and all forfeitures of controlled substances.

415. WITHDRAWAL OF REGISTRATION

415.1 The Director may withdraw registration of a registrant who is not licensed or registered in the state in which they are physically located, or in good standing under Federal law or the laws of state in which incorporated.

415.2 The Director shall give written notice to the applicant citing the basis for withdrawal. The effective date of withdrawal shall be ten (10) calendar days from the date of service of the notice, or immediately, in case of danger to the public health, safety or welfare.

415.3 The notice shall state that registration shall be automatically withdrawn unless, prior to the effective date, registrant submits official proof satisfactory to the Director of a license in good standing.

415.4 A registrant can reinstate registration by submitting official proof of compliance with Federal or state licensure or registration cited in the notice of withdrawal.

415.5 Once a registration has been withdrawn, a registrant cannot distribute drugs in the District.

416. OPPORTUNITY FOR A HEARING

416.1 The Director shall take action to deny, suspend, or revoke a license, or convert the license to a conditional license pursuant to Section 11 of the Act, D.C. Code § 33-1010.¹

416.2 Except for summary suspension undertaken pursuant to Section 10 of the Act, D.C. Code § 33-1009(a),² every applicant for or holder of a license or applicant for reinstatement after revocation shall be afforded notice and an

¹ D.C. Code § 33-1010 is now cited as D.C. Official Code § 48-710 (2001).

² D.C. Code § 33-1009(a) is now cited as D.C. Official Code § 48-709(a) (2001).

opportunity to be heard prior to the action of the Director, the effect of which would be one of the following:

- (a) To deny a license for good cause other than failure to meet the licensing requirements set forth in the Act and this chapter;
- (b) To suspend a license;
- (c) To revoke a license;
- (d) To refuse to reinstate a license;
- (e) To convert the license to a conditional license;
- (f) To refuse to issue a renewal license for any good cause other than failure to pay the prescribed fees;
- (g) Impose a civil fine pursuant to the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, D.C. Code Section 6-2701 et seq.;³ or
- (h) Reinstatement of the license.

417. NOTICE OF PROPOSED ACTION

417.1 When the Director proposes to deny a license for failure to meet the requirements of the Act or this chapter, the applicant shall be given written notice containing the following statements:

- (a) That the applicant has failed to satisfy the Director as to the applicant's qualifications;
- (b) The respect in which the applicant has failed to satisfy the Director;
- (c) That the denial will become final unless the applicant files a request for a hearing with the Director within fifteen (15) calendar days of the receipt of the notice; and
- (d) A description of the rights of the applicant at a hearing as specified in Section 423 of this chapter.

417.2 When the Director proposes to take any action of the type specified in Sections 416.2(a), (b), (c), (d), (e), or (f) of this chapter, the licensee shall be given a written notice containing the following statements:

³ D.C. Code § 6-2701 et seq. is now cited as D.C. Official Code § 2-1801.01 et seq. (2001)

(a) That the Director has sufficient evidence which, if not rebutted or explained, justifies the Director in taking the proposed action;

(b) That the Director may take the proposed action, unless within fifteen (15) calendar days of the receipt of the notice the respondent files with the Director a written request for a hearing or in the alternative submits documentary evidence for the Director's consideration before the Director takes final action; and

(c) A description of the rights of the licensee at a hearing as specified in Section 423 of this chapter.

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417.1 When the Director proposes to deny a license for failure to meet the requirements of the Act or this chapter, the applicant shall be given written notice containing the following statements:

(a) That the applicant has failed to satisfy the Director as to the applicant's qualifications;

(b) The respect in which the applicant has failed to satisfy the Director;

(c) That the denial will become final unless the applicant files a request for a hearing with the Director within fifteen (15) calendar days of the receipt of the notice; and

(d) A description of the rights of the applicant at a hearing as specified in Section 423 of this chapter.

417.2 When the Director proposes to take any action of the type specified in Sections 416.2(a), (b), (c), (d), (e), or (f) of this chapter, the licensee shall be given a written notice containing the following statements:

(a) That the Director has sufficient evidence which, if not rebutted or explained, justifies the Director in taking the proposed action;

(b) That the Director may take the proposed action, unless within fifteen (15) calendar days of the receipt of the notice the respondent files with the Director a written request for a hearing or in the alternative submits documentary evidence for the Director's consideration before the Director takes final action; and

(c) A description of the rights of the licensee at a hearing as specified in Section 423 of this chapter.

418. NOTICE OF HEARING

- 418.1 Any notice required by this chapter may be served either personally or by certified mail, return receipt requested, directed to the respondent at his or her last known address as shown by the records filed with the Director by the respondent.
- 418.2 If the notice is served personally, it shall be deemed to have been served at the time delivery is made to the respondent.
- 418.3 If the notice is served by certified mail, it shall be deemed to have been served on the date shown on the return receipt showing delivery or refusal of the respondent to receive notice.
- 418.4 In the event the respondent is no longer at the last known address as shown by the records filed with the Director and no forwarding address is available, the notice shall be deemed to have been served on the date the return receipt bearing such notification is received by the Director.
- 418.5 If a respondent scheduled for a hearing does not appear and no continuance has been or is granted, the Director may hear the evidence of those witnesses present, and the Director may proceed to consider the matter and render a decision on the basis of the evidence presented.

419. PROCEDURE WHEN A RESPONDENT FAILS TO RESPOND TO A HEARING NOTICE

- 419.1 If the respondent does not respond to the hearing notice within the time specified, the Director may, without a hearing, take the action proposed in the notice. The Director shall, in writing, inform the respondent and the Corporation Counsel of his or her action.

420. HEARINGS-SUMMARY SUSPENSION

- 420.1 A respondent who has been summarily suspended pursuant to Section 10 of the Act, D.C. Code § 33-1009⁴ shall be notified in writing of the action being taken and that the licensee is entitled to a hearing, upon written request within three (3) calendar days of the service of the notice.
- 420.2 The Director shall hold a hearing within three (3) calendar days of receipt of a timely request and shall issue a decision within three (3) calendar days of the

⁴ D.C. Code § 33-1009 is now cited as D.C. Official Code § 48-709 (2001).

hearing.

420.3 If a hearing is requested pursuant to this section, the request shall not serve to stay the issuance of an order suspending, revoking, or converting the license.

421. HEARINGS-CEASE AND DESIST ORDERS

421.1 The Director may issue a cease and desist order when a hazardous condition exists that may endanger the health, safety, or welfare of the community.

421.2 The violator shall be notified in writing to cease operations immediately and that the violator is entitled to appeal the cease and desist order.

421.3 A person subject to a cease and desist order may request a hearing within seven (7) business days, after service of the order but shall be required to comply with the order, pending appeal.

421.4 The Director shall hold a hearing within seven (7) calendar days of a receipt of a timely request and issue a decision within seven (7) calendar days after the hearing.

422. EMBARGO

422.1 If the Director determines that a drug is adulterated or misbranded, the Director may order that the drug be removed from availability for distribution, sale, consumption, or use, or that the drug be destroyed or embargoed.

422.2 A person subject to an embargo shall be notified in writing of the action being taken and the basis of the action.

422.3 Whenever a drug is embargoed the Director shall order the drug be segregated and isolated from other drug products, affixed with a tag or other appropriate marking giving notice that the drug is, or is suspected of being, adulterated or misbranded.

422.4 The Director may continue to order the embargo of the drug until a sample has been analyzed by a qualified person designated by the Director.

422.5 If the Director determines that an embargoed drug is not adulterated or misbranded, he shall notify the person subject to the embargo that the tag or other marking may be removed.

422.6 If the Director determines that an embargoed drug is adulterated or

misbranded the Director shall order that the drug be permanently removed from availability for distribution, sale, consumption, or use in the District of Columbia, or that the drug be destroyed.

422.7 It is unlawful for any person to remove or dispose of a drug that has been embargoed without permission from the Director.

423. CONDUCT OF HEARINGS

423.1 All hearings before the Director shall be open to the public.

423.2 The Director, or his or designee, shall hear the evidence and render a decision.

423.3 A respondent entitled to a hearing shall have the following rights:

(a) To be represented by counsel or other representative;

(b) To present all relevant evidence by means of witnesses, books, papers, documents and other relevant materials;

(c) To cross-examine all opposing witnesses on any matter relevant to the issues; and

(d) To have subpoenas issued, upon written request to the Director, to compel the attendance of witnesses and the production of relevant books, papers, documents, and other relevant materials

423.4 In conducting a hearing pursuant to this chapter, the Director is authorized to do the following:

(a) Administer oaths or affirmation to witnesses called to testify pursuant to Section 3 of D.C. Law 3-109, D.C. Code Section 1-338.1 (1987)⁵;

(b) Subpoena respondents, witnesses, books, papers, documents and other materials pursuant to Section 3 of D.C. Law 3-109, D.C. Code Section 1-338 (1987)⁶;

(c) Take testimony;

(d) Examine witnesses;

⁵ D.C. Code Section 1-338.1 (1987) is now cited as D.C. Official Code § 1-301-22 (2001).

⁶ D.C. Code Section 1-338 (1987) is now cited as D.C. Official Code § 1-301-21 (2001).

- (e) Order a continuance;
- (f) Enter into a consent agreement; and
- (g) Render a decision.

423.5 The Director shall receive and consider any evidence or testimony; however, the Director may exclude irrelevant, immaterial, or unduly repetitious evidence or testimony;

423.6 In any proceeding resulting from the Director's proposed action to deny licensure, the applicant shall have the burden of satisfying the Director of the applicant's qualifications.

423.7 In any proceeding resulting from the Director's proposed action (a) to refuse to renew or reinstate a license; or (b) to suspend, revoke or convert the license to a conditional license, the Director shall have the burden of proving that the action should be taken.

423.8 A complete record shall be made of all evidence presented during the course of the hearing. Any party to the proceedings, or his or her attorney of record, shall be furnished with a copy of the record upon request and payment of a fee prescribed by the Director.

424. DECISIONS

424.1 The decision of the Director shall include the following:

- (a) Findings of fact;
- (b) Conclusions of law; and
- (c) A statement informing the respondent of the right to have the decision reviewed by the Board of Appeals and Review, and the time period within which the request for such a review must be filed.

424.2 The Director shall serve upon the respondent, or his or her attorney of record, a copy of the written decision, either by personal service or certified mail, return receipt requested. If served by certified mail, it shall be deemed served on the date contained on the return receipt for acceptance or refusal, or the date of the unsuccessful attempt by the United States Postal Service to make delivery.

425. ADMINISTRATIVE AND JUDICIAL REVIEW

- 425.1 When a respondent fails, for good cause, to appear for a hearing which has been scheduled, the respondent may, within thirty (30) days from the date of the decision, apply to the Director to reopen the proceedings. The Director, upon finding the cause sufficient, may fix a time and place for the hearing and shall give notice to the parties.
- 425.2 The Director may reopen a proceeding for any cause deemed sufficient, provided that no appeal is pending or no decision has been issued regarding the case by the Board of Appeals and Review or any Federal or local court.
- 425.3 A respondent aggrieved by an adverse decision by the Director may seek a review of the decision by the Board of Appeals and Review according to its rules, as specified in Chapter 5 of Title 1 DCMR.
- 425.4 A respondent adversely affected by the decision of the Board of Appeals and Review may seek a review of the decision by the District of Columbia Court of Appeals according to the rules prescribed by the Court.
- 425.5 Within the time set by Court rule or order, the Director shall certify and file with the Clerk of the Court the record of the case as required by the Court.

425-426 [RESERVED]**§ 22-499. DEFINITIONS**

499.1 When used in this chapter, the following words or phrases shall have the meaning ascribed:

ACT - the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, D.C. Law 8-137, D.C. Code § 33-1001 et seq.⁷

CONDITIONAL LICENSE - a license issued pursuant to specific conditions.

CONTROLLED SUBSTANCE - a drug, substance, or immediate precursor, as defined under D.C. Code § 33-501 et seq.⁸

DEPARTMENT - the Department of Consumer and Regulatory Affairs.

⁷ D.C. Code § 33-1001 is now cited as D.C. Official Code § 48-701 et seq. (2001).

⁸ D.C. Code § 33-501 et seq. is now cited as D.C. Official Code § 48-901.02 et seq. (2001).

DIRECTOR - the Director of the Department of Consumer and Regulatory Affairs or a designee.

DISTRIBUTE - to negotiate a sale or sell any drug for resale; or to act as a broker, agent, distributor, jobber, or wholesaler of any drug.

DRUG - any substance as defined under D.C. Code § 2-2002(3).⁹

MANUFACTURE - to prepare, produce, propagate, compound, convert, process, or package a drug, either directly or indirectly, by extraction from a substance of natural origin, or independently by means of chemical synthesis; any packaging or repackaging of the substance or drug; labeling or relabeling of any drug package or container to further distribution from the original place of manufacture to the person who makes final delivery, distribution, or sale to the ultimate consumer or user. Does not include the preparation or compounding of a drug by a pharmacist, practitioner, or any other authorized person who prepares or compounds a drug incidental to administering or dispensing a drug or conducting research, teaching, or chemical analysis on a drug in the course of professional practice.

WHOLESALER - any person, including but not limited to, a manufacturer, repackager, own-label distributor, jobber, broker, agent, pharmacy, private label distributor, distributor warehouse, wholesale drug warehouse, independent wholesale drug trader, chain drug warehouse, retail pharmacy, or pharmacy that sells more than 5% of its drug inventory to a hospital or other pharmacy, which distributes a drug to a person other than a consumer or patient.

⁹ D.C. Code § 2-2002(3) is now cited as D.C. Official Code § 47-2885.02(3) (2001).

DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 10. REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND
DISPENSERS

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- 1000. Applications For Registration
 - 1004. Time And Method Of Payment/Refund
 - 1005. Persons Exempt From Registration Fee
 - 1006. Separate Registration For Independent Activities
 - 1007. Separate Registration For Separate Locations
 - 1008. Exemption Of Agents And Employees: Affiliated Practitioners
 - 1009. Modification, Transfer And Termination Of Registration
 - 1010. Certificate Of Registration
 - 1011. Procedural Rights Involving Suspension Or Revocation
 - 1012. Suspension Or Revocation Of Registration
 - 1013. Suspension Of Registration Pending Final Order
 - 1014. Extension Of Registration
 - 1015. Address For Notices
 - 1016. Violations
 - 1017. Failure To Comply With Rules
 - 1018-1029 [Reserved]
 - 1030. Controlled Substances Fees
 - 1099. Definitions
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1000. COVERAGE

- 1000.1 The rules in this chapter contain the procedures governing the registration and regulation of manufacturers, distributors, and dispensers of controlled substances pursuant to Title III of the District of Columbia Uniform Controlled Substances Act of 1981 (D.C. Law 4-29, effective August 5, 1981, §§ 33-501 through 33-567, D.C. Code, 1981 ed.)¹⁰, hereinafter referred to as the "Act."
- 1000.2 To the extent consistent with the Act (§§ 33-501 through 33-567), D.C. Code, 1981 ed.¹¹, regulations promulgated by the Federal Government pursuant to Title 21, Chapter II, of the Code of Federal Regulations (21 CFR Part 1300 to End), and in effect as of the effective date of this subtitle, shall be used as a guide in administering the law.

¹⁰ The District of Columbia Uniform Controlled Substances Act of 1981 §§ 33-501 through 33-567, D.C. Code, 1981 "Act" is now cited as D.C. Official Code § 48-901.02 et seq. (2001)

¹¹ The District of Columbia Uniform Controlled Substances Act of 1981 §§ 33-501 through 33-567, D.C. Code, 1981 "Act" is now cited as D.C. Official Code § 48-901.02 et seq. (2001)

1001. SCHEDULES OF CONTROLLED SUBSTANCES

- 1001.1 The Department shall propose annually, the schedules of controlled substances consistent with the criteria for each schedule as specified under the Act.
- 1001.2 In proposing the schedules of controlled substances, the Department shall adopt the designations, reschedulings, additions and deletions as determined by federal law or regulation, unless otherwise contraindicated for the District of Columbia.
- 1001.3 The Department shall submit annual proposed schedules of controlled substances to the Mayor for Council approval.
- 1001.4 Pursuant to § 206(a)(1) of D.C. Law 4-29, "The District of Columbia Uniform Controlled Substances Act of 1981," Sufentanil Citrate shall be added to the Schedule II list of controlled substances and shall be designated as "(R)."
- 1001.5 Pursuant to § 212 of D.C. Law 4-29, the "District of Columbia Uniform Controlled Substances Act of 1981", Loperamide shall be deleted from the Schedule V list of controlled substances.

1002. PERSONS REQUIRED TO REGISTER

- 1002.1 Every person who manufactures, distributes, dispenses, or conducts research with any controlled substance, or who proposes to engage in the manufacture, distribution, dispensing, or conducting of research with any controlled substance within the District of Columbia shall obtain annually a registration issued by the Director in accordance with the rules of this subtitle, unless exempted by federal or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.
- 1002.2 Persons conducting manufacturing activities of controlled substances outside of the District of Columbia and doing business within the District of Columbia shall obtain annually a registration in accordance with the rules of this subtitle, unless exempted by federal or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.
- 1002.3 Out-of-state persons conducting distributing activities of controlled substances to persons within the District of Columbia shall obtain annually a registration in accordance with the rules of this subtitle, unless exempted by federal or District of Columbia law or pursuant to §§ 1002.4 and 1002.5 of this chapter.
- 1002.4 Only persons actually engaged in the activities cited under §§ 1002.1 through 1002.3 are required to obtain a registration; related or affiliated persons who are not engaged in the activities cited in §§ 1002.1 through 1002.3 are not

required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration).

1002.5 Persons described in § 302(c) of the Act need not register and may lawfully possess controlled substances under this chapter.

1002.6 Persons requesting waiver of the requirement for registration pursuant to § 302(d) of the Act shall make the request in writing to the Director.

1003. APPLICATIONS FOR REGISTRATION

1003.1 Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Director.

1003.2 Any person who is registered may apply to be re-registered not less than sixty (60) days before the expiration date of his or her current registration. A registered person who fails to file for re-registration before the expiration date of his or her registration shall apply for a new registration; the existing registration will expire on the date specified.

1003.3 Applicants shall use registration forms provided by the Department. Forms for registration may be obtained by writing to the Department of Consumer and Regulatory Affairs, Service Facility Regulation Administration, Pharmaceutical and Medical Devices Control Division, 614 H Street, N.W., Room 1016, Washington, D.C. 20001.¹²

1003.4 The appropriate registration fee shall accompany the application.

1003.5 Applications submitted for filing shall be dated upon receipt. Applications which are complete shall be accepted for filing. Applications failing to comply with the requirements set forth in this chapter and the Act shall not be accepted for filing.

1003.6 In the case of minor defects as to completeness, the Director may accept the application for filing with a request to the applicant for additional information.

1003.7 A defective application shall be returned to the applicant within ten (10) days following its receipt with a statement of the reason for not accepting the application for filing.

¹² As of April 2007, the Pharmaceutical Control Division is now located at 717 14th Street, N.W., 6th Floor, Washington, D.C. 20005, 202-724-4900.

- 1003.8 A defective application may be corrected and resubmitted for filing at any time; the Director shall accept for review any application upon resubmission by the applicant.
- 1003.9 Accepting an application for filing does not preclude any subsequent request for additional information pursuant to this chapter and has no bearing on whether the application will be granted.
- 1003.10 The Director may require an applicant to submit the relevant documents or written statements in support of an application. The Director may deny an application if the applicant fails to provide information within fifteen (15) days of receipt of the Director's request.
- 1003.11 An application shall be considered withdrawn if the following occurs:
- (a) The applicant requests its return; or
 - (b) The applicant fails to respond to a registered or certified letter regarding the application within fifteen (15) days of its delivery to the applicant.

1004. TIME AND METHOD OF PAYMENT/REFUND

- 1004.1 Registration and re-registration fees shall be paid at the time the application for registration or re-registration is submitted for filing. Payment shall be made payable to the "District of Columbia Treasurer." If the application is not accepted for filing or is denied, the payment shall be returned to the applicant.

1005. PERSONS EXEMPT FROM REGISTRATION FEE

- 1005.1 The Director shall exempt from payment of a fee for registration or re-registration, any official employee or agency of the District of Columbia who is authorized to do the following:
- (a) To purchase controlled substances;
 - (b) To obtain the substances from official stocks;
 - (c) To dispense or administer the substances; or
 - (d) To conduct research, instructional activities, or chemical analysis with the substances, or any combination thereof, in the course of his or her official duties or employment.

1006. SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES

- 1006.1 The following groups of activities shall be deemed to be independent of each other:
- (a) Manufacturing controlled substances;
 - (b) Distributing controlled substances;
 - (c) Dispensing controlled substances listed in Schedules II through V;
 - (d) Conducting research with controlled substances listed in Schedules II through V;
 - (e) Conducting instructional activities with controlled substances listed in Schedules II through V;
 - (f) Conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV or V; Provided, that employees, agents, or affiliated practitioners in programs need not register separately. Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed shall be registered separately and shall obtain narcotic drugs by use of the federal Drug Enforcement Administration order forms;
 - (g) Conducting research and instructional activities with controlled substances listed in Schedule I;
 - (h) Conducting chemical analysis with controlled substances listed in any Schedule;
 - (i) Importing controlled substances;
 - (j) Exporting controlled substance listed in Schedules I through IV; and
 - (k) Operating as a compounder as defined in § 9900.
- 1006.2 Persons who engage in more than one (1) group of independent activities shall obtain a separate registration for each group of activities.
- 1006.3 Separate registration is not required for persons engaging in research with non-narcotic controlled substances in Schedules II through V where the registrant is already registered under this chapter in another capacity.

- 1006.4 Persons registered under federal law to conduct research with Schedule I substances may conduct research with Schedule I substances within the District of Columbia upon furnishing the Director evidence of that federal registration.
- 1006.5 Compliance by manufacturers and distributors with the provisions of the federal law respecting registration entitles them to be registered under this chapter.
- 1006.6 A person registered or authorized to conduct chemical analysis with controlled substances may do the following;
- (a) Manufacture and import such substance for analytical or instructional purposes; or
 - (b) Distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances.

1007. SEPARATE REGISTRATION FOR SEPARATE LOCATIONS

- 1007.1 A separate registration is required for each principal place of business or professional practice where controlled substances are manufactured, distributed, or dispensed by a person.
- 1007.2 The following locations shall not be deemed to be places requiring separate registration:
- (a) A warehouse where controlled substances are stored by or on behalf of a registered person, unless the substances are distributed directly from the warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of § 302(c) of the Act;
 - (b) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and
 - (c) An office used by a practitioner (who is registered at another location where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the

professional practice of the practitioner at the office, and where no supplies of controlled substances are maintained.

1008. EXEMPTION OF AGENTS AND EMPLOYEES: AFFILIATED PRACTITIONERS

1008.1 The following persons shall be exempt from registration:

(a) An agent or employee of a person who is registered to engage in any group of independent activities, provided the agent or employee is acting in the usual course of his or her business or employment;

(b) An individual practitioner, as defined in § 102(20)(A) of the Act (other than an intern, resident, foreign trained physician or physician who is an agent or employee of the District of Columbia Government), who is an agent or employee of another practitioner registered to dispense controlled substances when acting in the usual course of his or her employment administering and dispensing (other than by issuance of prescription) controlled substances; but only to the extent that the individual practitioner is authorized or permitted to do so by the jurisdiction of the District of Columbia under the registration of the employee or principal practitioner. (For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances if a pharmacy is so registered);

(c) An individual practitioner, who is an intern, resident, or foreign trained physician or a physician who is an agent or employee of the District of Columbia Government, when dispensing, administering and prescribing controlled substances under the registration of a hospital or other institution which is registered and by whom he or she is employed; Provided, that the following occurs:

(1) The dispensing, administering or prescribing is done in the usual course of his or her professional practice;

(2) The individual practitioner is authorized or permitted to do so in the District of Columbia;

(3) The hospital or other institution has verified that the individual practitioner is permitted to dispense, administer, or prescribe drugs within the District of Columbia;

(4) The individual practitioner is acting only within the scope of his or her employment in the hospital or institution;

(5) The hospital or other institution maintains a specific internal code number required by the Federal Drug Enforcement Administration for each intern resident or foreign trained physician so authorized; and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants, law enforcement agencies, and the Director upon request for the purpose of verifying the authority of the prescribing individual practitioner; and

(d) A local or federal law enforcement official, civil defense official or any other person with similar official responsibility as determined by the Director.

1009. MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

- 1009.1 Any registrant may apply to modify his or her registration to authorize the handling of additional controlled substances or to change his or her name or address, by submitting a letter of request to the Pharmaceutical and Medical Devices Control Division, Service Facility Regulation Administration, Department of Consumer and Regulatory Affairs, 614 H Street, N.W., Washington, D.C. 20001.¹³
- 1009.2 The requesting material shall contain the registrant's name, address and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his or her registration or the new name or address and shall be signed by the registrant.
- 1009.3 If a modification of registration is approved, the Director shall issue a new certificate of registration to the registrant, who shall maintain it with the old certificate of registration until expiration.
- 1009.4 The registrant shall notify the Director within seven (7) days of any change of address. The address on file with the Department may be relied upon by the Department in issuing notices required under this chapter.
- 1009.5 The registration of any person shall terminate if and when the person dies,

¹³ As of April 2007, the Pharmaceutical Control Division is now located at 717 14th Street, N.W., 6th Floor, Washington, D.C. 20005, 202-724-4900.

ceases legal existence, or discontinues business or professional practice.

- 1009.6 Any registrant who ceases legal existence or discontinues business or professional practice or who changes ownership of the business or professional practice, shall notify the Director within thirty (30) days of the fact in writing and surrender the current registration.
- 1009.7 Transfer or disposal of any controlled substances shall be the responsibility of the registrant or his or her legal representative.
- 1009.8 A new registration shall be required under the following circumstances:
- (a) If any partners are added or deleted from the partnership;
 - (b) If there is a change in the president or chief executive officer of the corporation; or
 - (c) If there is a change in the ownership of ten percent (10%) or more of the outstanding shares of the corporation.
- 1009.9 No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Director may specifically consent.

1010. CERTIFICATE OF REGISTRATION

- 1010.1 The Director shall issue a Certificate of Registration or Reregistration only when the applicant has met all the requirements of the Act and these rules and the Director has determined pursuant to § 303(a) of the Act that registration would not be inconsistent with the public interest.
- 1010.2 The Certificate of Registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the Schedules, as set forth in Title II of the Act, of the controlled substances which the registrant is authorized to handle, and the expiration date of the registration.
- 1010.3 The registrant shall prominently display the Certificate of Registration at the registered location.

1011. PROCEDURAL RIGHTS INVOLVING SUSPENSION OR REVOCATION

- 1011.1 If it appears to the Director that an application for registration should be

denied or that an existing registration should be suspended or revoked, the Director shall notify the applicant or registrant of the proposed denial, suspension, or revocation, briefly stating the reasons therefore and shall provide the applicant or registrant with an opportunity for a hearing in accordance with § 305 of the Act and chapter 11 of this subtitle.

1012. SUSPENSION OR REVOCATION OF REGISTRATION

- 1012.1 The Director may suspend or revoke a registration for any reason stated in § 304 of the Act.
- 1012.2 Upon service of the Order of the Director suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the Department.
- 1012.3 The Director may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.
- 1012.4 If revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by the revocation or suspension.
- 1012.5 No fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the Department.
- 1012.6 If the Director suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension of the effective date of the revocation order shall be placed under seal.
- 1012.7 No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court order the sale of perishable substances and the deposit of the proceeds of the sale with the court.
- 1012.8 Upon a revocation order becoming final, all controlled substances shall be forfeited in accordance with the provisions of § 502 of the Act.
- 1012.9 The Director shall promptly notify the Drug Enforcement Administration (hereinafter referred to as DEA) of all orders suspending or revoking registration and all forfeitures of controlled substances.

1013. SUSPENSION OF REGISTRATION PENDING FINAL ORDER

1013.1 If the Director finds pursuant to § 305(b) of the Act that there is an imminent danger to public health and safety, the Director may suspend any registration simultaneously with, or at any time subsequent to, the service upon the registrant of reasons therefore and a notice of hearing pursuant to § 1101.

1013.2 In cases covered by § 1013.1, the Director shall send the registrant the following:

(a) An order of immediate suspension which shall contain a statement of his or her findings regarding the danger to the public health or safety; and

(b) A notice of hearing on the suspension pursuant to § 201.

1013.3 Upon service of the order of immediate suspension, the registrant shall at the time of service return his or her Certificate of Registration to the Department.

1014. EXTENSION OF REGISTRATION

1014.1 In the event that an applicant for registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for reregistration at least sixty (60) days before the date on which the existing registration is due to expire, and the Director has issued no order on the application on the date in which the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Director so issues his or her order.

1014.2 The Director may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for reregistration at least sixty (60) days before expiration of the existing registration, with or without request by the registrant, if the Director finds that the extension is not inconsistent with the public health or safety.

1015. ADDRESS FOR NOTICES

1015.1 Unless the Act or this chapter otherwise provide, all notices required under this chapter to be sent to the Department or Director shall be sent to the Department of Consumer and Regulatory Affairs, Service Facility Regulation Administration, Pharmaceutical and Medical Devices Control Division, 614 H Street, N.W., Washington, D.C. 20001 or to successor agency by certified

mail, return receipt requested.¹⁴

1015.2 Every applicant or registrant shall provide the Department with an address to which all communications from the Department to the applicant or registrant shall be sent. The address shall be an actual street address and shall include the city or town, state and zip code number.

1015.3 Furnishing of post office box numbers or other forms of address shall not constitute sufficient compliance with § 1015.2.

1015.4 The address required by § 1015.1 shall be provided by the applicant or registrant either as part of its application for registration or reregistration or by letter to the Department sent certified mail, return receipt requested.

1016. VIOLATIONS

1016.1 Activities performed relative to the handling, management and use of controlled substances in the District of Columbia shall be performed in accordance with any and all Federal and other District of Columbia laws, rules and regulations. Violation of the laws, rules and regulations shall constitute a violation of this chapter.

1017. FAILURE TO COMPLY WITH RULES

1017.1 Failure of a registrant to comply with the rules as set forth in this chapter shall constitute a basis for revocation or suspension of the registrant's Certificate of Registration.

1030. CONTROLLED SUBSTANCES FEES

1030.1 The fees related to controlled substances are as follows:

- (a) Initial registration, \$ 50.00
- (b) Annual renewal, \$ 50.00
- (c) Late filing, \$ 25.00
- (d) Duplicate certificate, \$ 20.00

¹⁴ As of April 2007, the Pharmaceutical Control Division is now located at 717 14th Street, N.W., 6th Floor, Washington, D.C. 2005, 202-724-4900.

(e) License validation, \$ 20.00

(f) Reinspection, \$ 100.00

1099. DEFINITIONS

1099.1 When used in this chapter, the following words or phrases shall have the meaning ascribed:

Act - the District of Columbia Uniformed Controlled Substances Act of 1981, D.C. Law 4-29, effective August 5, 1981.¹⁵

Compounder - any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

Controlled Premises - (1) places where original or other records or documents required under the Act are kept or request to be kept, and (2) places, establishments, etc., where persons registered under this Act or exempted from registration under the Act may lawfully hold, manufacture, distribute, dispense, conduct research with, or otherwise dispose of controlled substances.

Department - the Department of Consumer and Regulatory Affairs or its successor agency.

Detoxification Treatment - the dispensing for a period not in excess of twenty-one (21) days, of a narcotic drug or narcotic drugs in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time.

Director - the Director of the Department of Consumer and Regulatory Affairs or the Director's designee.

Hearing Officer - either the Director or any person appointed by the Director.

Inspector - an employee of the Department authorized by the Director to make inspections under the Act.

Maintenance Treatment - the dispensing for a period in excess of twenty-one (21) days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

¹⁵ The District of Columbia Uniform Controlled Substances Act of 1981 §§ 33-501 through 33-567, D.C. Code, 1981 "Act" is now cited as D.C. Official Code § 48-901.02 et seq. (2001).

Narcotic Treatment Program - a program for maintenance and/or detoxification treatment with narcotic drugs.

Register and Registration - refers only to registration required and permitted by § 302 of the Act.

Registrant - any person who is registered pursuant to § 302 of the Act.

1099.2 The definitions contained in Title I, § 102 of the Act, shall have the same meaning in this chapter.

**TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 11. HEARINGS**

- 1100. Hearing Officer
 - 1101. Hearings And Notices
 - 1102. Summary Suspension And Denial Or Renewal
 - 1103. Hearing Procedures
 - 1104. Exhibits And Other Documentary Evidence
 - 1105. Official Notice
 - 1106. Disposition Of Cases
 - 1107. Transcripts
 - 1108. Burden Of Proof
 - 1109. Decisions
 - 1110. Motion For Rehearing Or Reconsideration
 - 1111. Judicial Review
 - 1112. Definitions
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1100. HEARING OFFICER

1100.1 Any hearing required by the Act or this chapter to be held by the Director may be conducted by the Director or a qualified hearing officer appointed by the Director.

1100.2 A hearing officer appointed by the Director shall have full authority to do the following:

- (a) Conduct the hearings;
- (b) Rule on all notices and other matters occurring during the hearing; and
- (c) When authorized by the Director, to render a final decision in the matter.

1101. HEARINGS AND NOTICES

1101.1 Except for an emergency suspension undertaken pursuant to § 305(b)(1) of the Act, § 33-435(b)(1), D.C. Code, 1981 ed¹⁶, the Director shall give an applicant or registrant written notice and an opportunity to be heard prior to taking any final action which would do any of the following;

¹⁶ Section 33-435(b)(1) no longer appears in the Code, See, D.C. Official Code § 48-903.05(b)(1).

- (a) Deny an application for registration;
- (b) Deny a renewal of registration;
- (c) Suspend registration; or
- (d) Revoke registration.

1101.2 The notice shall contain the following:

- (a) A statement of the proposed action;
- (b) A statement setting forth the reasons for the proposed action, including a specification of any specific act complained of;
- (c) Reference to any particular section of the Act or rules allegedly violated;
- (d) A statement that the applicant or registrant may secure a hearing before the Director or a hearing officer to contest the proposed action by depositing in the mail, within thirty (30) days of service of the notice, a certified letter addressed to the Director containing a request for a hearing or hand delivery same to the Office of the Director (receipt required for proof of delivery); and
- (e) A statement that if the applicant or registrant does not request a hearing within thirty (30) days after service of the notice of the proposed action, the applicant or registrant shall be deemed to have conceded the validity of the reason or reasons stated in the notice, and the denial, suspension or revocation shall be final without a hearing.

1101.3 Notice in connection with hearings under this chapter shall be given and service effected in accordance with § 305 of the Act, D.C. Law 4-29, effective August 5, 1981, § 33-435, D.C. Code, 1981 ed.¹⁷

1101.4 If the respondent does not mail a request for a hearing within the time and in the manner specified in § 1101.2, the Director may, without a hearing, take the action contemplated in the notice.

1101.5 The Director shall notify the respondent in writing of action taken under paragraph 1101.2(e).

¹⁷ Section 33-435(b)(1) no longer appears in the Code, See, D.C. Official Code §§ 48-903.04 and 48-903.05.

- 1101.6 If a hearing is timely requested pursuant to § 1101.2, the Director shall notify the person of the date, time and location of the hearing and the name of the hearing officer. The hearing shall be convened within thirty (30) days of the filing of the respondent's response to the Director's proposed action.
- 1101.7 Unless otherwise authorized by the Director, any notice from and to the Director shall be sent by certified mail, return receipt requested, as provided in § 305 of the Act.
- 1101.8 If an attorney enters his or her appearance for the respondent, any notice shall thereafter be served on the attorney, unless otherwise ordered by the Director or hearing officer.
- 1101.9 If the respondent is no longer at the last known address as shown on the records of the Department and no forwarding address is available, the notice shall be deemed to have been served on the date the return receipt bearing that notification is received by the Director.
- 1101.10 If the respondent shall believe the hearing officer selected to conduct the hearing is prejudiced against the respondent or his or her attorney, the respondent shall make a request in writing to the Director, at least ten (10) days prior to the date set for the hearing, to substitute another hearing officer. The request shall be accompanied by an affidavit signed by the respondent setting forth the facts upon which the claim of prejudice is predicated. Upon receipt of the request, the Director shall make a determination based upon sufficient evidence whether prejudice to the rights of the respondent exists and, if necessary, the Director may appoint a substitute hearing officer.

1102. SUMMARY SUSPENSION AND DENIAL OR RENEWAL

- 1102.1 A hearing shall be convened within five (5) days of the institution of proceedings in the following cases:
- (a) Summary suspension; and
 - (b) Denial or renewal.
- 1102.2 A registrant who has been summarily suspended or denied renewal under § 305 of the Act, § 33-435, D.C. Code, 1981 ed.¹⁸, shall be entitled upon written request to a postponement, for a reasonable period of time only, of the hearing scheduled pursuant to § 1102.1 of these rules.

¹⁸ Section 33-435(b)(1) no longer appears in the Code, See, D.C. Official Code §§ 48-903.04 and 48-903.05.

- 1102.3 Notice of hearing in summary suspension and non-renewal shall be made in accordance with § 305 of the Act (§ 33-435, D.C. Code, 1981 ed.)¹⁹.
- 1102.4 Except as otherwise noted in this chapter, all procedures relating to hearings as set forth in this chapter shall apply to hearings in summary suspensions and denials of renewal.

1103. HEARING PROCEDURES

- 1103.1 Each hearing shall be open to the public.
- 1103.2 At each hearing, the hearing officer shall be present to hear the evidence.
- 1103.3 A person entitled to a hearing shall have the following rights:
- (a) The right to be represented by counsel;
 - (b) The right to present all relevant evidence by means of witnesses books, papers, and other documents;
 - (c) The right to examine all opposing witnesses on any matter relevant to the issues; and
 - (d) The right to have subpoenas, pursuant to § 507 of the Act, § 33-457, D.C. Code, 1981 ed.²⁰, issued to compel the attendance of witnesses and the production of relevant books, papers and other documents, upon written request for subpoenas to the hearing officer.
- 1103.4 The Hearing Officer shall have the following powers:
- (a) To administer oaths or affirmations, either personally or through a designated agent, to witnesses called to testify;
 - (b) To subpoena respondents and other witnesses and relevant books, papers, and documents pursuant to § 507 of the Act, § 33-457, D.C. Code, 1981 ed.²¹;
 - (c) To take testimony to examine witnesses; and
 - (d) To direct continuance of any case for good cause shown.

¹⁹ Section 33-435(b)(1) no longer appears in the Code, See, D.C. Official Code §§ 48-903.04 and 48-903.05.

²⁰ Section 33-457 no longer appears in the Code, See, D.C. Official Code §§ 48-905.07.

²¹ Section 33-457 no longer appears in the Code, See, D.C. Official Code §§ 48-905.07.

- 1103.5 If any person refuses to respond to a subpoena, refuses to take the oath or affirmation as a witness, refuses to be examined, or refuses to obey any lawful order of the hearing officer, the hearing officer may apply to the proper court for an order requiring compliance.
- 1103.6 The hearing officer shall follow the general rules of evidence applicable to administrative hearings under the District of Columbia Administrative Procedure Act, P.L. 90-614, (D.C. Code, §§ 1-1501 et seq., 1981 ed.)²².
- 1103.7 The hearing officer shall exclude incompetent, irrelevant, immaterial, or unduly repetitious evidence or testimony.
- 1103.8 The hearing officer shall maintain order and shall not permit undue abuse or harassment of witnesses.
- 1103.9 The hearing officer may exclude testimony under the rules of privilege recognized by decisions of the courts of the District of Columbia or as provided by law, including, but not limited, to the following:
- (a) Communication between attorney and client;
 - (b) Communication between physician and patient;
 - (c) Records and files of any official or agency of government which, by statute or otherwise, are recognized as confidential; and
 - (d) Privileged matter enumerated in § 501(c) of the Act, (D.C. Official Code § 33-431(c), 1981 ed.)²³
- 1103.10 All testimony shall be taken under oath.

1104. EXHIBITS AND OTHER DOCUMENTARY EVIDENCE

- 1104.1 When a written exhibit is offered in evidence, one (1) copy shall be furnished to each of the parties at the hearing unless the parties have been furnished previously with copies or the hearing officer directs otherwise.
- 1104.2 If the hearing officer has not fixed a time for the exchange of exhibits, the parties shall exchange copies of exhibits at the earliest practical time, preferably before the hearing or, at the latest, at the commencement of the hearing.
- 1104.3 The hearing officer may permit a party to withdraw original documents

²² The District of Columbia Administrative Procedure Act is now cited as D.C. Official Code 2-501 et. seq. (2001).

²³ Section 33-431(c) no longer appears in the Code.

offered in evidence and substitute true copies.

- 1104.4 Documentary evidence may be received in the form of copies or excerpts if the original is not available.
- 1104.5 Upon request, parties shall be given an opportunity to compare the copy with the original when available.
- 1104.6 When relevant and material matter offered in evidence by any party is embraced in a book, paper, or document containing other matter not material or relevant, the party offering the same shall plainly designate the matter so offered. The immaterial and irrelevant parts shall be excluded and shall be segregated insofar as is practicable.
- 1104.7 If the hearing officer so directs, the relevant or material matter may be read into the record, or, if the hearing officer so directs, a true copy of the matter, in proper form, shall be received as an exhibit, and like copies shall be delivered by the party offering the same to opposing parties or to their attorneys appearing at the hearing, who shall be afforded an opportunity to examine the book, paper, or document, and to offer in evidence in like manner other portions thereof.
- 1104.8 If any portion of the record in any other proceeding, including a court proceeding, is offered in evidence, a true copy of that portion shall be presented for the record in the form of an exhibit unless one (1) of the following occurs:
- (a) The party offering the same agrees unconditionally to supply the copies at a later time designated by the hearing officer; or
 - (b) The parties represented at the hearing stipulate upon the record that the relevant matter may be incorporated by reference; or
 - (c) The hearing officer directs the incorporation by reference or waives the requirement of presentation of documentary evidence with the consent of the parties.
- 1104.9 No document or other writing shall be accepted for the record after the close of the hearing, except in accordance with an order issued by the hearing officer.

1105. OFFICIAL NOTICE

- 1105.1 Without limiting the discretionary powers of the hearing officer to notice other matters or documents which are properly the subject of official notice, the

following matters may be officially noticed in all proceedings under the provisions of this chapter:

- (a) Matters which are subject to judicial notice in the courts of the District of Columbia;
- (b) Matters of generally recognized technical or specialized facts within the knowledge and experience of the hearing officer; and
- (c) Facts contained in the applicant's or registrant's official file.

1106. DISPOSITION OF CASES

1106.1 If a respondent fails to appear at any scheduled hearing after proper service of notice, the hearing officer in the absence of a continuance or good cause being shown, may proceed with the hearing and make a decision in the absence of respondent.

1106.2 Unless otherwise provided by the Director, any contested case may be disposed of by stipulation, agreed settlement, consent order, or default as provided by § 1106.1. Any disposition, other than a default, shall be signed by the Director or the Director's designated agent.

1107. TRANSCRIPTS

1107.1 Hearings shall be recorded either stenographically or electronically and shall be available for transcribing upon the request of any party.

1107.2 The costs of transcripts of the record shall be borne by the parties requesting the transcripts.

1107.3 Changes in the official transcript shall be made only when they involve errors affecting substance.

1107.4 A motion to correct a transcript shall be filed within ten (10) days of receipt of the transcript.

1107.5 If no objection to the motion is filed within ten (10) days, the transcript shall, upon the approval of the hearing officer, be changed.

1107.6 If an objection is received, the motion and objection shall be submitted to the person who transcribed the record together with a request for a comparison of the transcript with the record.

1107.7 After receipt of the report of the person who made the transcription, an order shall be entered by the hearing officer settling the record and ruling on the motion.

1108. BURDEN OF PROOF

1108.1 In any proceeding resulting from proposed action to deny an applicant registration, the burden of proof shall be upon the applicant to demonstrate his or her qualifications.

1108.2 In any proceeding resulting from a proposed action to deny renewal or to suspend or revoke registration, the burden shall be on the Department to show that the proposed action should be taken.

1108.3 Notwithstanding the ultimate burden of proof regarding registration, in any proceeding the burden of proof of any exemption or exception under the Act or any affirmative defense is upon the person claiming it.

1109. DECISIONS

1109.1 Within ten (10) days of the close of the hearing or as soon thereafter as it is practicable, the hearing officer shall notify the applicant or registrant of the proposed decision in the case. A copy of the notice shall be sent to the Director if the Director did not personally hear the case.

1109.2 The notice of the proposed decision shall contain the following:

(a) A statement of proposed findings of fact and conclusions of law;

(b) A statement that these findings and conclusions shall become final unless a motion for rehearing or reconsideration is received within ten (10) days of the service of the proposed decision; and

(c) A statement as to respondent's appeal rights.

1109.3 The findings shall include specific findings on each relevant contested issue of fact. Proposed findings of fact shall, if set forth in statutory language, include a concise and explicit statement of the underlying fact supporting them.

1109.4 Findings of fact and conclusions of law shall be supported by and shall be in accordance with reliable, probative, and substantial evidence.

1109.5 Decisions made by a hearing examiner shall be made in consideration of the entire record of the proceeding, or upon such portion of the record of the proceeding as may be agreed upon by all the parties to the proceeding, and no

evidence, information, or other knowledge, except that of which official notice is taken shall be considered.

- 1109.6 A proposed decision shall become final unless a motion for a rehearing or reconsideration is received from respondent within ten (10) days of service of the proposed decision on respondent or unless otherwise directed by the Director.
- 1109.7 At the expiration of the period for filing a motion for rehearing or reconsideration the Director may, on the Director's own motion or order, do any of the following:
- (a) Issue a final decision and order; or
 - (b) Remand the matter for further proceedings.
- 1109.8 A final decision of the Director shall include findings of fact and conclusions of law in conformity with the District of Columbia Administrative Procedure Act, P.L. 90-614, § 1-1501 et seq., D.C. Code, 1981 ed²⁴, and these rules.
- 1109.9 A copy of the decision or order shall be delivered or mailed by certified mail, return receipt requested, to each party and their attorney of record. Notice shall be effective as provided in § 1101.7 and § 1101.8.
- 1109.10 The final decision shall contain a statement of respondent's appeal rights.

1110. MOTION FOR REHEARING OR RECONSIDERATION

- 1110.1 Motions for rehearing or reconsideration may be filed by respondent within ten (10) days of service of the proposed decision issued pursuant to § 1109.1 of these rules.
- 1110.2 Motions for rehearing or reconsideration shall be in writing and shall state with specificity the grounds upon which they are based.
- 1110.3 The hearing officer, if he or she was not the Director or authorized to make a final decision, shall forward a copy of respondent's motion for rehearing or reconsideration to the Director or person authorized to make a final decision, together with the hearing officer's recommendation.
- 1110.4 If the person who is to render a final decision in the matter did not personally hear the evidence, that person shall provide the respondent with an opportunity to present oral argument with respect to his or her motion and personally consider

²⁴ The District of Columbia Administrative Procedure Act is now cited as D.C. Official Code 2-501 et. seq. (2001).

the portions of the record as may be designated by the party, before rendering a final decision adverse to respondent.

1110.5 A timely motion for rehearing or reconsideration is a prerequisite to an appeal under § 1111 unless otherwise authorized by the Director.

1111. JUDICIAL REVIEW

1111.1 A person aggrieved by an adverse decision by the Director under this chapter may seek review in the District of Columbia Court of Appeals within fifteen (15) days of service of the decision or such other time as the court may prescribe for review of contested cases under § 11 of the District of Columbia Administrative Procedure Act, P.L. 90-614, (D.C. Code, § 1-1510, 1981 ed.)²⁵.

1199. DEFINITIONS

1199.1 The provisions of § 1099 of chapter 10 of this title and the definitions set forth in that section shall apply to this chapter.

²⁵ The District of Columbia Administrative Procedure Act is now cited as D.C. Official Code 2-501 et. seq. (2001).

**DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 12. CONTROLLED SUBSTANCES ACT RULES**

- 1200. Purpose
 - 1201. Schedule I Enumerated
 - 1202. Schedule Ii Enumerated
 - 1203. Schedule Iii Enumerated
 - 1204. Schedule Iv Enumerated
 - 1205. Schedule V Enumerated
-

1200. PURPOSE

1200.1 This chapter shall comprise all the enumerated schedules of controlled substances under the District of Columbia Uniform Controlled Substances Act of 1981 (Act), effective August 5, 1981 (D.C. Law 4-29; D.C. Official Code § 48-902.01), and all final rulemakings made by the Mayor or designee which add, delete, or reschedule a controlled substance under the authority of section 201 of the Act (D.C. Official Code § 48-902.01).

1201. SCHEDULE I ENUMERATED

1201.1 The controlled substances listed in this section are included in Schedule I of the Act unless removed therefrom pursuant to section 201 of the Act:

(a) Opiates: Unless specifically excepted or unless listed in another schedule, any of the following opiates including their isomers, esters, ethers, salts and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation;

- (1) Acetylmethadol;
- (2) Allylprodine;
- (3) Alphacetylmethadol;
- (4) Alphameprodine;
- (5) Alphamethadol;

- (6) Benzethidine;
- (7) Betacetylmethadol;
- (8) Betameprodine;
- (9) Betamethadol;
- (10) Betaprodine;
- (11) Clonitazene;
- (12) Dextromoramide;
- (13) Diampromide;
- (14) Diethylthiambutene;
- (15) Difenoxin;
- (16) Dimenoxadol;
- (17) Dimepheptanol;
- (18) Dimethylthiambutene;
- (19) Dioxaphetylbutyrate;
- (20) Dipipanone;
- (21) Ethylmethylthiambutene;
- (22) Etonitazene;
- (23) Etoxidine;
- (24) Furethidine;
- (25) Hydroxypethidine;
- (26) Ketobemidone;

- (27) Levomoramide;
- (28) Levophenacymorphan;
- (29) Morpheridine;
- (30) Noracymethadol;
- (31) Norlevorphanol;
- (32) Normethadone;
- (33) Norpipanone;
- (34) Phenadoxone;
- (35) Phenampromide;
- (36) Phenomorphan;
- (37) Phenoperidine;
- (38) Piritramide;
- (39) Proheptazine;
- (40) Properidine;
- (41) Propriam;
- (42) Racemoramide;
- (43) Thiophene;
- (44) Trimeperidine;
- (45) Acetyl-Alpha-Methylfentanyl;
- (46) Alpha-Methylfentanyl;
- (47) Alpha-Methylthiofentanyl;
- (48) Beta-hydroxyfentanyl;

(49) Beta-hydroxy-3-Methylfentanyl;

(50) 3-Methylfentanyl;

(51) 3-Methylthiofentanyl;

(52) MPPP;

(53) Para-fluorofentanyl;

(54) PEPAP;

(55) Thiofentanyl;

(56) Tilidine;

(b) Opium Derivates: Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetorphine;

(2) Acetyldihydrocodeine;

(3) Benzylmorphine;

(4) Codeine methylbromide;

(5) Codeine-N-Oxide;

(6) Cyprenorphine;

(7) Desomorphine;

(8) Dihydromorphine;

(9) Drotebanol;

(10) Etorphine (except hydrochlorine salt);

(11) Diacetylated morphine (heroin);

- (12) Hydromorphenol;
- (13) Methyldesorphine;
- (14) Methyldihydromorphine;
- (15) Morphine methylbromide;
- (16) Morphine methylsulfonate;
- (17) Morphine-N-Oxide;
- (18) Myrophine;
- (19) Nicocodeine;
- (20) Nicomorphine;
- (21) Normorphine;
- (22) Pholcodine;
- (23) Thebacon;

(c) **Hallucinogenic Substances:** Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances, its salts, isomers and salts of isomers, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation (for the purposes of this paragraph only, the term "isomer" includes the optical, position, and geometric isomers):

- (1) 4-Bromo-2,5-dimethoxyamphetamine;
- (2) 2,5-Dimethoxyamphetamine;
- (3) 4-Methoxyamphetamine;
- (4) 5-Methoxy-3,4-methylenedioxyamphetamine;
- (5) 4-Methyl-2,5-dimethoxyamphetamine;
- (6) 3,4-Methylenedioxyamphetamine;

- (7) 3,4,5-Trimethoxyamphetamine;
 - (8) Bufotenine;
 - (9) Diethyltryptamine;
 - (10) Dimethyltryptamine;
 - (11) Ethylamide analog of phencyclidine, PCE;
 - (12) Ibogaine;
 - (13) Lysergic acid diethylamide;
 - (14) Mescaline;
 - (15) Peyote;
 - (16) N-Ethyl-3-piperidyl benzilate;
 - (17) N-Methyl-3-piperidyl benzilate;
 - (18) Psilocybin;
 - (19) Psilocyn;
 - (20) Pyrrolidine analog of phencyclidine, PCPY;
 - (21) Thiophene analog of phencyclidine;
 - (22) (Repealed);
 - (23) Parahexyl;
 - (24) 4-Bromo-2,5-dimethoxyphenethylamine; and
 - (25) 3,4-Methylenedioxymethamphetamine;
- (d) Depressants: Unless specifically excepted or unless listed in another schedule, any material, compound, or mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system including its salts, isomers, and salts of isomers, whenever the existence of

such salts, isomers, and salts of isomers is possible, within the specific chemical designation:

(1) Gamma-Hydroxybutyric Acid [other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium xybutyrate];

(2) Mecloqualone;

(3) Methaqualone; and

(e) Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

(1) Fenethyline; and

(2) N-ethylamphetamine.

1202. SCHEDULE II ENUMERATED

1202.1 The controlled substances listed in this section are included in Schedule II of the Act unless removed therefrom pursuant to section 201 of the Act:

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis;

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextophan, nalbuphine, naltrexone, and their respective salts, but including the following:

(A) Raw opium;

(B) Opium extracts;

(C) Opium fluid extracts;

(D) Powdered opium;

(E) Granulated opium;

(F) Tincture of opium;

(G) Codeine;

(H) Ethylmorphine;

(I) Ethorphine Hydrochloride;

(J) Hydrocodone (K);

(K) Metopon;

(L) Morphine;

(M) Oxycodone;

(N) Oxymorphone;

(O) Thebaine;

(P) Hydromorphone;

(Q) Dihydrocodeine;

(R) Sufentanil;

(S) Alfentanil;

(T) Carfentanil;

(2) Opium: Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (1) of this paragraph, but not including the isoquinoline alkaloids of opium;

(3) Opium poppy or poppy straw;

(4) Coca leaves, except coca leaves or extracts of coca leaves from which cocaine, ecgonine, or derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, salts of isomers; or any compound, mixture, or preparation that contains any substance referred to in this paragraph;

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form that contains the phenanthrene alkaloids of the opium poppy);

(6) Hashish;

(7) Synthetic Tetrahydrocannabinols: Chemical equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:

(A) Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;

(B) Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers;

(C) Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers (compounds of these structures, regardless of numerical designation of atomic positions covered); and

(b) Opiates: Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrophan excepted:

(1) Alphaprodine;

(2) Anileridine;

(3) Benzitramide;

(4) Biphentamine;

(5) Diphenoxylate;

(6) Eskatrol;

(7) Fentanyl;

(8) Fetamine;

(9) Isomethadone;

- (10) Levomethorphan;
 - (11) Levorphanol;
 - (12) Metazocine;
 - (13) Methadone;
 - (14) Methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
 - (15) Moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
 - (16) Pethidine (meperidine);
 - (17) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
 - (18) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
 - (19) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
 - (20) Phenazocine;
 - (21) Piminodine;
 - (22) Racemethorphan;
 - (23) Racemorphan;
- (c) Stimulants: Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
- (1) Amphetamines, its salts, optical isomers, and salts of its optical isomers;
 - (2) Methamphetamine, its salts, isomers, and salts of isomers;
 - (3) Phenmetrazine and its salts;
 - (4) Methylphenidate and its salts; and
 - (5) (Repealed);

(6) Amphetamine/methamphetamine immediate precursor; Phenylacetone (Phenyl-2-propanone), P2P;

(d) Depressants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specifically chemical designation:

(1) Methaqualone;

(2) Amobarbital;

(3) Secobarbital;

(4) Pentobarbital;

(5) Phencyclidine;

(6) Phencyclidine immediate precursors:

(A) 1-Phenylethylamine; and

(B) 1-Piperidinocyclohexanecarbonitrile (PCC);

(7) Dronabinol;

(8) Nabilone; and

(9) Glutethimide.

1203. SCHEDULE III ENUMERATED

1203.1 The controlled substances listed in this section are included in Schedule III of the Act unless removed therefrom pursuant to section 201 of the Act:

(a) Schedule III shall consist of the following controlled substances:

(1) Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of

the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, positional, or geometric), and salts, isomers, and salts of isomers is possible within the specific chemical designation:

(A) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971 as excepted compounds under § 1308.32 of the Code of Federal Regulations (CFR), and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances;

(B) Benzphetamine;

(C) Chlorphenetermine;

(D) Chloretermine;

(E) Mazindol; and

(F) Phendimetrazine;

(2) Depressants: Unless listed in another schedule, any material compound, mixture, or preparation that contains any quantity of the following substances having a potential for abuse associated with depressant effect on the central nervous system:

(A) Any compound, mixture, or preparation containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital; or any salt thereof and 1 or more other active medicinal ingredients which are not listed in any schedule;

(B) Any suppository dosage form containing:

(i) Amobarbital;

(ii) Secobarbital;

(iii) Pentobarbital; or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository;

(C) Any substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid:

(i) Chlorhexadol;

(ii) Rescheduled to Schedule II;

(iii) Lysergic acid;

(iv) Lysergic acid amide;

(v) Methyprylon;

(vi) Sulfondiethylmethane;

(vii) Sulfonethylmethane;

(viii) Sulfonmethane;

(ix) Tiletamine & Zolazepam Combination Product;

(x) Vinbarbital; and

(D) Any drug product containing gamma-hydroxybutric acid including its salts, isomers, and salts of isomers.

(3) Nalorphine; and

(4) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any other following narcotic drugs, or any salts hereof:

(A) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium;

(B) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams dosage unit, with 1 or more active nonnarcotic ingredients in recognized therapeutic amounts;

(C) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a 4-fold or greater quantity of an

isoquinoline alkaloid of opium;

(D) Not more than 300 milligrams dihydrocodeine per 100 milliliters or not more than 15 milligrams per dosage unit with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(E) Not more than 1.8 grams of dihydrocodeine per milliliters or not more than 90 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(F) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with 1 or more ingredients in recognized therapeutic amounts;

(G) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts;

(H) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts; and

(I) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:

(1) Buprenorphine

(5) Anabolic Steroids: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, drug, or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progesterons, and corticosteroids) that promotes muscle growth and includes:

(A) Boldenone;

(B) Chlortestosterone (4-chlortestosterone);

(C) Clostebol;

(D) Dehydrochlormethyltestosterone;

(E) Dihydrotestosterone (4-dihydrotestosterone);

- (F) Drostanolone;
- (G) Ethylestrenol;
- (H) Fluoxymestorone;
- (I) Formebolone (formebolone);
- (J) Mesterolone;
- (K) Methandienone;
- (L) Methandranone;
- (M) Methandriol;
- (N) Methandrostenolone;
- (O) Methenolone;
- (P) Methyltestosterone;
- (Q) Mibolerone;
- (R) Nandrolone;
- (S) Norethandrolone;
- (T) Oxandrolone;
- (U) Oxymesterone
- (V) Oxymetholone;
- (W) Stanolone;
- (X) Stanozolol;
- (Y) Testolactone;
- (Z) Testosterone;

(AA) Trenbolone; and

(BB) Any salts, ester or isomer of a drug or substance described or listed in this paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by Secretary of Health and Human Services for such administration. If any person prescribes, dispenses or distributes such steroid for human use such person shall be considered to have prescribed, dispensed or distributed an anabolic steroid within the meaning of this paragraph.

(6) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved drug product. [Some other names for dronabinol: (6aR-trans)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran-1-ol] or (-)-delta-9-(trans)-tetrahydrocannabinol]; and

(7) Ketamine;

(b) The Mayor may except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in paragraphs (1) and (2) of subsection (a) of this section from the application of all or any part of this chapter if the compound, mixture, or preparation contains 1 or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiates the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

1204. SCHEDULE IV ENUMERATED

1204.1 The controlled substances listed in this section are included in Schedule IV of the Act unless removed therefrom pursuant to section 201 of the Act:

(a) Schedule IV shall consist of the following controlled substances:

(1) Depressants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (A) Barbital;
- (B) Chloral betaine;
- (C) Chloral hydrate;
- (D) Chlordiazepoxide;
- (E) Clonazepam;
- (F) Clorazepate;
- (G) Dextropropoxyphene;
- (H) Diazepam;
- (I) Ethchlorvynol;
- (J) Ethinamate;
- (K) Flurazepam;
- (L) Lorazepam;
- (M) Mebutamate;
- (N) Meprobamate;
- (O) Methohexital;
- (P) Methylphenobarbital (mephobarbital);
- (Q) Oxazepam;
- (R) Paraldehyde;
- (S) Petrichloral;
- (T) Phenobarbital;
- (U) Prazepam;

- (V) Alprazolam;
- (W) Bromazepam;
- (X) Camazepam;
- (Y) Clobazam;
- (Z) Clotiazepam;
- (AA) Cloxazolam;
- (BB) Delorazepam;
- (CC) Estazolam;
- (DD) Ethyl loflazepate;
- (EE) Fludiazepam;
- (FF) Flunitrazepam;
- (GG) Halazepam;
- (HH) Haloxazolam;
- (II) Ketazolam;
- (JJ) Loprazolam;
- (KK) Lormetazepam;
- (LL) Medazepam;
- (MM) Midazolam;
- (NN) Nimetazepam;
- (OO) Nitrazepam;
- (PP) Oxazolam;

(QQ) Omitted;

(RR) Pinazepam;

(SS) Quazepam;

(TT) Temazepam;

(UU) Tetrazepam; and

(VV) Triazolam;

(2) Fenfluramine: Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible: Fenfluramine;

(3) Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation:

(A) Diethylpropion;

(B) Phentermine;

(C) Pemoline (including organometallic complexes and chelates thereof);

(D) Cathine;

(E) Fencamfamin;

(F) Fenproporex;

(G) Mefenorex;

(H) Pipradrol;

(I) SPA;

(4) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation that contains any quantity of the following substances, including its salts:

(A) Dextropropoxyphene (Alpha-(+)-4-demethylamino-1),2-diphenyl-1-1-3-methyl-2-propionoxybutane;

(B) Pentazocine; and

(5) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof of not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

1205. SCHEDULE V ENUMERATED

1205.1 The following controlled substances listed below are included in Schedule V of the Act unless removed therefrom pursuant to section 201 of the Act:

(a) Narcotic drugs containing non-narcotic active medicinal ingredients: Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or salts thereof, which also contains 1 or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal quantities other than those possessed by the narcotic drug alone;

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;

(2) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

(3) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;

(4) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;

(5) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit; and

(6) Not more than 0.5 milligrams of difenopin and not less than 25 micrograms of

atropine sulfate per dosage unit;

(b) Cannabis;

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) Rescheduled to Schedule III.

(d) Propylhexedrine;

(e) Pyrovalerone.

DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 13. PRESCRIPTIONS AND DISTRIBUTIONS

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1300 GENERAL PROVISIONS

- 1300.1 This chapter shall apply to all categories of prescriptions drugs.
- 1300.2 Unless otherwise prohibited in this chapter or by District or federal law, a pharmacist may accept as valid for dispensing, a written prescription, an oral prescription, a telephone facsimile prescription, or an electronic prescription, issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices.
- 1300.3 A prescription shall only be issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices. If the prescription is for a controlled substance, the practitioner must also have a valid federal Drug Enforcement Agency (DEA) registration number and if applicable, a valid District of Columbia controlled substance registration or be exempt from registration pursuant to § 302 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D.C. Law 4-29, D.C. Official Code § 48-901.01).
- 1300.4 A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner only pursuant to the directions and order of the practitioner, and in conformance with the applicable federal and District of Columbia laws and regulations, and this chapter.
- 1300.5 A prescription shall only be filled by a licensed pharmacist or individual practitioner legally authorized to dispense a prescription.
- 1300.6 Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription they dispense. If the pharmacist questions the accuracy or authenticity of prescription, he or she shall verify the order with the practitioner prior to dispensing.
- 1300.7 Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist knows that the prescription was issued without a valid patient-practitioner relationship.
- 1300.8 An internet based or telephone consultation or questionnaire evaluation is not adequate to establish a valid patient-practitioner relationship except as follows:
- (a) In the event of a documented medical emergency;
 - (b) In an on-call or cross-coverage arrangement; or

- (c) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

1300.9 Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he or she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

1301 WRITTEN PRESCRIPTION ORDERS

1301.1 In addition to conforming to all applicable federal and District requirements, a written prescription drug order shall contain the following:

- (a) The printed or typed full name, address, and telephone number of the practitioner;
- (b) The original, legal signature of the practitioner, in ink;
- (c) The date of issuance;
- (d) The full name of the patient;
- (e) The name, strength and quantity of the drug prescribed, directions for use, and number of refills, when applicable; and
- (f) Be written in ink, indelible pencil or typewriter.

1301.2 In addition to the requirements of § 1301.1, a prescription drug order for a controlled substance shall also include the following:

- (a) The patient's address;
- (b) The practitioner's Federal Drug Enforcement Administration (DEA) registration number;
- (c) The practitioner's District of Columbia controlled substances registration number, if applicable;
- (d) Be signed by the practitioner in the same manner as the practitioner would sign a check or legal document (for example: "J.H. Smith" or "John H. Smith").

- 1301.3 Any person who is exempted from registration under federal or District of Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.
- 1301.4 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., “ U.S. Army ” or “ Public Health Service ”) and the individual’s service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1301.5 The service identification number for a Public Health Service employee is his or her social security identification number or, if applicable, his or her National Provider Identifier (NPI) number. Each prescription shall have the name of the individual stamped or printed on it, as well as the signature of the individual.
- 1301.6 The dispensing pharmacist shall document the following information on each prescription order that has been dispensed:
- (a) The name or initials of the pharmacist who performed the final verification; and
 - (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include but not be limited to, a change in quantity, directions, or number of refills.
- 1301.7 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1302 ORAL PRESCRIPTION ORDERS

- 1302.1 A pharmacist shall not dispense an oral prescription drug order for a controlled substance listed in Schedule II except as provided in § 1306.5 of this chapter.
- 1302.2 An oral prescription drug order from a practitioner or a practitioner’s designated agent shall:
- (a) Only be received by a pharmacist; and
 - (b) Be immediately reduced to writing.

- 1302.3 In addition to conforming to all applicable federal and District requirements, an oral prescription drug order shall contain the following:
- (a) The full name, address, and telephone number of the practitioner;
 - (b) The date of issuance;
 - (c) The full name and address of the patient;
 - (d) The name, strength, and quantity of the drug, directions for use, and number of refills, when applicable; and
 - (e) The name of the practitioner's designated agent authorized to orally communicate the prescription to the pharmacist.
- 1302.4 In addition to the requirements of § 1302.3, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:
- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number; and
 - (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable.
- 1302.5 The dispensing pharmacist shall document the following information on the written record of each prescription order that has been dispensed:
- (a) The name or initials of the pharmacist who performed the final verification; and
 - (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.
- 1302.6 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.
- 1302.7 For any person who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions for controlled substances issued by the exempted practitioner the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act, in lieu of the registration number of the practitioner required by this

chapter.

- 1302.8 For an official who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., “ U.S. Army ” or “ Public Health Service ”) and the individual’s service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1302.9 For any Public Health Service employee that is exempted from registration under federal or District of Columbia statute, the pharmacist shall include the individual’s social security identification number or, if applicable, his or her National Provider Identifier (NPI) number, office, title, and business address on the prescription.

1303 TELEPHONE FACSIMILE PRESCRIPTION ORDERS

- 1303.1 A practitioner shall not transmit a prescription via telephone facsimile if in doing so it would interfere with a patient’s freedom to choose a pharmacy, or without a patient’s consent.
- 1303.2 A pharmacist shall not dispense a telephone facsimile prescription drug order for a controlled substance listed in Schedule II, except as permitted under § 1306 of this chapter.
- 1303.3 A telephone facsimile prescription shall be transmitted only by a practitioner or a practitioner’s designated agent directly from the practitioner’s office or a health care facility to the pharmacy with no intervening person having access to the prescription drug order.
- 1303.4 To maintain the confidentiality of patient records:
- (a) The pharmacy and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and telephone facsimile transmissions; and
 - (b) The pharmacy shall implement and maintain procedures, system controls and other efforts to ensure compliance with the Health Insurance Portability and Accountability Act (“ HIPAA ”), federal and District laws regarding the confidentiality and protection of patient information.
- 1303.5 The pharmacy shall implement and maintain procedures to verify the authenticity of the telephone facsimile transmission and its source of origin which may include:

- (a) Maintenance of a practitioner's telephone facsimile number reference;
- (b) Verification of the telephone number of the originating telephone facsimile equipment; and
- (c) Telephone verification with the practitioner's office that the prescription as transmitted via telephone facsimile contains the same exact information it contained when originated by the practitioner and contains no alterations by any intervening parties.

1303.6

In addition to conforming to all applicable federal and District requirements, a telephone facsimile prescription drug order shall contain the following at the time it is transmitted:

- (a) A prescription bearing the following information:
 - (1) The printed or typed full name, address, telephone number and facsimile number of the practitioner;
 - (2) The signature of the practitioner;
 - (3) The date of issuance;
 - (4) The full name and address of the patient;
 - (5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable; and
 - (6) A statement which indicates that the prescription was transmitted via telephone facsimile;
- (b) Along with the prescription, the following information shall be transmitted:
 - (1) The name, address, and facsimile number of the pharmacy to which the prescription was transmitted;
 - (2) The date the prescription was transmitted via facsimile to the pharmacy, if the date is different from the date of issuance of the prescription;
 - (3) If transmitted by a designated agent, the full name of the designated agent; and
 - (4) A clearly legible statement that:
 - (A) The telephone facsimile transmission is intended only for the recipient to which it was addressed and contains information that is confidential;

(B) The recipient is prohibited from distribution or dissemination of the information contained in the transmission unless permitted by federal or District law; and

(C) If the recipient is not the intended recipient or the authorized agent of the intended recipient, the recipient should immediately notify the sender by telephone and return the original message to the sender.

- 1303.7 In addition to the requirements of § 1303.6, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:
- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number;
 - (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable;
 - (c) Be signed by the practitioner in the same manner as the practitioner would sign a check or legal document (for example: " J.H. Smith " or " John H. Smith "); and
 - (d) Any other requirements under District or federal law.
- 1303.8 Any person who is exempted from registration under federal or District of Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.
- 1303.9 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., " U.S. Army " or " Public Health Service ") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1303.10 The service identification number for a Public Health Service employee is his or her social security identification number or, if applicable, his or her National Provider Identifier (NPI) number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.
- 1303.11 The dispensing pharmacist shall document the following information on each facsimile prescription order that has been dispensed:

- (a) The name or initials of the pharmacist who performed the final verification; and
- (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.

1303.12 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1304 ELECTRONIC PRESCRIPTION ORDERS

1304.1 A practitioner shall not electronically transmit a prescription if in doing so it would interfere with a patient's freedom to choose a pharmacy, or without a patient's consent.

1304.2 A pharmacist shall not dispense an electronic prescription for a controlled substance listed in any schedule, unless otherwise authorized or permitted by federal law or regulations.

1304.3 An electronic prescription may be transmitted only by a practitioner or a practitioner's designated agent:

- (a) Directly to a pharmacy through a secure computer to computer transmission;
- (b) Directly to a pharmacy through a secure computer to facsimile transmission; or
- (c) Processed by a commercial intermediary that is duly authorized to operate in the District of Columbia, if applicable, and which ensures the confidentiality and security of the transmission process.

1304.4 The original electronic transmission shall be readily retrievable through the pharmacy computer system and shall be immediately reduced to hardcopy and filed in accordance with District of Columbia regulations.

1304.5 To maintain the confidentiality of patient records:

- (a) The pharmacy computer system and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and electronic transmissions; and
- (b) The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, system controls, and other efforts to ensure compliance

with HIPAA, federal and District laws concerning the confidentiality and protection of patient information.

- 1304.6 The Director of Pharmacy or Pharmacist in Charge shall create and maintain an ongoing security program and procedures which are capable of identifying misuse or unauthorized use of electronic signatures;
- 1304.7 The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, computer system controls, and other efforts, including contractual arrangements with commercial intermediaries, to:
- (a) Verify the authenticity of the electronic transmission and its source of origin;
 - (b) Ensure that the electronic transmission contains the same exact information it contained when originated by the practitioner;
 - (c) Ensure that the electronic transmission contains no alterations by any intervening parties;
 - (d) Prevent unauthorized access and changes to electronically transmitted prescriptions; and
 - (e) Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the validity of the transmission.
- 1304.8 In addition to conforming to all applicable federal and District requirements, an electronic prescription order shall conform to federally recognized national transmission standards and contain the following information at the time it is transmitted:
- (a) A prescription bearing the following information:
 - (1) The full name, address, and telephone number of the practitioner;
 - (2) The electronic signature of the practitioner;
 - (3) The date of issuance;
 - (4) The full name and address of the patient; and
 - (5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable.
 - (b) Along with the prescription, the following information shall be transmitted:

- (1) The National Council on Prescription Drug Programs (NCPDP) pharmacy number of the pharmacy to which the prescription was transmitted;
- (2) The date the prescription was transmitted to the pharmacy, if the date is different from the date of issuance of the prescription; and
- (3) If transmitted by the prescriber's designated agent, the full name of the designated agent.

- 1304.9 The dispensing pharmacist shall document the following information on each electronic prescription order that has been dispensed:
- (a) The name or initials of the pharmacist who performed the final verification; and
 - (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.
- 1304.10 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.
- 1304.11 Electronic transmission technology shall not be used to circumvent or violate any provision of District or federal laws or regulations.

1305 ISSUANCE OF CONTROLLED SUBSTANCE PRESCRIPTIONS

- 1305.1 The prescribing practitioner and the pharmacist shall be jointly responsible for compliance with this chapter in prescribing and dispensing a controlled substance.
- 1305.2 A prescription for a controlled substance shall be issued or dispensed only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.
- 1305.3 A prescription for a controlled substance shall be issued for treatment of individual patients. A prescription for a controlled substance shall not be issued to an individual practitioner for general dispensing purposes.
- 1305.4 A prescription for a controlled substance listed in any schedule shall be used for the purpose of continuing the patient's dependency only when its issuance is pursuant to authorized clinical treatment in a narcotic treatment rehabilitation program.
- 1305.5 Any person issuing a prescription and any person knowingly filling a prescription

which is not in conformity with this chapter shall be subject to the penalties provided for violations of the Act and this chapter.

- 1305.6 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 Act, and a person knowingly filling such a prescription, and the person issuing it, shall both be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

1306 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

- 1306.1 Except as otherwise authorized in this section, a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, shall only be dispensed pursuant to a valid written prescription signed by the prescribing practitioner, unless otherwise authorized by federal law.
- 1306.2 A prescription for a controlled substance listed in Schedule II shall not be filled if submitted more than thirty (30) days after the date on which the prescription was issued.
- 1306.3 A prescription for a controlled substance listed in Schedule II shall not be refilled and shall be cancelled out by a line drawn through the entire prescription order, with the date dispensed and initials of the person that dispensed the drug.
- 1306.4 A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via telephone facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to issuance of the controlled substance to the patient or the patient's representative. The original prescription shall be maintained in accordance with the requirements of this chapter and as required under federal and District law.
- 1306.5 In emergency situations, as defined under § 1306.6 of this chapter, a pharmacist may dispense Schedule II drugs upon the oral prescription of a practitioner. The pharmacist shall comply with the following requirements as set forth in 21 CFR § 1306.11(d) and failure to do so may result in suspension or revocation of a pharmacy registration:
- (a) The quantity prescribed and dispensed is limited to no more than a seven (7) day supply to treat the patient during the emergency period (dispensing beyond the emergency period shall 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 by District and federal law;
- (c) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call back to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure the practitioner's identity; and
- (d) Within seven (7) days after authorizing an emergency oral prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1301 of this chapter, the prescription shall:
 - (1) Have written on its face "Authorization for Emergency Dispensing," and the date of the oral order; and
 - (2) The written prescription shall be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach the written prescription to the oral emergency prescription which was previously reduced to writing. The pharmacist shall notify, in writing, the Director if the prescribing individual practitioner fails to deliver a written prescription to him or her. Failure of the pharmacist to notify the Director shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

1306.6 As used in this section "emergency situation" means those situations in which the prescribing practitioner determines the following:

- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;
- (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and
- (c) 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.

- 1306.7 A prescription for a Schedule II controlled substance to be compounded for 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 institutional or home health care pharmacy by telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.
- 1306.8 A prescription for a Schedule II controlled 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 telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.
- 1306.9 A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care program certified or paid for by Medicare under Title XVIII or a hospice program which is licensed by the District may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by telephone facsimile. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirement of this Title and federal and District law.
- 1306.10 An individual practitioner may administer or dispense directly to a patient a Schedule II controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.
- 1306.11 An institutional practitioner may administer or dispense directly, (but not prescribe) a controlled substance listed in Schedule II only pursuant to:
- (a) A valid written prescription signed by the prescribing individual practitioner; or
 - (b) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.
- 1307 PARTIAL FILLING OF PRESCRIPTIONS LISTED IN SCHEDULE II**
- 1307.1 The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity for a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).

- 1307.2 The remaining portion of the prescription may be filled within seventy-two (72) hours of the partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.
- 1307.3 A Prescription for Schedule II controlled substance 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 and in accordance with federal law. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist shall also observe the following:
- (a) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient;
 - (b) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient";
 - (c) 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 the federal and District law;
 - (d) 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 date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist;
 - (e) The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed; and
 - (f) 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 sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

1308 LABELING OF SUBSTANCES LISTED IN SCHEDULE II

- 1308.1 The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package the following:

- (a) A label showing the date of filling;
- (b) The pharmacy name and address;
- (c) The serial number of the prescription;
- (d) The name of the patient;
- (e) The name of the prescribing practitioner; and
- (f) Directions for use and cautionary statements , if any, contained in the prescription or required by law.

1308.2 The label of a drug listed in Schedules II, III, IV, and V 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 no smaller than six (6) point type.

1308.3 The requirements of § 1308.1 do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, if the following limitations are observed:

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

1308.4 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.

1309 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV AND V

1309.1 Unless otherwise permitted under federal law, a pharmacist shall dispense directly

a controlled substance listed in Schedule III, IV or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act only pursuant to:

- (a) A valid written prescription signed by the prescribing practitioner;
- (b) A telephone facsimile of a written prescription, signed by the prescribing practitioner, transmitted by the practitioner or the practitioner's designated agent to the pharmacy; or
- (c) An oral prescription of a practitioner immediately reduced to writing by the pharmacist containing all information required under § 1302 of this chapter.

1309.2 An individual practitioner may administer or dispense directly to a patient a Schedule III, IV or V controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.

1309.3 An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedule III, IV, or V only pursuant to:

- (a) A valid written prescription signed by an individual practitioner;
- (b) A telephone facsimile of a written prescription or order for medication transmitted by the individual practitioner or the practitioner's designated agent to the institutional practitioner or pharmacist;
- (c) An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required under § 1302 of this chapter; or
- (d) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.

1310 REFILLING OF PRESCRIPTIONS LISTED IN SCHEDULES III, IV OR V

1310.1 A prescription for a controlled substance listed in Schedule III or IV may not be filled or refilled more than six (6) months after the date on which the prescription was issued.

1310.2 A prescription authorized to be refilled may not be refilled more than five (5) times.

1310.3 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 a

patient profile. The following information must be retrievable by the prescription number:

- (a) The name of the controlled substance, or the name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially;
- (b) The strength and dosage form of the controlled substance;
- (c) The date of each refilling and the quantity dispensed;
- (d) The identity or initials of the dispensing pharmacist for each refill; and
- (e) The total number of refills for that prescription.

1310.4 Each refilling of a prescription shall state the amount dispensed.

1310.5 If the pharmacist merely initials and dates the back of the prescription, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.

1310.6 The prescribing practitioner may authorize additional refills of a Schedule III, IV or V prescription controlled substance on the original prescription or through an oral refill authorization transmitted to the pharmacist provided that the following conditions are met:

- (a) The total quantity authorized, including the amount of the original prescription, does not exceed five (5) refills or extend beyond six (6) months from the date of issue of the original prescription;
- (b) The pharmacist obtaining the oral authorization shall record the date, quantity of refill, and number of additional refills authorized, on the reverse of the original prescription and initial the prescription documenting that he or she received the authorization from the prescribing practitioner who issued the original prescription; and
- (c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

1310.7 Additional quantities of prescription controlled substances listed in Schedule III, IV or V, beyond the five (5) refill, six (6) month limitation, shall only be authorized by a prescribing practitioner through the issuance of a new and separate prescription.

1310.8 As an alternative to the procedures provided under § 1310.3 of this chapter, an automated data processing system may be used for the storage and retrieval of

refill information for prescription drug orders for controlled substances in Schedule III, IV, or V, subject to the conditions outlined under 21 CFR § 1306.22(b).

1311 PARTIAL FILLING OF PRESCRIPTIONS LISTED IN SCHEDULES III, IV OR V

1311.1 The partial filling of a prescription for a controlled substances listed in Schedules III, IV or V is permissible within six (6) months after date thereof provided that the following occurs:

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

(b) Each partial filling is recorded in the same manner as a refilling.

1311.2 The remaining portion of a partially filled prescription may be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

1312 LABELING OF SUBSTANCES LISTED IN SCHEDULES III, IV OR V

1312.1 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 following:

(a) The pharmacy name and address;

(b) The serial number and date of initial filling;

(c) The name of the patient;

(d) The name of the practitioner issuing the prescription; and

(e) Directions for use and cautionary statements, if any, contained in this prescription or as required by law.

1312.2 The requirements of § 1312.1, do not apply when a controlled substance listed in Schedule III or IV is prescribed for administration to an ultimate user who is institutionalized; Provided, that the following occurs:

- (a) Not more than thirty (30) day supply of one hundred (100) dosage units, which ever is less, of the controlled substance listed in Schedule II, IV or V is dispensed at one time;
- (b) The controlled 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 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.

1313 FILING OF PRESCRIPTION ORDERS

- 1313.1 Prescription orders for controlled substances in Schedules I and II shall be maintained in a file separate from all other records of the pharmacy.
- 1313.2 Prescription orders for controlled substances in Schedules III, IV and V shall be maintained either in a separate prescription file or in such form that they are readily retrievable from the other prescription records of the pharmacy. They will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is marked in red ink in the lower right corner with the letter "C" no less than one-inch high and filed in the usual consecutively numbered prescription file for non-controlled substances.
- 1313.3 All prescription orders shall be in compliance with requirements under this section, the Act and Title 21, CFR Part 1306, where applicable.

1314 DISPENSING WITHOUT A PRESCRIPTION

- 1314.1 A controlled substance listed in Schedule II, III, IV or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that the following occurs:
- (a) The dispensing is made only by a pharmacist (as defined in 21 CFR, § 1306.02(d)), and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);

- (b) Not more than 240 cc. (8 ounces) of any controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other controlled substance, nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48) hour period; except pursuant to a written or oral prescription of a duly licensed practitioner in possession of a Federal Controlled Substances Registration number;
- (c) The purchaser is at least eighteen (18) years of age;
- (d) The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate);
- (e) A bound record book for dispensing of controlled substances under this section is maintained by pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record-keeping requirement of 21 CFR, § 1304.04); and
- (f) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal or District of Columbia laws or regulations, or this chapter.

1315 MAIL ORDER PRESCRIPTION

- 1315.1 Before dispensing prescriptions for Schedules II, III, IV, or V non-narcotic controlled substances by mail, the registrant legally authorized to dispense controlled substances, shall assure that the prescription is valid and written by a prescriber appropriately licensed by that state and registered with the Federal government. The verification may be made either in writing or orally, and shall be noted by date and initials of person dispensing, on the back of the prescription.
- 1315.2 The prescription shall contain all requirements specified for prescriptions of Schedules II, III, IV, or V respectively, as listed within this chapter and shall be packaged and mailed in conformance with the applicable federal laws and regulations of the U.S. Department of Justice, Drug Enforcement Administration 21 CFR §§ 1300 *et seq.*, and the U.S. Postal Service 18 U.S.C. § 1716.

1316 TRANSFER BETWEEN PHARMACIES OF PRESCRIPTION INFORMATION FOR REFILL PURPOSES

- 1316.1 The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible, subject to the requirements of § 1316.3 of this chapter, between pharmacies on a one-time basis only. However, pharmacies utilizing a linked pharmacy system may transfer up to the maximum number of refills permitted by law.
- 1316.2 The transfer of original prescription information for a non-controlled substance for the purpose of refill dispensing is permissible subject to the requirements of § 1316.3 of this chapter.
- 1316.3 Any authorized transfer of original prescription information between non-linked pharmacy systems for the purpose of refill dispensing shall be subject to the following requirements:
- (a) The transfer shall be communicated directly between two licensed Pharmacists;
 - (b) The transferring pharmacist shall record on the invalidated prescription, in hardcopy or electronically, the following information:
 - (1) The words "VOID" and "TRANSFER";
 - (2) The name, address, and telephone number of the pharmacy to which it was transferred;
 - (3) The name of the pharmacist receiving the prescription information;
 - (4) For controlled substances, the DEA registration number of the prescriber and of the pharmacy to which the prescription is being transferred and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy to which the prescription is being transferred; and
 - (5) The date of the transfer and the name of the pharmacist transferring the information;
 - (c) The pharmacist receiving the transferred prescription information shall reduce to writing the following information:
 - (1) Write the word "TRANSFER" on the face of the transferred prescription;
 - (2) All information required to be on a prescription pursuant to 21

CFR § 1306.05 and this chapter;

- (3) Date of issuance of original prescription;
- (4) Original number of refills authorized on original prescription;
- (5) Date of original dispensing;
- (6) Number of valid refills remaining ;
- (7) The transferring pharmacy's name, address, and telephone number;
- (8) Name of pharmacist who transferred the prescription; and
- (9) For controlled substances, the DEA registration number of the prescriber and the pharmacy from which the prescription was transferred, and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy from which the prescription information was transferred;

1316.4 Direct pharmacist to pharmacist communication is not required between pharmacies utilizing a linked pharmacy system to transfer prescription drug orders or information for dispensing purposes. However, the common electronic file shall contain a complete record of each prescription drug order and refill dispensed, and a hard copy record of each prescription drug order accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order.

1316.5 The original and transferred prescription(s) shall be maintained for a period of two (2) years from the date of initial filling in accordance with District of Columbia regulations.

1316.6 Pharmacies electronically accessing the same prescription record shall satisfy all information requirements as required of a manual prescription transferral.

1316.7 A pharmacist at the transferring pharmacy may not refill a prescription that has been transferred to another pharmacy.

1316.8 The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order.

1317 ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES

1317.1 The administering or dispensing directly (but not prescribing) of controlled substances listed in any schedule to a controlled substance dependent person for

the purpose of detoxification or for continuing his or her dependence upon these drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be permissible; provided, that the following conditions are met:

- (a) Approval is obtained before the initiation of this program by submission of a “ Notice of Claimed Investigation Exemption for a New Drug ” to the Food and Drug Administration [which will be reviewed concurrently by FDA for scientific merit and by the Pharmaceutical Control Division, for drug control requirements]; and
- (b) That the clinical investigation thereafter accords with this approval, as required by the Federal Act and Federal regulations.

1317.2 Any practitioner who violates any of the provisions of the federal law or regulations shall be in violation of this chapter.

1317.3 Nothing in this chapter shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) controlled substances to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day’s medication may be administered to the person or issued for the person’s use at one time. The emergency treatment may be carried out for not more than three (3) days and may not be renewed or extended.

1317.4 The rules of this chapter are not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense controlled substances to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

1318-1319 [RESERVED]

1320 DISTRIBUTION BY DISPENSER TO ANOTHER PRACTITIONER

1320.1 A practitioner who is registered to dispense a controlled 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 his or her patients; Provided, that the following conditions are satisfied:

- (a) The practitioner to whom the controlled substance is to be distributed is registered appropriately to dispense that controlled substances;

- (b) The distribution is recorded by the distributing practitioner in accordance with 21 CFR, § 1304.24(e), and by the receiving practitioner in accordance with 21 CFR, § 1304.24(c);
- (c) If the substance is listed in Schedule I or II, an order form is used as required by the federal regulations; and
- (d) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the twelve (12) month period in which the practitioner is registered to dispense does not exceed five percent (5%) of the total number of dosage units of all controlled dangerous substances distributed and dispensed by the practitioner during the twelve (12) month period.

1320.2 If, at any time during the twelve (12) month period during which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him or her to another practitioner pursuant to this chapter will exceed five percent (5%) of the total number of dosage units of all controlled substances distributed and dispensed by him or her during the twelve (12) month period, the practitioner shall obtain a registration to distribute controlled substances.

1321 MANUFACTURE AND DISTRIBUTION OF NARCOTIC SOLUTIONS AND COMPOUNDS BY A PHARMACIST

1321.1 As an incident to a distribution under § 1500.2, a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substances in a proportion not exceeding twenty percent (20%) of the complete solution, compound, or mixture.

1322 DISTRIBUTION TO SUPPLIER

1322.1 A person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he or she obtained it or to the manufacturer of the substance; Provided, that a written record is maintained which indicates the following:

- (a) The date of the transaction;
- (b) The name, form, and quantity of substance;
- (c) The name, address, and registration number, if any, of the person making the distribution; and

(d) The name, address, and registration number, if known, of the supplier or manufacturer.

1322.2 An order form shall be used in the manner prescribed in 21 CFR, § 1305, and shall be maintained as the written record for a controlled substance listed in Schedule I or II which is returned. A person not required to register pursuant to § 1302(c) or § 1007(b)(1) of the Federal Act [21 U.S.C. 823(c) or 21 U.S.C. 957(b)(1)] shall be exempt from maintaining the records required by this chapter.

1323 DISTRIBUTION UPON DISCONTINUANCE OR TRANSFER OF BUSINESS

1323.1 A registrant desiring to discontinue business activities and who has controlled substances in his or her possession, shall comply with 21 CFR, § 1307.14(a). The District of Columbia certificate of registration shall be returned to the Pharmaceutical Control Division for cancellation at the same time the federal registration is returned to DEA.

1323.2 A registrant desiring to discontinue business activities with respect to controlled substances (by transferring those business activities to another person), shall submit in person or by registered or certified mail, return receipt requested, to the Department of Health, Health Care Regulation and Licensing Administration, Pharmaceutical Control Division, at least fourteen (14) days before the date of the proposed transfer (unless the Director 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 the business, or moved to another location (if the latter, the address of the new location should be listed); and
- (d) The date on which the transfer of controlled substances will occur.

1323.3 Unless the registrant-transferor is informed by the Director, before the date on which the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his or her possession to the registrant-transferee in accordance with the procedures outlined under 21 CFR, § 1307.14(c).

**1324 PROCEDURE FOR DISPOSING OF LEGALLY OBTAINED
CONTROLLED SUBSTANCES**

1324.1 Any registrant in possession of legally obtained controlled substances and desiring or required to dispose of any of these substances shall contact Drug Enforcement Administration, Regional Office, for instructions and to request the necessary form (DEA-41).

1325-1329 [RESERVED]

1330 GENERICALLY EQUIVALENT PRESCRIPTION DRUGS

1330.1 The Formulary of Drug Products for the District of Columbia shall be the chemical and generic drugs contained in the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (also known as the “Orange Book”), and its monthly updates, issued by the Department of Health and Human Services of the United States, 1988. This drug formulary is incorporated by reference as a part of this chapter.

1330.2 The publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” shall be available for public inspection at the Commission of Public Health, Department of Human Services.

1330.3 A copy of the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” may be obtained from the Superintendent of Documents, Government Printing Office of the United States, Washington, D.C. 20402.

1331 PHARMACY FEES

1331.1 The fees related to pharmacies are as follows:

- | | |
|---------------------------|----------|
| (a) Annual Fee | \$150.00 |
| (b) Late Fee | \$ 75.00 |
| (c) Duplicate Certificate | \$ 20.00 |
| (d) License Validation | \$ 20.00 |

1332 DRUG MANUFACTURERS AND DISTRIBUTORS FEES

1332.1 The licensure fees for drug manufacturers and distributors located within the District of Columbia are as follows:

- (a) Annual Fee \$200.00
- (b) Late Fee \$100.00
- (c) Duplicate Certificate \$ 20.00
- (d) License Validation \$ 20.00

1332.2 The registration fees for drug manufacturers and distributors located outside the boundaries of the District of Columbia are as follows:

- (a) Annual Fee \$100.00
- (b) Late Fee \$ 50.00
- (c) Duplicate Certificate \$ 20.00

1399 DEFINITIONS

1399.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

Act--District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01).

Administer--the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Adulterated drug or medical device--as defined in § 501 of the Federal Food, Drug and Cosmetic Act, (Pub. L. 96-354, 21 USC § 351) as amended.

Automated data processing system--a system utilizing computer software and hardware for the purpose of recordkeeping.

Community/Retail pharmacy--a pharmacy that provides services to the public or general community on an outpatient bases, whether at retail, through third party payment, or other measure of no or minimum cost to the consumer.

Compounding--the preparation or mixing, of a drug or device as the result of a practitioner's prescription drug order or for the purpose of, or as an incident to,

research, teaching, or chemical analysis and not for sale or dispensing. Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

Computer generated facsimile--a computer to facsimile transmission sent by a computer that has a facsimile modem through which documents can be sent.

Controlled premises-- (1) places where original or other records or documents required under the Act are kept or requested to be kept, and (2) places or establishments, where persons registered under the Act or exempted from registration under the Act may lawfully hold, manufacture, distribute, dispense, conduct research with, or otherwise dispose of controlled substances.

Controlled substances--those drug items or chemicals regulated under the Federal Controlled Substances Act of 1970, (Pub.L. 91-513, 21 USC § 801 et seq.) as amended; and the District of Columbia Uniform Controlled Substances Act of 1981, (D.C. Law 4-29, D.C. Official Code § 48-901 et seq.) as amended.

Department--The District of Columbia Department of Health.

Director--The Director of the District of Columbia Department of Health.

Dispense--the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or medical device to a patient or patient's agent.

Distribute--the actual, constructive, or attempted transfer from one person to another, other than by administering or dispensing, of a drug or medical device whether or not there is an agency relationship.

Drug--

- (a) Any substance recognized as a drug, medicine, or medicinal chemical in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, or official Veterinary Medicine Compendium or other official drug compendium or any supplement to any of them;
- (b) Any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal;
- (c) Any chemical substance (other than food) intended to affect the structure or any function of the body of man or other animal; and
- (d) Any substance intended for use as a component of any items specified in subparagraph (a), (b), or (c) of this paragraph, but not including

medical devices or their components, parts, or accessories.

Electronic--relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic, or similar capabilities.

Electronic prescription--a prescription drug order which is transmitted by an electronic device to the receiver (pharmacy), or which is transmitted computer to computer between a practitioner's office and a pharmacy, and which contains an electronic signature. An electronic prescription includes computer generated facsimile prescription drug orders but does not include telephone facsimile prescription drug orders.

Electronic record-- a record created, generated, sent, communicated, received, or stored by electronic means.

Electronic signature-- a confidential, unique, personalized electronic security code, key, number or other identifier attached to or logically associated with a record that is used for secure electronic data transmissions which identifies and authenticates the signatory and is executed or adopted by the signatory with the intent to sign the record.

Generically equivalent drugs-- drugs that are:

- (a) Pharmaceutical equivalents in that they contain identical amounts of the same active drug ingredients in the same dosage form and meet compendial or other applicable standards of identity strength, quality, and purity;
- (b) Bioequivalents in that they do not present a known or potential bioequivalence problem or if they do present such a known or potential problem they are shown to meet an appropriate bioequivalence standard; and
- (c) Adequately labeled and are manufacture under conditions which, at a minimum, comply with FDA Current Good Manufacturing Practice Regulations.

HIPAA-- The Federal Health Insurance Portability and Accountability Act of 1996.

Individual Practitioner-- an individual who is licensed or registered in the District of Columbia to prescribe a prescription drug or medical device in the course of his or her professional practice, including a physician, dentist, veterinarian, podiatrist, optometrist, or advanced practice nurse. It does not include a pharmacist, pharmacy, or an institutional practitioner.

Institutional practitioner-- an intern, resident physician, fellow, or person in an equivalent professional position who:

- (a) Is not yet licensed under District of Columbia law to administer, dispense, or prescribe controlled substances;
- (b) Is enrolled in a bona fide professional training program in a base hospital or institutional training facility registered by the Federal Drug Enforcement Administration and District of Columbia; and
- (c) Is authorized by the base hospital or institutional training facility to administer, dispense, or prescribe controlled substances.

Linked pharmacy system-- pharmacies within the same retail name chain utilizing a common electronic file or database to transfer prescription drug orders or information for dispensing purposes between or among pharmacies within the same retail chain which also participates in the same common prescription file.

Mayor-- the Mayor of the District of Columbia or the Mayor's designated agent.

Medical device-- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (a) Recognized in the official National Formulary, the official United States Pharmacopoeia, or any supplement thereto;
- (b) Intended for use in the diagnosis of disease or any other condition, or in the cure, mitigation, treatment, or prevention disease in man or other animal; or
- (c) Intended to affect the structure of any function of the body of man or other animal, and which does achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and which does not depend upon being metabolized for the achievement of any of its principal intended purposes.

Misbranded drug or medical device-- as defined in section 501 of the Federal Food, Drug and Cosmetic Act, (Pub. L. 96-354, 21 USC § 352) as amended.

Narcotic Drug-- any of the following whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

- (a) Opium, opiates, derivatives of opium and opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation. Such term does not include the isoquinoline alkaloids of opium;

- (b) Poppy straw and concentrate of poppy straw;
- (c) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine and derivatives of ecgonine or their salts have been removed;
- (d) Cocaine, its salts, optical and geometric isomers, and salts of isomers;
- (e) Ecgonine, its derivatives, their salts, isomers and salts of isomers; or
- (f) Any compound, mixture, or preparation which contains any quantity of these substances.

Narcotic treatment program-- a program engaged in maintenance or detoxification treatment with narcotic drugs.

Original prescription-- the original written prescription drug order; the original oral drug order that has been reduced to writing by the pharmacist; the original telephone facsimile prescription, or the original electronic prescription.

Over-the-counter drug-- drugs which may be sold without a prescription and which are packaged for use by the consumer and labeled in accordance with the requirements of the laws and regulations of the District of Columbia and the federal government.

Patient-practitioner relationship-- means that at a minimum the practitioner has met face to face with the patient, has obtained a patient history, and conducted a physical examination or evaluation adequate to establish a diagnosis, identify underlying conditions and contraindications to the treatment recommended.

Pharmacist-- a person who is licensed in the District of Columbia to engage in the practice of pharmacy.

Pharmacy-- any establishment or institution, or any part thereof, where the practice of pharmacy is conducted; drugs are compounded or dispensed, offered for sale, given away, or displayed for sale at retail; or prescriptions are compounded or dispensed.

Practice of pharmacy-- the interpretation and evaluation of prescription orders; the compounding, dispensing, and labeling of drugs and devices, and the maintenance of proper records therefore; the responsibility of advising, where regulated or otherwise necessary, of therapeutic values and content, hazards, and use of drugs and devices; and the offering of performance of those acts, services, operations, and transactions necessary in the conduct, operation, management, and control of a pharmacy.

Practitioner-- an individual licensed, registered, certified, or otherwise permitted by law to prescribe, dispense, and to administer drugs or medical devices, or to conduct research with respect thereto, within the course of such persons' professional practice or research.

Prescriber-- the practitioner who issues a prescription.

Prescription-- any order for a drug, medicinal chemical, or combination or mixtures thereof, or for a medically prescribed medical device, in writing, dated and signed by an authorized health professional or given orally to a pharmacist by an authorized health professional or the person's authorized agent and immediately reduced to writing by the pharmacist or pharmacy intern, specifying the address of the person for whom the drug or device is ordered and directions for use to be placed on the label.

Prescription drug-- any of the following:

- (a) a drug which is required under federal law to be labeled with either of the following statements prior to being dispensed or delivered:
 - (1) "Caution: Federal law prohibits dispensing without prescription";
or
 - (2) "Caution: Federal law restricts this drug to use by, or on the other of, a licensed veterinarian.
- (b) a drug which is required by any applicable federal, or District of Columbia law or regulation to be dispensed pursuant only to a prescription drug order or is restricted to use by practitioners only; or
- (c) a drug which is restricted to use by health professionals and allied practitioners for research.

Proprietor of a pharmacy-- a person designated as proprietor in an application for a pharmacy license. The proprietor may be an individual a corporation, a partnership, or an unincorporated association, and shall at all times own a controlling interest in the pharmacy.

Provider pharmacy-- the community pharmacy or the institutional pharmacy providing remote pharmacy services.

Registrant-- a person who is registered under the District of Columbia Uniformed Controlled Substances Act of 1981 effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01).

Remote automated medication system-- an automated medication system that is located in a health care facility that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

Remote pharmacy services-- the provision of pharmacy services, including the storage and dispensing of prescription drugs, in a facility that is not at the same location as the provider pharmacy.

Remote site-- a facility not located at the same location as the pharmacy at which remote pharmacy services are provided using an automated medication dispensing system.

Reverse distributor-- a duly authorized party who receives drugs, including controlled substances, acquired from another duly authorized party for the purpose of:

- (a) returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or
- (b) where necessary, processing such substances or arranging for processing such substances for disposal.

Starter dose-- a dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered.

Security procedure-- a procedure employed for the purpose of verifying that an electronic signature, record, or performance is that of a specific person or for detecting changes or errors in the information in an electronic record. The term includes a procedure that requires the use of algorithms or other codes, identifying words or numbers, encryption, or callback or other acknowledgment procedures.

Telepharmacy system-- a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

- (a) audio and video;
- (b) still image capture; and
- (c) store and forward.

Telephone Facsimile prescription-- a prescription drug order which is transmitted by a telephone electronic device which sends an exact image to the receiver (pharmacy).

DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 15. INSPECTIONS

- 1500. Authority To Make Inspections
 - 1501. Inspections
 - 1502. Records And Reports
 - 1503. Accountability Audits
 - 1504. Order Forms
 - 1505. Retention Of Records
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1500. AUTHORITY TO MAKE INSPECTIONS

1500.1 In carrying out its functions under the Act, the Chief Pharmaceutical Control Officer and his or her designee, is authorized in accordance with §§ 302(f) and 505 of the Act to enter controlled premises and conduct administrative and non-administrative inspections thereof, for the purpose of doing 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 this chapter including, but not limited to, inventory and other records required to be kept pursuant to this chapter, prescription and distribution records required to be kept pursuant to this chapter, 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) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled substances and other substances or materials, containers, and labeling found at the controlled premises relating to the Act;
- (c) Making a physical inventory of all controlled substances on hand at the premises;
- (d) Collecting samples of controlled substances or precursors (in the event any samples are collected during an inspection, the inspector shall issue a receipt for such samples to the owner, operator, or agent in charge of the premises);

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

(f) Except as provided by the Act, all other things therein (including records, files, papers, processes, controls and facilities) appropriate for verification of the records, reports, documents referred to in this section or otherwise bearing on the provisions of the Act cited in this section and this chapter.

1500.2 If an administrative inspection warrant is required for inspection pursuant to § 505 of the Act (§ 33-555, D.C. Code, 1981 ed.²⁶), the Chief shall be responsible for seeking the warrant.

1500.3 The Chief may, without a warrant, inspect books and records pursuant to an administrative subpoena issued in accordance with § 507 of the Act (§ 33-557, D.C. Code, 1981 ed.²⁷) and in situations described in § 505(a)(4) of the Act (§ 33-555(a)(4), D.C. Code, 1981 ed.²⁸).

1500.4 An inspection authorized by this section shall not extend to financial data, sales data, other than shipment data, or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.

1500.5 Refusal by the registrant or owner, operator, agent or other person in charge of the controlled premises to allow an inspection shall constitute a basis for suspension or revocation of registration in the following circumstances:

(a) When inspection is authorized pursuant to an administrative inspection warrant issued pursuant to § 505(b) of the Act (§ 33-555(b), D.C. Code, 1981 ed.²⁹); and

(b) When inspection is authorized pursuant to this chapter and §§ 505(a)(4)(B), (C), (D) or (E) of the Act (§§ 33-555(a)(4) (B), (C), (D) or (E), D.C. Code, 1981 ed.³⁰)

²⁶ Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

²⁷ Section 33-557, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.07(2001).

²⁸ Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

²⁹ Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

³⁰ Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

1501. INSPECTIONS

- 1501.1 An inspection shall be carried out by an inspector from the Department's Service Facility Regulation Administration, Pharmaceutical and Medical Devices Control Division or other employee authorized by the Act and/or the Director.
- 1501.2 The inspector prior to entry shall do the following:
- (a) State the purpose of his or her inspection to the owner, operator, agent or other person in charge of the premises to be inspected; and
 - (b) Present appropriate credentials to the owner, operator, agent or other person in charge for making the inspection.
- 1501.3 Appropriate credentials for the making of the inspection shall include, but are not limited to, the following:
- (a) Duly issued identification card, badge, etc., of the Department for the inspector;
 - (b) Notice of inspection issued by the Service Facility Regulation Administration, Pharmaceutical and Medical Devices Control Division containing the following:
 - (1) The name and title of the owner, operator, agent or other person in charge of the premises;
 - (2) The controlled premises name;
 - (3) The controlled premises address to be inspected;
 - (4) The date of the inspection;
 - (5) The findings from the inspection; and
 - (6) The signature of the inspector.
 - (c) An administrative inspection warrant when required by § 505(b) of the Act.
- 1501.4 Any person to whom a registration or exemption has been issued shall retain copies of Inspection Reports and Violation Notices issued by the Service Facility Regulation Administration, Pharmaceutical and Medical Devices Control Division or designees, and shall maintain the reports or notices on the registered premises in a manner so as to make them available upon request of the Director

or inspector for a period of at least two (2) years.

1501.5 It shall be the duty of the Chief Pharmaceutical Control Officer or his or her designee to investigate a complaint of a violation of any provisions of the Act or this chapter.

1501.6 No person shall hinder, obstruct, or in any way interfere with the Chief Pharmaceutical Control Officer or his or her designee in the performance of official duty in carrying out the provisions of the Act or this chapter or any other applicable law or regulations.

1502. RECORDS AND REPORTS

1502.1 Every registrant shall keep records, maintain inventories and file reports in conformance with the requirements of federal law including the requirements prescribed under Part 1304, 21 CFR.

1503. ACCOUNTABILITY AUDITS

1503.1 Accountability audits in pharmacies shall be accomplished through a review of invoices, prescription file, other records required by federal and District of Columbia laws and regulations, and this chapter.

1503.2 Accountability audits of medical, dental, and veterinary practitioners shall be accomplished through a review of records required to be kept by federal and District of Columbia laws and regulations, and this chapter.

1503.3 Accountability audits of manufacturers and distributors (including wholesalers) shall be accomplished through a review of invoices received and distributed and other records required by federal and District of Columbia laws and regulations, and this chapter.

1504. ORDER FORMS

1504.1 Controlled Substances in Schedule I or II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law and regulations respecting order forms shall be deemed compliance with this chapter.

1505. RETENTION OF RECORDS

1505.1 All records required by this chapter shall be retained for a period of at least two (2) years.

1599. DEFINITIONS

1599.1 The provisions of § 1099 of chapter 10 of this title and the definitions set forth in that section shall apply to this chapter.

DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS
TITLE 22. PUBLIC HEALTH AND MEDICINE
CHAPTER 19. PHARMACIES

Sec

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1900. GENERAL PROVISIONS

1900.1 This chapter regulates the licensure and operation of pharmacies.

1900.2 Chapter 65 (Pharmacists) of Title 17 DCMR supplements this chapter.

1901. CLASSIFICATIONS OF PHARMACIES

1901.1 Licenses shall be issued for the following categories of pharmacies as defined in this chapter.

- (a) Retail pharmacy/Community pharmacy;
- (b) Nuclear pharmacy;
- (c) Institutional pharmacy; and
- (d) Special or limited use pharmacy.

1902. NEW LICENSURE OF PHARMACIES

1902.1 Except as otherwise provided in this chapter, an applicant for a new license to operate a pharmacy shall furnish proof satisfactory to the Director of the following:

- (a) That a valid certificate of occupancy where required by the Department has been issued for the premises where the pharmacy will be located;
- (b) If the pharmacy is owned by a corporation, that the corporation is in good standing with the District of Columbia or the state of incorporation, if the pharmacy is incorporated in a state other than the District of Columbia;
- (c) That each person listed on the application (individuals, partners, or officers of the corporation) has not been convicted of a felony involving drugs; and
- (d) Other information as may be necessary to properly evaluate the applicant and application.

1902.2 The application for a pharmacy license shall be made on a form to be prescribed by the Director and shall be accompanied by the required fee as required by section 9(a) of the Act.

1902.3 Application for a pharmacy license shall include the name and license number of the licensed pharmacist who shall be known as the "responsible manager" for a retail/community pharmacy and a special or limited use pharmacy, the "Director of Pharmacy" for an institutional pharmacy, and the "responsible nuclear pharmacist" for a nuclear pharmacy, who shall ensure that the pharmacy complies with all applicable laws and regulations pertaining to the operation of the respective pharmacy and practice of pharmacy.

1903. RENEWAL LICENSURE OF PHARMACIES

1903.1 The Director shall mail a renewal notice to a licensee by first class mail to the licensee's last known address on file with the Director at least sixty (60) days prior to the expiration of the license.

1903.2 The failure of a licensee to receive the renewal notice required by this section does not relieve the licensee of the responsibility of renewing the license by the expiration of the existing license.

1903.3 If the Director does not receive the application for renewal of a license at least thirty (30) days prior to its expiration, the license shall lapse, but may be \ reinstated within thirty (30) days of expiration upon receipt of a completed renewal application and the payment of any late fee. Reinstatement of a license that has been expired for over thirty (30) days shall be at the discretion of the Director.

1903.4 Prior to the renewal of a license, the Director shall make an inspection of a pharmacy as provided in section 1925 of this chapter to determine compliance with the Act and this chapter.

1903.5 The Director shall send a written report of the findings of the inspection to the licensee no later than fifteen (15) days after the conclusion of the inspection.

1904. ISSUANCE, SCOPE, DISPLAY, AND TERM OF LICENSE

1904.1 The Director shall issue a license for a pharmacy that; the Director determines is in compliance with the Act and this chapter.

1904.2 The Director shall indicate on the face of the license:

- (a) The pharmacy classification for which the license is issued; and
- (b) Any restrictions on the license for special or limited use pharmacies.

- 1904.3 A license is valid only for the proprietor, the premises, and the pharmacy name designated on the license.
- 1904.4 A license shall be displayed in a conspicuous place on the premises as required by section 1909.3(b) of this chapter.
- 1904.5 A license is the property of the District government and shall be returned to the Director immediately upon the occurrence of any of the following events:
- (a) Suspension or revocation of the license;
 - (b) Refusal or failure to renew the license;
 - (c) Voluntary surrender by the licensee;
 - (e) Change in ownership of the pharmacy;
 - (f) Death of the proprietor;
 - (g) Failure of the pharmacy to open for business within thirty (30) days after the license has been issued;
 - (h) Failure of the pharmacy to operate for any reason for more than 90 consecutive days after it has opened for business; or
 - (i) Closure of a pharmacy.
- 1904.6 The term of a license issued or renewed pursuant to this chapter is one (1) year and shall expire on May 31 of each year regardless of the issuance date unless the Director changes the renewal system pursuant to section 1904.7.
- 1904.7 The Director may change the renewal system to another system for the administrative convenience of the Director.
- 1904.8 If the Director changes the renewal system pursuant to section 1904.7 of this chapter, the term of a license that is in effect on the date of the Director's determination may be extended up to two (2) years in order to permit an orderly transition.
- 1905. CHANGE IN NAME, OWNERSHIP, OR LOCATION**
- 1905.1 A proprietor desiring to change the name of a pharmacy shall apply to the Director on a form prescribed by the Director and pay the required fee.

- 1905.2 A proprietor desiring to change the location of a pharmacy within the District shall apply for a new license in accordance with the requirements set forth in section 1902 of this chapter.
- 1905.3 If a modification in the name is approved or a new location approved, the Director shall issue a new license indicating the new name or location. The licensee is not permitted to use the new name or location until it has received official notification from the Director of approval of the change.
- 1905.4 A proprietor desiring to change the ownership of a pharmacy shall notify the Director at least sixty (60) days prior to the date of the change. The prospective proprietor shall apply for a new license in accordance with section 1902 of this chapter.
- 1905.5 When a pharmacy changes proprietorship, the license shall become void and shall be surrendered promptly to the Director, and a license shall be obtained by the new proprietor whether or not there is any change in the name of the pharmacy as required in section 9 (f) the Act.
- 1905.6 The Director may issue a license to a new proprietor of a pre-existing licensed pharmacy without a pre-licensure inspection as required by section 1925 of this chapter, provided the new proprietor certifies in the application for a new license that the pharmacy will not undergo substantial physical or operational changes in the first year of licensure.

1906. CLOSING A PHARMACY

- 1906.1 Whenever a pharmacy plans to discontinue operation, the owner shall notify the Director of the closing of the pharmacy not later than fifteen (15) days prior to the anticipated date of closing. This notice shall be submitted in writing and shall contain the following information:
- (a) The date the pharmacy will close;
 - (b) The names and addresses of the persons who shall have custody of the prescription files, the bulk compounding records, the repackaging records, all drugs including the controlled substances, and inventory records of the pharmacy to be closed; and
 - (c) The names and addresses of any persons who will acquire any of the drugs and controlled substances from the pharmacy to be closed, if known at the time the notification is filed.
- 1906.2 Not later than fifteen (15) days after the pharmacy has closed, the owner shall submit to the Director the following:

- (a) The pharmacy license; and
- (b) A written statement containing the following information:
 - (1) Confirmation that all drugs have been transferred to an authorized person or persons, or destroyed. If the drugs were transferred, the names and addresses of the persons to whom they were transferred;
 - (2) If controlled substances were transferred, a list of the names, addresses, and District of Columbia and federal controlled substances registration numbers of the persons to whom the substances were transferred, the substances transferred, the amount of each substance transferred, the date on which the transfer took place, and a copy of DEA Form 222 for the transfer of Schedule II controlled substances.
 - (3) Confirmation that the Drug Enforcement Administration (DEA) registration and all unused DEA 222 forms (order forms) were returned to the DEA;
 - (4) Confirmation that all pharmacy labels and blank prescriptions which were in the possession of the pharmacy were destroyed; and
 - (5) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

1907. PHYSICAL STANDARDS

- 1907.1 The physical standards contained in this section shall apply to all pharmacies unless otherwise exempted by this chapter or the Director.
- 1907.2 A pharmacy shall meet the applicable requirements of the District of Columbia zoning, building, fire, plumbing, and electrical codes.
- 1907.3 A pharmacy shall not be permitted in either a temporary or trailer-type facility, except by special or limited use license as approved by the Director.
- 1907.4 The prescription drug compounding and dispensing area shall:
 - (a) Be a minimum of 150 square feet in area, except that a pharmacy licensed prior to the effective date of these rules may be of a lesser square footage as approved by the Director;
 - (b) Have a minimum of ten (10) square feet of counter space for the pharmacist-in-charge, with additional space for each additional

pharmacist on duty, to compound and dispense drugs safely and efficiently, except that a pharmacy licensed prior to the effective date of this chapter may be of lesser square footage of counter space as approved by the Director;

(c) Be separated from other areas by a barrier which renders the area inaccessible to unauthorized persons;

(d) Be lighted by a minimum of one hundred (100) foot candles;

(e) Provide an unobstructed view of the pharmacist on duty;

(f) Have a sink equipped with potable hot and cold running water from goose-necked faucets within immediate access; and

(g) Have refrigeration facilities exclusively for the storage of drugs requiring cold storage with a thermometer controlling the interior temperature to keep it maintained between thirty-six (36) and forty-six (46) degrees Fahrenheit.

1907.5 All areas where drugs are stored shall be maintained at a temperature safe for the storage of drugs as specified by the United States Pharmacopoeia/National Formulary (USP/NF) or the United States Food and Drug Administration (USFDA).

1908. SANITATION STANDARDS

1908.1 The sanitary standards contained in this section shall apply to all pharmacies and drug storage areas.

1908.2 A pharmacy shall be maintained in a clean and sanitary condition.

1908.3 A pharmacy shall be dry, well ventilated, and free of infestation by rodents, birds, insects, and other vermin.

1908.4 Trash shall be kept in covered waste receptacles.

1908.5 Trash, sewage, and other refuse shall be removed from a pharmacy in a timely and sanitary manner.

1908.6 A toilet with a hand washing sink shall be located in an area reasonably accessible by pharmacy personnel.

1908.7 Plumbing facilities shall be kept in good repair.

1908.8 Each rest room shall be supplied with soap or detergent, toilet paper, and air

driers or single service towels.

1908.9 Pursuant to section 12(b) of the Act, no person shall work in any capacity in a pharmacy if he or she:

(a) Is afflicted with boils, infectious wounds, sores, or an acute respiratory infection;

(b) Is wearing unclean garments;

(c) Is a chronic alcoholic; or

(d) Does not follow hygienic work practices, including the washing of hands thoroughly before commencing work and as often as is necessary thereafter to remove soil and contamination.

1909. GENERAL OPERATING STANDARDS

1909.1 A pharmacy shall be operated only by a licensed pharmacist as required by section 10(a) of the Act.

1909.2 A pharmacist shall be on duty during all times that a pharmacy is open for business as required by section 10(a) of the Act.

1909.3 The following items shall be posted conspicuously in the vicinity of the pharmacy practice area:

(a) Certificate of Occupancy permit (where applicable);

(b) Pharmacy license;

(c) Federal and District of Columbia Controlled Substances Registration;

(d) Licenses of pharmacists on duty; and

(e) Certificates of registration of pharmacy interns.

1909.4 A pharmacy shall stock, maintain, sell, compound, dispense, or distribute only FDA registered drugs and medical devices.

1909.5 A pharmacy shall sell, dispense, or otherwise distribute only drugs and medical devices that are safe for their intended purposes, and that are neither misbranded nor adulterated.

1909.6 Drugs and medical devices with expired dating, or that are otherwise misbranded or adulterated, shall not be stored with currently dated products or those that are safe for their intended purposes, but shall be separated from active stock and so identified.

1910. MINIMUM EQUIPMENT AND REFERENCES

1910.1 A pharmacy shall keep current copies with supplements of the following reference materials in the immediate compounding and dispensing area:

- (a) The official United States Pharmacopoeia/National Formulary;
- (b) The United States Pharmacopoeia Drug Dispensing Information Reference Book;
- (c) The District of Columbia Drug Formulary or its equivalent pursuant to D.C. Code, Title 33, Chapter 7;
- (d) The District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, D.C. Law 3-98;
- (e) The District of Columbia Health Occupations Revision Act of 1985, D.C. Law 6-99;
- (f) Chapters 10, 11, 13, 15 (Controlled Substances), and 19 (Pharmacies) of Title 22 of the District of Columbia Municipal Regulations;
- (g) Chapter 65 (Pharmacists) of Title 17 of the District of Columbia Municipal Regulations;
- (h) Title 21 of the United States Code of Federal Regulations implementing the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513;
- (i) A drug interaction reference book;
- (j) A toxicology reference book; and
- (k) A pharmacology reference book.

1910.2 A pharmacy shall maintain the following equipment:

- (a) A prescription numbering machine or system;
- (b) Adequate supply of prescription labels, auxiliary labels and

containers with regular and child-proof caps;

(c) Antidote chart and local poison center telephone number; bound volume for over-the-counter schedule V controlled substances, hypodermic syringes and needles, and other items required by federal and District of Columbia laws and regulations; and

(d) A prescription balance sensitive to 15 mg. and a set of certified apothecary and metric weights.

1910.3 A pharmacy shall be equipped to provide emergency information about reactions to poison from a current source.

1911. SECURITY AND SAFEGUARDS AGAINST DRUG DIVERSION

1911.1 No drugs shall be permitted within a pharmacy until a license is obtained from the Director.

1911.2 A pharmacy shall have a security alarm system which:

(a) Detects unauthorized entry into the premises;

(b) Provides zone protection for the drug storage, compounding, and dispensing areas;

(c) Has an auxiliary source of power; and

(d) Is in good repair and operating order at all times.

1911.3 The prescription drug compounding and dispensing area and the drug storage area shall be separately enclosed and secured in such a manner as to prevent diversion and unauthorized access.

1911.4 Access to the prescription drug compounding, dispensing, and storage areas shall be restricted to:

(a) Pharmacists employed by the pharmacy;

(b) Ancillary persons who require entry for the purpose of discharging a job related duty in the presence of a pharmacist; and

(c) Persons legally entitled to engage in inspections or enforcement duties.

1911.5 The following drugs, medical devices, and medical supplies shall not be kept or displayed in an area that is accessible to the public:

- (a) Prescription or legend drugs and medical devices;
- (b) Devices that may be used in the administration of controlled substances; and
- (c) Over-the-counter medicine that contains a controlled substance.

- 1911.6 Any controlled substances stored outside of the prescription drug compounding and dispensing area shall be kept in a locked storage area.
- 1911.7 A pharmacy shall be securely locked and protected by an alarm at all times while a pharmacist is not on duty.
- 1911.8 If only a designated area of an establishment is used as a pharmacy, the pharmacy area shall be securely enclosed and capable of being locked and equipped with an alarm system and inaccessible from the rest of the establishment.

1912. PACKAGING AND HANDLING OF DRUGS AND MEDICAL DEVICES

- 1912.1 A pharmacy shall maintain on a current basis a complete and accurate record for a period of two (2) years of all prescription drugs and devices received, sold, dispensed, or otherwise disposed of by the pharmacy.
- 1912.2 A pharmacy shall dispense drugs or medical devices in new and clean containers or in the manufacturer's original container or package.
- 1912.3 A pharmacy shall dispense drugs in child-resistant containers unless there is written documentation that the patient has requested otherwise, pursuant to the Federal Poison Prevention Act of 1970 (16 CFR Part 1700).
- 1912.4 A pharmacy shall not reuse a manufacturer's bottle or container.
- 1912.5 A pharmacy shall not reuse a bottle or container that has held toxic, adulterated, or misbranded substances.
- 1912.6 A pharmacy shall obtain drugs only from suppliers licensed or registered as required by federal and District law.
- 1912.7 A pharmacy shall obtain only drugs that are in the original manufacturer's or distributor's container.

- 1912.8 A pharmacy shall exercise direct personal supervision of the prepackaging of drugs.
- 1912.9 A pharmacy shall keep a log of drugs that have been prepackaged under a pharmacist's supervision. The log must contain the following information:
- (a) The name of the drug;
 - (b) The name of the manufacturer or distributor;
 - (c) The strength of the drug;
 - (d) The lot and control number of the drug;
 - (e) The expiration date;
 - (f) The date of prepackaging;
 - (g) The quantity of drugs prepackaged; and
 - (h) The name of the pharmacist supervising the packaging.
- 1912.10 The pharmacy shall keep the log described in section 1912.9 of this chapter for two (2) years from the date of packaging.
- 1912.11 All drugs and medical devices held by a pharmacy shall be stored in a proper and safe manner as to insure complete and accurate identification of the product, in an appropriate container or package that provides for protection of the product, and as required by this chapter and other applicable federal and District of Columbia laws or regulations or that of the manufacturer.

1913. LABELING OF DISPENSED DRUGS

- 1913.1 A container in which a prescription drug or device is sold or dispensed must bear a label containing the following information:
- (a) The name, address, and telephone number of the pharmacy;
 - (b) The name of the patient;

- (c) The name of the prescriber;
- (d) Directions for usage;
- (e) The serial number of the prescription and the date filled;
- (f) The generic, chemical, or brand name and strength of the drug dispensed unless omission is specifically requested by the prescriber in writing pursuant to the District of Columbia Prescription Drug Price Information Act, D.C Law 1-81, D.C. Code §§33-701 through 33-748 (1988)³¹; and
- (g) The expiration date of the product according to the manufacturer or one (1) year from the date the drug or medical device is dispensed, whichever comes first, subject to the discretion of the pharmacist to select an earlier date on which the life of a compounded drug product may expire.

1913.2 A pharmacy shall be responsible for labeling each prepackaged container with the following information:

- (a) The name of the drug;
- (b) The name of the manufacturer if the drug is generic;
- (c) The drug strength and quantity;
- (d) The manufacturer's control number; and
- (e) The expiration date of the product according to the manufacturer or one (1) year from the date the drug or medical device is prepackaged, whichever comes first, or as required under section 1913.1 (g) of this chapter for a compounded product.

1914. RECORDS OF PRESCRIPTIONS AND THE DISPENSING OF DRUGS

1914.1 A pharmacy shall keep a chronological record of each prescription that is filled, including the following information:

- (a) The name and address of the patient;

³¹ Section 33-701 et. seq (1989) is now cited as D.C. Official Code § 48-801.01 et. seq. (2001)

- (b) The address of the patient for Schedule II controlled substances where required by District of Columbia and federal controlled substances regulations;
- (c) The name and address of the prescriber and date prescribed;
- (d) The name, strength, dosage form, and quantity of the drug prescribed, and quantity dispensed if different from the quantity prescribed;
- (e) Directions for use;
- (f) The date the prescription was compounded or dispensed;
- (g) The name or initials of the dispensing pharmacist;
- (h) The prescriber's Drug Enforcement Administration (DEA) number and District of Columbia Controlled Substances number when required by law or regulation;
- (i) The expiration date of the drug dispensed; and
- (j) Any other information required by District of Columbia or federal law or regulations.

1914.2 A pharmacy shall keep a record of each prescription that is refilled and file it with the original record of the prescription. The prescription must contain the following information:

- (a) The date of the refill;
- (b) The name or initials of the dispensing pharmacist;
- (c) The quantity of the drug dispensed; and
- (d) The name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially.

1914.3 A pharmacy shall not fill a prescription that indicates on its face that it is a copy.

1914.4 The transfer of original prescription information for the purpose of refill dispensing is permissible subject to the following requirements:

(a) The transfer shall be communicated directly between two licensed pharmacists;

(b) The pharmacist making the transfer shall record:

(1) The date of the transfer;

(2) The name and address of the pharmacy to which the prescription is transferred;

(3) The name of the pharmacist transferring the prescription; and

(4) The words "VOID" and "TRANSFER" on the face of the original prescription.

(c) The pharmacist receiving the prescription information shall record:

(1) Date of issuance of the original prescription;

(2) The number of valid remaining refills and date of last refill;

(3) The pharmacy name, address, DEA and District of Columbia registration numbers, if applicable, and original prescription number from which the prescription information was transferred; and

(4) The word "TRANSFER" on the face of the transferred prescription.

1914.5 Both the original and transferred prescriptions shall be maintained for a period of two (2) years from the date of last refill.

1915. COMPUTERIZED RECORDKEEPING

1915.1 As an alternative to manual procedures, an automated data processing system may be used for the recordkeeping system if the following conditions are met:

(a) The system shall have the capability of producing readable documents of all original and refilled prescription information. During the course of an on-site inspection, the record may be read from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Director. In the case of administrative proceedings before the Director, or upon request by the Director or his

or her agent, records shall be provided in a paper printout form; and

(b) The information shall include, but not be limited to, the prescription requirements and records of dispensing as indicated in section 1914 of these rules.

1915.2 The pharmacist shall be responsible for the completeness and accuracy of the information entered into a computerized record keeping system about each prescription that he or she:

(a) Dispenses;

(b) Refills;

(c) Provides to a patient; or

(d) Transfers to another pharmacist.

1915.3 The pharmacist responsible for the completeness and accuracy of the entries into the computer system shall provide documentation that prescription information entered into the computer is correct.

1915.4 A pharmacy may document computerized recordkeeping in either the following ways:

(a) Maintain a bound logbook, or separate file, in which each pharmacist involved in dispensing shall sign a statement daily, attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. The book or file shall be maintained at the pharmacy for a period of two (2) years after the date of last dispensing; or

(b) Provide a daily printout of prescription information. The printout shall be maintained two (2) years from the date of the last dispensing.

1915.5 Documentation required in sections 1915.1(b) and 1915.2 of this chapter shall be provided within twenty-four (24) hours of the date of dispensing.

1915.6 An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall insure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded.

1915.7 Within ninety-six (96) hours after the automated data processing system is restored to operation, the information recorded in the auxiliary recordkeeping system shall be entered into the automated data processing system.

- 1915.8 A pharmacy using an automated data processing system, shall comply with all applicable District of Columbia and federal laws and regulations.
- 1915.9 A pharmacy shall be responsible for continuity in the maintenance of records if the relationship with the supplier of data processing services terminates.
- 1915.10 A pharmacy shall maintain adequate safeguards for record security to assure patient confidentiality.
- 1915.11 A pharmacy utilizing an automated data processing system shall satisfy all requirements for a manual mode of prescription transferal required by sections 1914.4 and 1914.5 of this chapter.
- 1915.12 The automated system shall have the capacity to print on paper within a reasonable time frame all information entered into the system.
- 1915.13 Pharmacies which access the same prescription records electronically, such as pharmacies under a single ownership which electronically access the same prescription records, shall not be required to cancel the original prescription.
- 1915.14 A pharmacy that utilizes a computer system for recordkeeping purposes shall satisfy all data and information keeping requirements of this chapter.
- 1915.15 A pharmacy shall be accountable for the completeness and accuracy of all prescription information that is entered into its computer.
- 1915.16 All prescription entries made into a computerized recordkeeping system shall include the initials or identification code of the dispensing pharmacist responsible for the transaction giving rise to the entry.

1916. MAILING PRESCRIPTION DRUGS

- 1916.1 A pharmacist shall supervise the dispensing of prescription drugs by mail.
- 1916.2 A pharmacy shall not mail a controlled substance or other drug, the mailing of which is prohibited by law.
- 1916.3 Prescription drugs and devices shall be sent by first class mail or delivery service unless the purchaser agrees in advance to another means of delivery.
- 1916.4 The mailing of antibiotics that have been reconstituted is prohibited.
- 1916.5 The mailing of any prescription drug generally recognized to be subject to significant deterioration due to heat, cold, fermentation, or prolonged agitation is

prohibited.

1916.6 Prescription drugs and medical devices shall be sent in containers as required by applicable District of Columbia or federal law and that are resistant to breaking, denting and tampering.

1917 RESERVED

1918. DISPOSAL OF DRUGS

1918.1 A pharmacy shall comply with applicable District and federal laws and regulations when disposing of controlled substances, and radiopharmaceuticals.

1918.2 A record of the disposal of all other drugs shall be made on a form supplied by the Director.

(a) A copy of the form shall be forwarded to the Director within ten (10) days of the disposal.

(b) The form shall be retained on the pharmacy premises of the licensee or registrant for at least two (2) years following the disposal.

1918.3 A pharmacy in possession of legally obtained drugs not required by any other law or regulation to be handled and disposed of in a specific manner, may dispose of the products in one of the following manners, provided complete records of the disposition are maintained by the licensee or registrant on the premises for at least two (2) years:

(a) By destruction in the presence of an authorized agent of the Director;

(b) By destruction in the presence of the pharmacist on duty and one other authorized pharmacy employee; or

(c) By other means approved by the Director to assure that the products do not become available to unauthorized persons or pollute the environment.

1918.4 A pharmacy shall notify the Director in writing ten (10) days in advance of a sale, transfer, distribution, or auction of drugs or medical devices in bulk.

1919. SALE OR DISPOSITION OF DRUGS AT AUCTION

- 1919.1 It shall be unlawful for any licensee to sell, distribute, or otherwise dispose of any drugs at an auction sale without notifying the Director and the Commissioner of Public Health in writing of the proposed action at least ten (10) days in advance of the auction.
- 1919.2 The Director, or any duly authorized agent, is authorized to inspect the drugs proposed to be sold, distributed, or otherwise disposed of, and to prohibit the sale of the items if, in his or her opinion, the products are unfit for human use or consumption. No sale of the products shall be conducted in violation of an order of the Director.

1920. SALE OR DISPOSITION OF DRUGS AFTER BURGLARY OR CATASTROPHIC EVENT

- 1920.1 Burglaries and damage to a pharmacy or its inventory by fire, flood, or other causes shall be reported immediately by the licensee or agent of the licensee to the Director by contacting either:
- (a) The Pharmaceutical and Medical Devices Control Division, 614 H Street, N.W., Room 1016, Washington, D.C. 20001; (202) 727-7218 during regular business hours³²; or
 - (b) The Mayor's Command Center (202) 727-6161.
- 1920.2 Neither drugs or other merchandise contained therein shall be dispensed, sold, held for sale, or given away by any pharmacy damaged by fire or flood or other causes until the Director has determined through an on site inspection by his or her designees that the merchandise is not adulterated or otherwise unfit for sale, use, or consumption as required by section 10(d) of the Act.
- 1920.3 Damaged premises shall also be inspected by the Director to determine their continued suitability for pharmacy operations as required by section 10(d) of the Act.

1921. OPERATIONAL STANDARDS FOR INSTITUTIONAL PHARMACIES

- 1921.1 An institutional pharmacy shall be managed by a pharmacist (hereafter referred to as "Director of Pharmacy") who is licensed to practice pharmacy in the District of Columbia.

³² As of April 2007, The Pharmaceutical Control Division is now located at 717 14th Street, NW., 6th Floor, Washington, D.C. 20005; (202) 724-4900.

- 1921.2 The Director of Pharmacy shall be a full-time employee of the institutional facility in which the institutional pharmacy is located, except that the Director of Pharmacy may be a part-time employee when the pharmacy department or service is not located on site and a formal agreement exists for the provision of pharmaceutical services to the institution.
- 1921.3 The Director of Pharmacy shall be responsible for maintaining and making available:
- (a) A sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and inpatient-care areas, current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and other materials and information deemed necessary by the appropriate committee of the institutional facility, if any;
 - (b) Reference materials on toxicology, pharmacology, bacteriology, sterilization, and disinfection;
 - (c) Sufficient drugs to meet the needs of the patients of the institutional facility, and other appropriate equipment for the preparation thereof;
 - (d) Metric-apothecaries weight and measure conversion tables and charts to all applicable personnel; and
 - (e) Written policies and procedures that delineate the operation and activities of the provision of pharmacy services for the institutions that insure compliance with this section and applicable sections of this chapter.
- 1921.4 Trained technical and administrative personnel may be employed in a support capacity in institutional pharmacies, provided that the support activities performed are under the supervision of a pharmacist.
- 1921.5 Secretarial and clerical assistance, and related support may be provided as required to assist with recordkeeping, report submission, and other administrative duties.
- 1921.6 Areas occupied by an institutional pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.
- 1921.7 An institutional pharmacy, or any part thereof, shall be locked in the absence of personal and direct supervision by authorized personnel.
- 1921.8 The Director of Pharmacy shall designate in writing, by title and specific area,

those persons who have access to particular areas within the pharmacy during non-business hours of the pharmacy.

1921.9 Authorized persons may have access to the designated area in the institutional pharmacy, and may remove drugs in compliance with the institution's established policy and procedures.

1921.10 Personnel authorized to have access to the designated area in the institutional pharmacy, prior to being permitted access to the pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required.

1921.11 Education and training required by section 1921.10 of this chapter, to be given by the Director of Pharmacy, shall require, at a minimum, the following records and procedures:

(a) Removal of any drug from the pharmacy by a legally authorized person shall be recorded on a suitable form showing name of drug, strength, amount, date, time, and signature of the authorized person; and

(b) The form shall be left within the cabinet or similar container from which the drug was removed and placed conspicuously so that the form and container will be checked properly and promptly by the pharmacist.

1921.12 During the times that an institutional pharmacy may be unattended by a licensed pharmacist, arrangements shall be made in advance by the Director of Pharmacy for provision of drugs to the licensed medical staff and other authorized personnel of the institutional facility by use of night cabinets, interim medication boxes, or by similar means, and, in emergency circumstances, by access to a designated area of the pharmacy by persons authorized to handle, manage, or administer medication.

1921.13 If night cabinets are used pursuant to section 1921.12 of this chapter, the following procedures shall be used:

(a) In the absence of a licensed pharmacist, cabinets, or containers utilized for the storage of drugs or other enclosures constructed and located outside of the pharmacy area for the use by authorized personnel, shall be locked and shall be sufficiently secure to deny access to unauthorized persons by force or otherwise.

(b) The Director of Pharmacy, in conjunction with the appropriate committee of the institutional facility, shall develop inventory listings

of those drugs to be included in night cabinets or the enclosures pursuant to section 1921.12 of this chapter and shall insure that:

(1) All drugs available in the cabinet or similar container shall be properly stored and labeled; and

(2) Prepackaged drugs shall be available in amounts sufficient for immediate therapeutic requirements.

(c) Utilization of the night cabinets or similar containers or other enclosures shall require written orders and proofs of use, if applicable.

(d) All drugs maintained in night cabinets shall be inventoried on a regular basis, but no less than every six (6) months.

(e) A complete audit of all activity concerning the night cabinets or similar containers or other enclosures shall be conducted no less than one time per month.

(f) Written policies and procedures shall be established to implement the requirements of this subsection, for the use of drug storage and distribution systems.

1921.14

When any drug is not available from floor supplies, interim containers, or night cabinets, and the drug is required to treat the immediate needs of a patient, the drug shall be obtained from the pharmacy in accordance with the following requirements:

(a) One (1) supervisory registered professional nurse, and only one (1) in any given eight (8) hour shift, is responsible for removing drugs from the pharmacy. The responsible nurse may, in times of emergency, delegate this duty to another nurse;

(b) The responsible nurse shall be designated by position in writing by the appropriate committee of the institutional facility, and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required; and

(c) The education and training shall be given by the Director of Pharmacy, who shall require, at a minimum, the following records and procedures:

(1) Removal of any drug from the pharmacy by an authorized nurse must be recorded on a suitable form showing patient name, room number, name of drug,

strength, amount, date, time and signature of nurse; and

(2) The form shall be left with the container from which the drug has been removed, both placed conspicuously so that it will be found by a pharmacist and checked properly and promptly.

- 1921.15 Drugs may be dispensed from the institutional pharmacy only upon written orders, direct copies, or facsimiles thereof, or telephone orders, legally allowed and reduced to writing, of authorized practitioners. Telephone or verbal orders not countersigned within seventy-two (72) hours shall be voided.
- 1921.16 The Director of Pharmacy shall maintain a listing, including signatures, of those practitioners who are authorized to issue orders to the pharmacy.
- 1921.17 Orders employing abbreviations and chemical symbols shall be utilized and filled only if the abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility.
- 1921.18 Drug orders for use by inpatients shall contain the following information:
- (a) Patient name, identification number, and room number;
 - (b) Drug name;
 - (c) Strength;
 - (d) Directions for use and route of administration; and
 - (e) Date and physician's signature, or signature of his or her authorized representative.
- 1921.19 Orders for drugs for use by outpatients shall contain all items required by section 1921.18 of this chapter, in addition to the physician's address and DEA registration number, and the patient's address, if applicable.
- 1921.20 The Director of Pharmacy shall be responsible for the following:
- (a) Preparation and sterilization of parenteral medications manufactured within the institutional facility;
 - (b) Admixture of parenteral products; and
 - (c) Education and training of nursing personnel concerning incompatibility and provision of proper incompatibility information

when the admixture of parenteral products is not accomplished within the institutional pharmacy.

- 1921.21 There shall be a suitable area for the manipulation of parenteral medications. When laminar airflow hoods are used, quality control requirements shall include cleaning of the equipment, microbiological monitoring as required by the infection control committee, and periodic checks for operational efficiency at least every twelve (12) months by a qualified inspector. Appropriate records shall be maintained.
- 1921.22 All drugs dispensed by an institutional pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and adequately labeled to identify the generic chemical or brand name, strength, a lot number, and expiration date.
- 1921.23 The Director of Pharmacy shall develop and implement policies and procedures to insure that discontinued and outdated drugs, and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition, or that the Director of Pharmacy, or his or her designee, make proper disposition of such drugs at the storage site.
- 1921.24 The Director of Pharmacy shall develop and implement a recall procedure to assure the medical staff and the pharmacy staff that all drugs included on the recall are returned to the pharmacy for proper disposition.
- 1921.25 The Director of Pharmacy shall document suspected and reported adverse drug reactions to the prescriber.
- 1921.26 In the event of an adverse drug reaction, an entry reflecting the reaction shall be made on the patient's pharmacy record.
- 1921.27 The Director of Pharmacy shall make reports of suspected reactions to The Hospital Reporting Program of the FDA, to the manufacturer, and to the United States Pharmacopoeia, and shall report drug product defects accordingly.
- 1921.28 The Director of Pharmacy shall maintain the following records for a period of two (2) years:
- (a) Physicians' orders, direct copies or facsimiles thereof;
 - (b) Proofs of use of Schedule II Controlled Substances and any other drugs requested or required;

- (c) Reports of suspected adverse drug reactions;
- (d) Inventories of night cabinets, emergency kits, and similar systems;
- (e) Inventories of the pharmacy;
- (f) Biennial inventories of controlled substances;
- (g) Alcohol and flammable reports; and
- (h) Any other records and reports as may be required by law and regulations.

1921.29 The Director of the Pharmacy, not less than once a month, shall inspect the pharmacy and all areas of the institution where drugs distributed by the pharmacy are stored or maintained, and make appropriate written records and notations of those inspections. An inspection shall verify that:

- (a) Licensed pharmacists are responsible for all drugs dispensed and orders are checked by licensed pharmacists prior to leaving the pharmacy;
- (b) Ancillary pharmacy personnel are properly directed and supervised;
- (c) Drugs requiring special storage conditions are properly stored;
- (d) Outdated drugs are retired from stock in the institutional pharmacy or the facility it serves;
- (e) Controlled substances which have been distributed are properly and adequately documented and recorded by pharmacy personnel;
- (f) Emergency kits designated pursuant to section 1921.30 of this chapter are adequate and in proper supply both within the pharmacy and at outside storage locations; and
- (g) Security and storage standards are met.

1921.30 For an institutional facility which does not have an on site institutional pharmacy, drugs may be provided for use by authorized personnel through emergency kits located at the facility, provided the emergency kits meet the following requirements:

- (a) The emergency kit contains those drugs which may be required to meet the immediate therapeutic needs of patients and which are not

available from any other authorized source in sufficient time to prevent risk or harm to patients by delay resulting from obtaining the drugs from other sources;

(b) All emergency kit drugs shall be provided by a licensed pharmacist;

(c) The supplying pharmacist and the appropriate committee of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits;

(d) Emergency kits shall be stored in secure areas, suitable to prevent unauthorized access by force or otherwise, and to insure a proper environment for preservation of the drugs;

(e) The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and it is for use in emergencies only, and the label shall also contain a listing of the drugs contained therein, including name, strength, quantity and expiration of the contents, and the name, addresses, and telephone numbers of the supplying pharmacist;

(f) All drugs contained in emergency kits shall be labeled with information required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients of the facility;

(g) Drugs shall be removed from emergency kits only pursuant to a valid physician's order by authorized personnel, or by the supplying pharmacist;

(h) Whenever an emergency kit is opened, the supplying pharmacist shall be notified, and the pharmacist shall restock and reseal the kit within a reasonable time so as to prevent risk of harm to patients. In the event the kit is opened in an unauthorized manner, the pharmacist and other appropriate personnel of the facility shall be notified;

(i) The expiration date of an emergency kit shall be the earliest date of any drugs supplied in the kit. Upon this occurrence, the supplying pharmacist shall open the kit and replace expired drugs with current dated drugs and reseal it; and

(j) The supplying pharmacist shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to insure compliance with the provisions of this subsection, and other applicable sections of this chapter.

1921.31 The Director of Pharmacy shall be responsible for developing procedures for an ongoing quality assurance program of pharmaceutical services that includes a mechanism for reviewing and evaluating drug related patient care, as well as an appropriate response to findings. This written plan should clearly establish responsibility and the need for documentation of an effective program.

1922. OPERATIONAL STANDARDS FOR NUCLEAR PHARMACIES

1922.1 A pharmacy, institution, or other establishment that dispenses radiopharmaceuticals shall obtain from the Director a nuclear pharmacy license. The license to operate a nuclear pharmacy shall be conditioned upon approval of Nuclear Regulatory Commission (NRC) where applicable. Copies of the most current inspection reports by the Director and NRC shall be available on the premises of the nuclear pharmacy.

1922.2 All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist ("responsible nuclear pharmacist") who has met the standards of training for NRC for medically used and radioactive by-product materials, and any other standards required by the Board of Pharmacy or any applicable District of Columbia or federal law or regulation. A nuclear pharmacist shall be responsible for all operations of the licensed area and shall be present at all times that the nuclear pharmacy is open for business.

1922.3 One or more other licensed pharmacists shall be designated by the nuclear pharmacist to act in case of an emergency, or in the nuclear pharmacist's absence, to obtain single doses of radiopharmaceutical for an immediate emergency, and shall document this information in the control system.

1922.4 A nuclear pharmacy shall maintain current editions or revisions of the following reference materials:

- (a) District of Columbia and federal laws and regulations governing the use of applicable radioactive materials; and
- (b) U.S. Public Health Service, Radiological Health Handbook.

1922.5 A nuclear pharmacy shall have the following equipment:

- (a) Dose Calibrator;
- (b) Refrigerator;
- (c) Class A prescription balance of greater sensitivity;

- (d) Single or multiple channel scintillation counter;
- (e) Microscope and themocyclometer;
- (f) Exhaust Hood (Radiochemical hood and filter system);
- (g) Appropriate standard for a periodic calibrator standardization;
- (h) Moly Assay Kit;
- (i) Decontamination solution;
- (j) Autoclave, or access to one;
- (k) Pyrogen oven, or access to one, capable of 250C for 45 minutes;
- (l) Portable radiation survey meter capable of detecting 0.005 micro curies of the radio nuclides in question; and
- (m) Laminar flow hood and other equipment necessary for radiopharmaceutical services provided as required by the Board of Pharmacy.

- 1922.6 A prescription order for a radiopharmaceutical shall be dispensed on a unit dose basis. A pharmacist may furnish radiopharmaceuticals for office use only to practitioners for an individual patient.
- 1922.7 Radioactive drugs shall be dispensed only upon a prescription order form from a licensed medical practitioner authorized to possess, use, and administer radiopharmaceuticals.
- 1922.8 A nuclear pharmacy shall dispense only radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.
- 1922.9 A nuclear pharmacy shall comply with all applicable laws and regulations of District of Columbia and Federal agencies, including the laws and regulations governing any non-radioactive drugs, and any medical devices that may be dispensed.
- 1922.10 The responsible nuclear pharmacist shall develop and implement written policies and procedures to insure compliance with the provisions of this section and other applicable sections of this chapter.

1923. PARENTERAL SOLUTIONS

1923.1 Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have a designated area for the preparation of sterile products for dispensing. Pharmacies shall ensure the following standards for this designated area:

(a) It shall meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as a laminar air flow hood or clean room in accordance with Federal Standard 209(b), "Clean Room and Work Station Requirements", Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration (41 CFR Part 5).

(b) It shall have cleanable surfaces, walls, and floors.

(c) It shall be ventilated in a manner not interfering with laminar air flow.

(d) The laminar air flow hood shall be certified annually in accordance with Federal Standard 209(b). Certification records shall be retained for a minimum of (2) years.

(e) The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions. Items related to the compounding of parenteral solutions shall not obstruct the intake of the laminar flow hood. There shall be sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment, and waste.

(f) There shall be a sink with hot and cold running water located with the parenteral solution compounding area.

(g) There shall be a refrigerator or freezer of sufficient capacity to meet the storage requirements for all materials requiring refrigeration.

1923.2 In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag-in, bag-out design. The pharmacy shall ensure that contaminated air plenum that are under positive air pressure are leak tight. The hood must be certified annually in accordance with National Sanitation Foundation Standard 49 or manufacturer's specifications. Certification records shall be retained for a minimum of two (2) years.

- 1923.3 In addition to existing labeling requirements, parenteral product labels shall include:
- (a) Telephone number of the pharmacy;
 - (b) Name and concentrations of all ingredients contained in the parenteral product, including primary solution;
 - (c) Instructions for storage and handling; and
 - (d) A label for all cytotoxic agents which shall state: "Chemotherapy - Dispose of Properly".
- 1923.4 Pharmacies engaged in the practice of compounding and dispensing of parenteral solutions shall have on the premises, or readily accessible, a patient record for each patient being treated with parenteral therapy. In addition to existing recordkeeping requirements, the following records shall be maintained in the pharmacy:
- (a) Records of the furnishing of all prescriptions and medical supplies;
 - (b) Progress notes documenting contact with the patient or physician relative to parenteral therapy; and
 - (c) Other data relevant to parenteral therapy.
- 1923.5 Gowns and gloves shall be worn when preparing cytotoxic agents.
- 1923.6 The managing pharmacist shall ensure that all pharmacists engaging in compounding parenteral solutions have training or have demonstrated previous training in the safe handling and compounding of parenteral solutions, including cytotoxic agents.
- 1923.7 Pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious materials and materials containing cytotoxic residues.
- (a) The procedures shall include cleanup of spills and shall conform with applicable District of Columbia and federal law and regulations.
 - (b) The pharmacy shall ensure the return of these materials or shall communicate the proper destruction of these materials to the caregiver.
- 1923.8 The pharmacist is responsible for developing and maintaining a quality assurance program that insures a clean and sanitary environment for the preparation of sterile products and insures that the parenteral products that are

produced are sterile. Documentation of these activities shall be available to the Director.

1923.9 The quality assurance program required by section 1923.8 of this chapter shall include, but not be limited to, provisions for the following:

(a) Cleaning and sanitizing the parenteral medication area;

(b) Surveillance of parenteral solutions for microbiological

contamination and actions taken in the event that testing for contamination proves positive;

(c) Where bulk compounding of parenteral solutions is performed, the surveillance of parenteral solutions for microbiological contamination and pyrogens, and documentation of the results prior to dispensing to the patient;

(d) Periodic documentation of the room and refrigerator temperatures in which compounded parenteral products are stored;

(e) Steps to be taken in the event of a drug recall; and

(f) Written justification of expiration dates for compounded parenteral products.

1923.10 Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have written policies and procedure which describe the methods and approaches employed by the pharmacy in dispensing, compounding, and labeling parenteral solution.

1923.12 Pharmacies engaged in the practice of compounding and dispensing parenteral solutions shall have current reference materials located in or immediately available to the pharmacy, which shall include information on:

(a) All drugs and chemicals used in parenteral therapy; and

(b) All parenteral therapy manufacturing, dispensing, distribution, and counseling services provided.

1924 RESERVED

1925. INSPECTION AND INVESTIGATION OF PHARMACIES

- 1925.1 The Director or a duly authorized agent in accordance with section 17 of the Act, D.C. Code § 2-2016³³, and after presenting proper identification, may enter at reasonable times any pharmacy for the purpose of making inspections to determine compliance with this chapter or with other laws or regulations applicable to the practice of pharmacy. This inspection may include:
- (a) The examination of the pharmacy records, including prescriptions, invoices, and inventory records;
 - (b) The obtaining of prescriptions, information, and samples pertaining to drugs dispensed;
 - (c) The examination of any drugs, medical devices, or any other pharmaceutical products or medicinal chemicals that are in the pharmacy; and
 - (d) The review of any records and publications that are required by any applicable District of Columbia or federal laws or regulations to be kept in a pharmacy.
- 1925.2 Inspections of pharmacy operations covered by these rules shall be conducted for a new license, at least annually thereafter, and as often as the Director deems necessary.
- 1925.3 The Director shall delegate pharmacists to investigate complaints of violations of the Act, this chapter, and all other applicable laws and regulations regarding

1926. TAKING OF SAMPLES

- 1926.1 Whenever the Director or other authorized agent of the Department has reason to believe that a drug or medical device is maintained or dispensed in violation of these rules or other District or federal laws or regulations, he or she may take a sample of that item or items pursuant to this section.
- 1926.2 In addition to sample taking authorized pursuant to section 1926.1 of this chapter, the Director or authorized agent may take a reasonable number of samples as a part of the regular pharmacy inspection process to check for compliance with the Act, this chapter, and other

³³ Section 2-2016 of the D.C. Code is now cited as D.C. Official Code § 47-2885.16 (2001).

laws or regulations applicable to the practice or pharmacy.

- 1926.3 The Director or authorized agent may affix to a product, device, or drug a tag or other appropriate marking giving notice that the sample product has been marked for inspection.

1927. OPPORTUNITY FOR A HEARING

- 1927.1 The Director shall take action to deny, suspend or revoke a pharmacy license pursuant to section 11 of the Act, D.C. Code § 2-2010.³⁴
- 1927.2 Except for a summary suspension undertaken pursuant to section 11(b) of the Act, D.C. Code § 2-2010(b),³⁵ every applicant for or holder of a license or applicant for reinstatement after revocation shall be afforded notice and an opportunity to be heard prior to the action of the Director, the effect of which would be one of the following:
- (a) To deny a license for cause other than failure to qualify;
 - (b) To suspend a license;
 - (c) To revoke a license;
 - (d) To refuse to reinstate a license;
 - (e) To refuse to issue a renewal license for any cause other than failure to pay the prescribed fees; or
 - (f) Impose a civil fine pursuant to the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, D.C. Code sec. 6-2701 et seq.³⁶

1928. NOTICE OF CONTEMPLATED ACTION

- 1928.1 When the Director contemplates denying a license for failure to qualify, he or she shall give the applicant written notice containing the following statements:
- (a) That the applicant has failed to satisfy the Director as to the applicant's qualifications;
 - (b) The respect in which the applicant has failed to satisfy the Director;

³⁴ Section 2-2010 of the D.C. Code is now cited as D.C. Official Code § 47-2885.10 (2001).

³⁵ Section 2-2010 of the D.C. Code is now cited as D.C. Official Code § 47-2885.10 (2001).

³⁶ Section 6-2701 et. seq. is now cited as D.C. Official Code § 2-1801.01 et. seq. (2001)

(c) That the denial will become final unless the respondent files a request for a hearing with the Director within fifteen (15) days of the receipt of the notice; and

(d) A description of the rights of the respondent at a hearing as specified in section 1932.3.

1928.2 When the Director contemplates taking any action of the type specified in section 1927.2(b), (c), (d), or (e) of this chapter, he or she shall give the licensee a written notice containing the following statements.

(a) That the Director has sufficient evidence which, if not rebutted or explained, justifies the Director in taking the contemplated action;

(b) That the Director may take the proposed action, unless within fifteen (15) days of the receipt of the notice the respondent files with the Director a written request for a hearing or in the alternative submits documentary evidence for the Director's consideration before the Director takes final action; and

(c) A description of the rights of the respondent at a hearing as specified in section 1932.3.

1929. NOTICE OF HEARING

1929.1 Any notice required by this chapter may be served either personally or by certified mail, return receipt requested, directed to the respondent at his or her last known address as shown by the records of the Department of Consumer and Regulatory Affairs.

1929.2 If notice is served personally, it shall be deemed to have been served at the time delivery is made to the respondent.

1929.3 If notice is served by certified mail, it shall be deemed to have been served on the date shown on the return receipt showing delivery or refusal of the respondent to receive notice.

1929.4 In the event the respondent is no longer at the last know address as shown by the records of the Department of Consumer and Regulatory Affairs and no forwarding address is available, the notice shall be deemed to have been served on the date the return receipt bearing such notification is received by the Director.

1929.5 If a respondent scheduled for a hearing does not appear and no continuance has been or is granted, the Director may hear the evidence of those witnesses present, and the Director may proceed to consider the matter and render a decision on the basis of the evidence presented.

1930. PROCEDURE WHEN A RESPONDENT FAILS TO RESPOND TO A HEARING NOTICE

1930.1 If the respondent does not respond to the hearing notice within the time specified, the Director may, without a hearing, take the action contemplated in the notice. The Director shall, in writing, inform the respondent, the Corporation Counsel, and the Board of his or her action.

1931. HEARINGS-SUMMARY SUSPENSION AND DENIAL OF RENEWAL

1931.1 A hearing shall be convened within five (5) days of the institution of proceedings in the following cases:

(a) Summary suspension; and

(b) Denial of renewal.

1931.2 A respondent who has been summarily suspended pursuant to section 11 (b) of the Act, D.C. Code § 2-1010(b),³⁷ or notified of intent to deny renewal, shall be entitled, upon written request, to a hearing, or to a postponement, for a reasonable time only, of the hearing scheduled pursuant to this section.

1931.3 If a hearing is requested pursuant to this section, the request shall not serve to stay the issuance of the order suspending or denying the license.

1931.4 Except as otherwise noted in this chapter, all procedures relating to hearings as set forth within this chapter shall apply to hearings on summary suspensions and denials of renewal.

1932. CONDUCT OF HEARINGS

1932.1 All hearings before the Director shall be open to the public.

1932.2 The Director, or his or her designee, shall hear the evidence and render a

³⁷ Section 2-2010 of the D.C. Code is now cited as D.C. Official Code § 47-2885.10 (2001).

decision.

1932.3 A respondent entitled to a hearing shall have the following rights:

- (a) To be represented by counsel or other representative;
- (b) To present all relevant evidence by means of witnesses, books, papers, and documents.
- (c) To examine all opposing witnesses on any matter relevant to the issues; and
- (d) To have subpoenas issued, upon written request to the Director, to compel the attendance of witnesses and the production of relevant books, papers, and documents.

1932.4 In conducting a hearing pursuant to this chapter, the Director is authorized to do the following:

- (a) Administer oaths or affirmation to witnesses called to testify pursuant to section 3 of D.C. Law 3-109, D.C. Code § 1-338.1 (1987);³⁸
- (b) Subpoena respondents, witnesses, books, papers, and documents pursuant to section 3 of D.C. Law 3-109, D.C. Code § 1-338 (1987);³⁹
- (c) Take testimony;
- (d) Examine witnesses;
- (e) Order a continuance; and
- (f) Enter into a consent agreement.

1932.5 The Director shall receive and consider any evidence or testimony; however, the Director may exclude irrelevant, immaterial, or unduly repetitious evidence or testimony.

1932.6 In any proceeding resulting from the Director's contemplated action to deny licensure, the applicant shall have the burden of satisfying the Director of the applicant's qualifications.

1932.7 In any proceeding resulting from the Director's contemplated action to refuse to renew, to suspend, or to revoke a license, or to refuse to

³⁸ D.C. Code § 1-338.1 is now cited as D.C. Official Code § 1-301.21 (2001).

³⁹ D.C. Code § 1-338.1 is now cited as D.C. Official Code § 1-301.21 (2001).

restore a license, the Department shall have the burden of proving that the action should be taken.

- 1932.8 A complete record shall be made of all evidence presented during the course of a hearing. Any party to the proceedings shall be furnished with a copy of the record upon request and payment of a fee prescribed by the Director.

1933. DECISIONS

- 1933.1 The decision of the Director shall include the following:

(a) Findings of fact;

(b) Conclusions of law; and

(c) A statement informing the respondent concerning his or her right to have the decision reviewed by the Board of Appeals and Review, and the time period within which the request for such a review must be filed.

- 1933.3 Within seven (7) days after the decision is issued, the Director shall serve upon the respondent, or his or her attorney of record, a copy of the written decision, either by personal service or certified mail, return receipt requested. If served by certified mail, it shall be deemed served on the date contained on the return receipt for acceptance or refusal, or the date of the unsuccessful attempt of the postal service to make delivery.

1934. ADMINISTRATIVE AND JUDICIAL REVIEW

- 1934.1 When a respondent fails, for good cause, to appear for a hearing which has been scheduled, the respondent may, within thirty (30) days from the date of the decision, apply to the Director to reopen the proceedings. The Director, upon finding the cause sufficient, may fix a time and place for the hearing and shall give notice to the parties.

- 1934.2 The Director may reopen a proceeding for any cause he or she deems sufficient, provided that no appeal is pending or no decision has been issued regarding the case by the Board of Appeals and Review or a court.

- 1934.3 A respondent aggrieved by an adverse decision by the Director may seek a review of the decision by the Board of Appeals and Review

according to its rules, chapter 5 of Title 1 DCMR.

- 1934.4 A respondent adversely affected by the decision of the Board of Appeals and Review may seek a review of the decision by the District of Columbia Court of Appeals according to the rules prescribed by the Court.
- 1934.5 Within the time set by Court rule or order, the Director shall certify and file with the Clerk of the Court the record of the case as required by the Court.

1999. DEFINITIONS

1999.1 When used in this title, the following terms and phrases shall have the meanings ascribed:

Act - the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, D.C. Law 3-98, D.C. Code §§ 2-2001 through 2-2023, as amended.⁴⁰

Adulterated drug or device - the meaning as defined in section 501 of the Federal Food, Drug and Cosmetic Act, Pub. L. 96-354, 21 U.S.C. 351, as amended.

Applicant - a person, partnership, or corporation applying for a license to practice pharmacy under this chapter.

Automated Data Processing System - a system utilizing computer software and hardware for the purpose of recordkeeping.

Community/Retail pharmacy - a pharmacy as defined under HORA that provides pharmacy services to the public or general community on an outpatient basis, whether at retail, through third party payment, or other measure of no or minimum cost to the consumer.

Computer - programmable electronic device capable of multi-functions, including, but not limited to, storage, retrieval, and processing information.

Controlled substances - those drug items or chemicals regulated under the federal Controlled Substances Act of 1970, Pub. L. 91-513, 21 U.S.C. 800 et seq. and 900 et seq., as amended, and the District of Columbia Uniform Controlled Substances Act of 1981, D.C. law 4-29, D.C. Code §§ 33-501 et seq., as amended.⁴¹

⁴⁰ D.C. Code §§ 2-2001 through 2-2023 is now cited as D.C. Official Code §§ 47-2885.01 et. seq. (2001)

⁴¹ D.C. Code §§ 33-501 et seq. is now cited as D.C. Official Code §§ 48-901.01 et. seq. (2001)

CRT - cathode ray tube used to impose visual information on a screen.

Department - the Department of Consumer and Regulatory Affairs.

Director - the Director, Department of Consumer and Regulatory Affairs.

Division - the Pharmaceutical, Radiological, and Medical Devices Control Division, Department of Consumer and Regulatory Affairs.

Downtime - that period of time when a computer is inoperable.

Expired drug or medical device - expiration of the date required by the Federal Food, Drug and Cosmetic Act, Public Law 96-354, 21 U.S.C. 352 to be placed on the label of the original container by the manufacturer, packer, or distributor for which the product may be placed on the market for use or consumption.

Hardware - the fixed component parts of a computer.

HORA - the District of Columbia Health Occupations Revisions Act of 1985, D.C. Law 6-99, D.C. Code §§ 2-3301 through 2-3311.⁴²

Institutional pharmacy - a pharmacy or that portion thereof, as defined by HORA, which is in an institutional establishment, hospital, infirmary, or any other organization or entity whose primary purpose is to provide a physical environment for patients to obtain pharmaceutical health care services (except those places where practitioners are duly licensed to engage in private practice) and which is engaged in the sale, dispensing, or distribution of drugs.

Misbranded drug or medical device - the meaning as defined in section 501 of the Federal Food, Drug and Cosmetic Act, Public Law 96-354, 21 U.S.C. 352 as amended.

Nuclear pharmacy - a pharmacy as defined under HORA that provides those pharmacy services that are engaged in the production, distribution, and dispensing of radiopharmaceuticals.

Pharmacy - the meaning as defined under HORA, D.C. Code § 2-3301.2(11)(B)(i).⁴³

Prescriber - a health professional currently licensed or legally authorized to prescribe the particular drugs and medical devices.

⁴² D.C. Code §§ 2-3301 through 2-3311 is now cited as D.C. Official Code §§ 3-1201.01 et. seq. (2001)

⁴³ D.C. Code §§ 2-3301.2(11)(B)(i) is now cited as D.C. Official Code §§ 3-1201.02(11)(B)(i) (2001)

Prescription - the meaning as defined under HORA.

Prescription drug - one of the following drugs:

(a) A drug which under federal law is required, prior to being dispensed or delivered, to be labeled in substance with either of the following statements:

(1) "Caution: Federal law prohibits dispensing without prescription." or

(2) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.";

(b) A drug which is required by any applicable federal or District law or regulation to be dispensed on prescription only; or

(c) A drug that is restricted to use by health professional and allied practitioners for research.

Printout - a hard copy produced by a computer that is readable without the aid of any special device.

Radiopharmaceutical quality assurance - means, but is not limited to, the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine its suitability for use on humans and animals, including internal test assessment, authentication of product history, and the keeping of proper records.

Respondent - a person, partnership, or corporation to whom the Director sends a notice of anticipated action against the license or application therefore.

Software - computer programs, procedures, and storage of required information data.

Special or limited use pharmacy - a pharmacy as defined under HORA that provides pharmacy services that are primarily for a special purpose or are limited by the type of drugs dispensed, such as sterile parenteral solutions.

Stop date - in institutional settings, the length of time to administer a medication as indicated by the prescribing practitioner, or established institutional policy on length of administration of drugs by category in the absence of the prescriber's notation.

Systems backup - (auxiliary records maintenance) hard copy, disk, tape, or equivalent used if the computer system becomes inoperative.