

# **DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS**

## **TITLE 22. PUBLIC HEALTH AND MEDICINE**

### **CHAPTER 4. DRUG MANUFACTURE AND DISTRIBUTION**

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#### **§ 22-400. 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.

## **§ 22-401. 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.

## **§ 22-402. 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.

### **§ 22-403. 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.

### **§ 22-404. 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.

#### **§ 22-405. 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.

#### **§ 22-406. 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.

#### **§ 22-407. 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.

#### **§ 22-408. 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 of electronic records.

## **§ 22-409. 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.

## **§ 22-410. 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.

## **§ 22-411. 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.

## **§ 22-411. 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.

**§ 22-412. 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.

**§ 22-413. 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.

**§ 22-414. 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.

## **§ 22-415. 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.

## **§ 22-416. 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),<sup>2</sup> 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:

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<sup>1</sup> 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).

- (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.;<sup>3</sup> or
- (h) Reinstatement of the license.

## **§ 22-417. 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

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

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.

## **§ 22-417. 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:

- (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.

## **§ 22-418. 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.

## **§ 22-419. 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.

## **§ 22-420. 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.

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

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 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.

## **§ 22-421. 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.

## **§ 22-422. 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.

## **§ 22-423. 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)<sup>5</sup>;

(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)<sup>6</sup>;

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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).

(c) Take testimony;

(d) Examine witnesses;

(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.

## **§ 22-424. 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.

## **§ 22-425. 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.

## **§ 22-425-426 [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.<sup>7</sup>

**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.<sup>8</sup>

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

**DEPARTMENT** - the Department of Consumer and Regulatory Affairs.

**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).<sup>9</sup>

**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.

**WHOLESALE** - 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.

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

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