

*District of Columbia  
Pharmacy Laws*



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# SECTION I.



# PHARMACY LICENSING AND OPERATION

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 7. HUMAN HEALTH CARE AND SAFETY**  
**SUBTITLE A. GENERAL**  
**CHAPTER 7A. FUNCTIONS OF THE DEPARTMENT OF HEALTH**  
**SUBCHAPTER I. GENERAL POWERS, FEES, AND FUNDS**

§ 7-731. Exclusive agency powers

- (a) Notwithstanding the licensing powers and responsibilities given to other District of Columbia agencies and officials in subchapters I-A and I-B of Chapter 28 of Title 47 of the District of Columbia Official Code, the Department of Health, as established by Reorganization Plan No. 4 of 1996, effective July 17, 1996 (part A of subchapter XIV of Chapter 15 of Title 1), shall be the exclusive agency to:
- (6) Regulate pharmacies and pharmacy personnel;
  - (7) Determine which drugs and other substances shall be classified as controlled substances, and identify persons and facilities that handle, manage, distribute, dispense, and conduct research with controlled substances;
  - (8) Regulate radiological and medical devices;
  - (9) Regulate the manufacture, distribution, and dispensing of controlled substances;
- (b) For the purpose of this section, the term "regulate" shall include all licensing, certification, investigation, inspection, permitting, registration, and enforcement functions, including the issuance of civil infractions, except that the Department of Consumer and Regulatory Affairs shall continue to issue licenses for businesses engaged in functions as set forth in subsection (a)(3), (a)(5), (a)(10), (a)(11), and (a)(12) of this section.
- (c) The Mayor shall establish fees to implement this section. All fines and fees collected pursuant to this section shall be deposited as nonlapsing funds in the Department of Health Regulatory Enforcement Fund to the credit of the administration within the Department of Health responsible for collecting the fees to support the activities of those programs, except that fines and fees collected pursuant to Chapter 21 of Title 8 shall be deposited in the Rodent Control Fund. After September 30, 2002, fines and fees generated through rodent control activities shall be deposited in the Department of Health Regulatory Enforcement Fund.

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 47. TAXATION, LICENSING, PERMITS, ASSESSMENTS, AND FEES**  
**CHAPTER 28. GENERAL LICENSE LAW**  
**SUBCHAPTER IV. OTHER LICENSES**  
**PART C. PHARMACY**

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- § 47-2885.01. Purposes, scope
  - § 47-2885.02. Definitions
  - § 47-2885.03. General prohibitions
  - § 47-2885.04. Board of Pharmacy; licensing of pharmacists. (Repealed)
  - § 47-2885.05. Board of Pharmacy; licensing of pharmacists. (Repealed)
  - § 47-2885.06. Registration of pharmacy interns.
  - § 47-2885.07. Denial, suspension, or revocation of pharmacist's license or pharmacy intern's registration. (Repealed)
  - § 47-2885.08. Licensing of pharmacies.
  - § 47-2885.09. Operation of pharmacy
  - § 47-2885.10. Denial, suspension, or revocation of pharmacy license.
  - § 47-2885.11. Pharmacy personnel
  - § 47-2885.12. Bulk sales or transfers
  - § 47-2885.13. Deteriorating drugs; sample drugs; returned drugs.
  - § 47-2885.14. Labeling of prescriptions.
  - § 47-2885.15. Records
  - § 47-2885.16. Inspections
  - § 47-2885.17. Peddling drugs prohibited
  - § 47-2885.17a. Public place defined
  - § 47-2885.18. Duties of Mayor.
  - § 47-2885.19. Fees.
  - § 47-2885.20. Penalties, prosecutions; injunction
  - § 47-2885.21. Review
  - § 47-2885.22. Severability
  - § 47-2885.23. Effect of part on prior regulations
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**§ 47-2885.01. Purposes; scope**

- (a) The purposes of this part are:
- (1) To license pharmacies and pharmacists;
  - (2) To register pharmacy interns;
  - (3) To regulate the practice of pharmacy; and
  - (4) To establish a Board of Pharmacy in the District of Columbia in order to protect the public health and welfare.

- (b) This part shall not apply to:
- (1) A duly licensed medical practitioner who personally dispenses or administers drugs or poisons as the practitioner deems proper in the treatment of the practitioner's patients;
  - (2) The administering of drugs by a registered or licensed nurse under the direction of a medical practitioner to the practitioner's patient or patients;
  - (3) Or otherwise interfere with the sale of over-the-counter drugs; or
  - (4) Any person who is a wholesaler or manufacturer, or any employee of such person, when engaged in the discharge of his or her official duties.
- (c) Nothing in this part shall be construed as altering or affecting in any way laws of the District of Columbia or any federal act requiring a written prescription for controlled substances or other dangerous drugs.

#### **§ 47-2885.02. Definitions**

For purposes of this part:

- (1) The term "Board" means the District of Columbia Board of Pharmacy established by the District of Columbia Health Occupations Revision Act of 1985.
- (2) The term "dispense" means to sell, distribute, leave with, give away, dispose of, prepare or deliver a drug.
- (3) The term "drug" means:
  - (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 does not include medical devices or their components, parts, or accessories.
- (4) The term "labeling" means the process of affixing a label to any drug container, but does

not include the labeling by a manufacturer, packer, or distributor of an over-the-counter drug, packaged legend drug, or medical device.

- (5) The term "Mayor" means the Mayor of the District of Columbia or the Mayor's designated agent.
- (6) The term "medical device" means 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 of disease in man or other animal; or
  - (C) Intended to affect the structure or any function of the body of man or other animal, and which does not 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.
- (7) The term "medicinal chemicals" means chemicals used in the treatment of illness or disease.
- (8) The term "over-the-counter drug" means drugs which may be sold without a prescription and which are prepackaged 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.
- (9) The term "person" means any individual, partnership, association, corporation, company, joint stock association, or any organized group of persons whether incorporated or not, or any trustee, receiver, or assignee thereof.
- (10) The term "pharmacist" means any person who is licensed in the District of Columbia to engage in the practice of pharmacy.
- (11) Repealed.
- (12) The term "pharmacy intern" means any person who is registered in the District of Columbia to engage in the practice of pharmacy under the direct supervision of a pharmacist.

- (13) The term "practice of pharmacy" means the practice defined in § 3-1201.02(11).
- (14) The term "practitioner" means a person licensed and permitted by such license (other than a pharmacist) to prescribe, to dispense, or to conduct research with respect to, or to administer, drugs within the course of such person's professional practice or research.
- (15) Repealed.
- (16) The term "proprietor of a pharmacy" means a person designated as proprietor in an application for a pharmacy license under § 47-2885.08. 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.
- (17) The term "radiopharmaceuticals" means radioactive drugs and chemicals within the classification of legend drugs as defined under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.) or regulations issued by the Mayor pursuant to this part.

#### **§ 47-2885.03. General prohibitions**

- (a)-(c) Repealed.
- (d) It shall be unlawful for any person to operate, maintain, open or establish a pharmacy within the District of Columbia without first having obtained a license or registration from the Mayor.
- (e) Repealed.
- (f) It shall be unlawful for any establishment or institution, or any part thereof, that does not provide services of the practice of pharmacy, as defined within this part, to use or have upon it, or displayed within it, or affixed to or used in connection with it, a sign bearing the word or words "pharmacy," "apothecary," "drugstore," "druggist," or any word or words of similar or like import which would tend to indicate that the practice of pharmacy is being conducted in the establishment or institution.

#### **§ 47-2885.04. Board of Pharmacy; licensing of pharmacists (Repealed)**

#### **§ 47-2885.05. Board of Pharmacy; licensing of pharmacists (Repealed)**

#### **§ 47-2885.06. Registration of pharmacy interns**

- (a) To register as a pharmacy intern, a person shall establish to the satisfaction of the

Board of Pharmacy that the applicant:

- (1) Is currently registered in and attending a duly accredited college or school of pharmacy or is a graduate of such college or school of pharmacy; and
  - (2) Has provided such additional evidence as the Board has determined is necessary for the position of pharmacy intern; and
  - (3) Has complied with the other standards required for registration by the Non-Health Related Professions and Occupations Licensure Act of 1998.
- (b) The Mayor may, by regulation, provide for the registration of pharmacy interns who obtain their practical experience outside of the District of Columbia.
- (c) Registration as a pharmacy intern may be renewed for successive periods of 1 year if the Mayor is satisfied that the applicant is in good faith and with reasonable diligence working toward his or her pharmaceutical degree or, if he or she has already received his or her degree, has been unable with reasonable diligence to accumulate the number of hours of service required by the Mayor.

**§ 47-2885.07. Denial, suspension, or revocation of pharmacist's license or pharmacy intern's registration (Repealed)**

**§ 47-2885.08. Licensing of pharmacies**

- (a) The application for a pharmacy license shall be made on a form to be prescribed by the Mayor and shall be accompanied by the required fee. The license shall be valid for a period of time to be determined by the Mayor. No license fee shall be required for the operation of a pharmacy by the United States government or by the District of Columbia government.
- (b) Application for renewal of a pharmacy license shall be made not later than 30 days before the expiration date of the license to avoid lapse. An additional fee for late filing not exceeding the amount of the renewal fee shall be established by the Mayor.
- (c) Each pharmacy license issued shall apply only to the operation of the pharmacy at the location for which it is issued.
- (d) A pharmacy license is not transferable.
- (e) Whether or not the proprietor of a pharmacy is a pharmacist, the pharmacy license shall be issued in the name of the proprietor.
- (f) When a pharmacy changes proprietorship, the license shall become void and shall be promptly surrendered to the Mayor, and a license shall be obtained by the new

proprietor whether or not there is any change in the name of the pharmacy.

- (g) Any license issued pursuant to this section shall be issued as a Public Health: Pharmacy and Pharmaceuticals endorsement to a basic business license under the basic business license system as set forth in subchapter I-A of this chapter.

#### **§ 47-2885.09. Operation of pharmacy**

- (a) A pharmacy shall be operated only by a licensed pharmacist. During all times when the pharmacy is open for business a pharmacist shall be on duty. The pharmacist on duty shall post his or her license in a conspicuous place during the time he or she is on duty. The hours that the pharmacy is open for business shall be conspicuously displayed on the outside of the pharmacy.
- (b) The pharmacist on duty shall control all professional aspects of the practice of pharmacy; any usurpation, in reference or impairment of the exercise of professional judgment of the pharmacist on duty by a nonpharmacist proprietor or personnel shall be deemed the practice of pharmacy and constitute a violation of this part.
- (c)(1) If only part of an establishment or institution is used as the pharmacy and if the pharmacy is not open to the public at the times when the rest of the establishment is open to the public, the pharmacy shall be securely enclosed so as to prevent unauthorized access to pharmacy areas and to prevent the diversion of drugs stored in pharmacy areas.
- (2) The pharmacy and any storage areas for prescription drugs outside of the pharmacy shall be substantially constructed.
- (3) All doors shall be capable of being securely locked, and access shall be restricted to pharmacists, the proprietor of the pharmacy, or persons authorized by a pharmacist with the consent of the proprietor.
- (4) The key or keys to areas are to be under the control or in the possession of the pharmacist on duty or the proprietor of the pharmacy.
- (d) Burglaries and damage to the pharmacy or its contents by fire, flood, or other causes shall be reported immediately to the Mayor. Neither drugs nor other merchandise shall be dispensed, sold, held for sale, or given away in any pharmacy damaged by fire, flood, or other causes until the Mayor has determined that the merchandise is not adulterated or otherwise unfit for sale, use, or consumption. Damaged premises shall be inspected by the Mayor to determine their continued suitability for pharmacy operations.

#### **§ 47-2885.10. Denial, suspension, or revocation of pharmacy license**

- (a) The Mayor may refuse the issuance or renewal, or may revoke, or may suspend for

not more than 90 days, a license issued pursuant to this part for any 1 or a combination of the following reasons:

- (1) Conviction of any felony, or a finding by the Mayor that any provision of this part has been violated, or that any law or regulation of the District of Columbia or of the United States relating to drugs has been violated by any person named in the application for pharmacy licensure;
  - (2) Furnishing false or misleading information to the Mayor, or failing to furnish information requested by the Mayor, or refusing to allow an inspection in accordance with this section and § 47-2885.16; or
  - (3) Selling, or offering for sale, adulterated or misbranded drugs or devices.
- (b) The Mayor shall forthwith suspend a license issued pursuant to this part whenever the Mayor finds that the failure of a pharmacy to comply with any provision of this part or with any District of Columbia or federal law or regulation applicable to such pharmacy is of such a serious nature and magnitude that an imminent danger to the health or safety of the public is presented. In such a case, if a hearing is requested, such request or hearing shall not serve to stay the issuance of an order suspending the license.

#### **§ 47-2885.11. Pharmacy personnel**

- (a)(1) No personnel working in any capacity, the activities of which include contact with any merchandise or drugs in a pharmacy or the care of dispensing, manufacturing, or storage facilities, who is affected by, or believed by the Mayor, upon reasonable grounds to be affected by, a communicable disease and no person who is or is believed by the Mayor, upon reasonable grounds, to be a carrier of a communicable disease shall actively engage in any work in a pharmacy.
- (2) No proprietor of any pharmacy or manager of any pharmacy shall intentionally permit any person who is, or is believed by the Mayor, upon reasonable grounds, to be, a carrier of a communicable disease to engage or continue to be engaged in any work in the pharmacy.
- (b) No person shall work in any capacity in a pharmacy if he or she:
- (1) Is afflicted with boils, infectious wounds, sores, or an acute respiratory infection;
  - (2) Is wearing unclean garments;

- (3) Is a chronic alcoholic as that term is defined in § 24-602<sup>1</sup>; or
- (4) 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.

#### § 47-2885.12. Bulk sales or transfers

- (a)(1) Bulk sales or transfers of drugs or medical devices shall not be made unless the Mayor is notified prior to the proposed transaction and the Mayor finds that the drugs or medical devices are fit for the use for which they were originally intended. For the purposes of this section, the term "bulk sales or transfers" shall mean the sale or transfer of the entire inventory, or any substantial part thereof, in any 1 transaction or in any merchandising effort referred to as an "auction sale," a "bankruptcy sale," "distress sale," or a "closing-out sale"; but the term "bulk sales or transfers" shall not include transfers between stores having common ownership.
- (2) A sale of merchandise to a single customer having a value of \$ 500 or more in any 1-week period shall be considered the sale of a substantial part of the inventory and as 1 transaction unless the sale constitutes the filling of a prescription, or results from a cooperative buying order. If drugs are acquired by such transactions in other jurisdictions, the Mayor shall be notified, and the drugs shall be officially inspected and released by the Mayor prior to sale or other disposition in the District. Bulk quantities of drugs may be transferred only to persons legally entitled to sell or dispense the drugs.
- (b) This section supplements and does not replace Chapter 21 [Closing-Out Sales] of this title.

#### § 47-2885.13. Deteriorating drugs; sample drugs; returned drugs

- (a) Drugs which may deteriorate shall at all times be stored under conditions specified on the label of the original container and in accordance with applicable District of Columbia or federal laws or regulations, and shall not be sold or dispensed after the

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<sup>1</sup> D.C. Official Code § 24-602 (2001). Definitions.

For purposes of this subchapter:

- (1) The term "chronic alcoholic" means any person who chronically and habitually uses alcoholic beverages to the extent that:
  - (A) They injure his health or interfere with his social or economic functioning; or
  - (B) He has lost the power of self-control with respect to the use of such beverages.
- (2) The term "Court" means the Superior Court of the District of Columbia.
- (3) The term "Mayor" means the Mayor of the District of Columbia.

expiration date designated on the label of the original container, and in accordance with applicable District of Columbia or federal laws or regulations.

- (b) Drugs designated "sample" shall not be sold.
- (c) A drug which has been returned after leaving the pharmacy shall not be placed in stock for reuse or resale, except manufacturer packaged unit dose or unit of use drugs which have been unopened and unaltered.

#### **§ 47-2885.14. Labeling of prescriptions**

All drugs shall be dispensed in a suitable container appropriately labeled for subsequent administration to or use by an individual entitled to the drug. Any drug dispensed, except to inpatients of a licensed hospital, shall include on the label of the container the name of the drug and the strength of the drug when applicable, unless otherwise directed by the prescribing practitioner, and the name, address and telephone number of the pharmacy filling the prescription, the prescription number, the date of issuance and the name of the prescriber, directions for use, the name of the individual for whom the prescription is written, and other information and labeling which may be required by any District of Columbia or federal laws or regulations.

#### **§ 47-2885.15. Records**

- (a) There shall be maintained in every pharmacy, or in the establishment or institution where a pharmacy is located, a suitable book, file, or other easily retrievable record, in which shall be preserved for a period of not less than 2 years every prescription compounded or dispensed at said pharmacy.
- (b)(1) There shall be maintained a bound volume recording the information required by law or regulation concerning the over-the-counter sales of those drugs which are listed in schedule V established or amended pursuant to the federal Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 801 et seq.).
- (2) There shall also be maintained a bound volume in which shall be entered similar information concerning each sale of:
  - (A) Hypodermic syringes, needles, or other medical devices which may be used in the administration of controlled substances;
  - (B) Gelatin capsules and glassine envelopes in quantities sufficient to indicate an intention to use such items in the distribution of controlled substances; and
  - (C) Diluents or adulterants, such as lactose or quinine, in quantities sufficient to indicate an intention to use such substances for the illegal distribution or

dispensing of any controlled substance.

- (c) The records required to be maintained by this section shall be available for inspection by the Mayor during regular business hours.

#### **§ 47-2885.16. Inspections**

- (a) Persons designated by the Mayor shall be permitted, after presenting proper identification, to enter at reasonable times any pharmacy or drug outlet for the purpose of making inspections to determine compliance with this part or with other laws or regulations applicable to the practice of pharmacy. Persons designated by the Mayor shall be pharmacists for the purpose of making inspections to determine compliance with those sections of this part and other applicable laws and regulations regarding the practice of pharmacy as defined within this part.
- (b) This inspection may include, but shall not be limited to, the examination of the pharmacy's records, including prescriptions, and the obtaining of information and samples pertaining to drugs on hand or dispensed.

#### **§ 47-2885.17. Peddling drugs prohibited**

It shall be unlawful for any person to sell or offer for sale by peddling, or to offer for sale from house to house, or to offer for sale by public outcry, or by vending in the street, any drug, medicine, chemical, or controlled substance as defined in the District of Columbia Uniform Controlled Substances Act of 1981, or any compound or combination thereof, or any implement, appliance, or other agency for the treatment of disease, injury, or deformity; except, as may be otherwise authorized by law, no person shall throw, cast, deposit, drop, scatter, or leave, or cause to be thrown, cast, deposited, dropped, scattered, or left, any drug, medicine, chemical, or controlled substance as defined in the District of Columbia Uniform Controlled Substances Act of 1981, or any compound or combination thereof, upon any public highway or place, or, without the consent of the owner or occupant thereof, upon any premises in the District of Columbia. An offer for sale by peddling includes remaining or wandering about a public place and:

- (1) Repeatedly beckoning to, repeatedly stopping, repeatedly attempting to stop, or repeatedly attempting to engage passers-by in conversation;
- (2) Repeatedly stopping or attempting to stop motor vehicles; or
- (3) Repeatedly interfering with the free passage of other persons for the purpose of selling any controlled substance proscribed by the District of Columbia Uniform Controlled Substances Act of 1981.

**§ 47-2885.17a. Public place defined**

For the purposes of § 47-2885.17, the term "public place" means any street, sidewalk, bridge, alley, plaza, park, driveway, parking lot, transportation facility, or the doorways and entrance ways to any building which fronts on any of these locations, or a motor vehicle in or on any such place.

**§ 47-2885.18. Duties of Mayor**

(a) The Mayor shall:

- (1) Administer and enforce the provisions of this part;
- (2) Repealed;
- (3) Adopt and publish such regulations as may be necessary for the implementation of this part, including, but not limited to, regulations concerning the following:
  - (A)-(C) Repealed;
  - (D) The establishment of various classifications of pharmacies, including, but not limited to, retail, institutional, radio, or nuclear pharmacies;
  - (E)-(G) Repealed;
  - (H) Establishment of minimum standards for the operation of pharmacies, including the minimum requirements for technical equipment and professional reference materials;
  - (I) The safe and proper storage, and maintenance of drugs, and the disposal of drugs;
  - (J) The requirements to assure that pharmacies shall be clean, in good repair, well ventilated and illuminated, and equipped with the necessary dispensing facilities, and adequate facilities for the purposes of cleansing hands, equipment and utensils, and the premises therein; such facilities may be located in areas adjacent to the pharmacy where only part of an establishment or institution is used as the pharmacy; and
  - (K) The establishment of regulations covering the storage and dispensing of radiopharmaceuticals.

(b) Repealed.

**§ 47-2885.19. Fees**

- (a) The initial fees shall be as follows: (1) Repealed; (2) pharmacy license, \$ 85; (3) every person who sells over-the-counter preparations shall pay an annual license fee of \$ 52. The fees referred to in this subsection shall be established in such amounts as will, in the judgment of the Mayor, approximate the costs to the District of Columbia government for administering this part. The Mayor is authorized to change the fees from time to time for any services rendered under this part; provided, that, the Mayor gives 30 days notice prior to changing such fees.
- (b) The Mayor is authorized after 30 days notice to establish and to change, as may be necessary, the expiration dates of licenses and registrations provided for in this part. Upon the change of an expiration date, the renewal fee for the licenses, or registrations, shall be prorated on the basis of the time covered.

**§ 47-2885.20. Penalties; prosecutions; injunction**

- (a) Any person who violates any provision of this part shall be guilty of a misdemeanor and shall be punished by a fine of not more than \$ 500 or by imprisonment for not more than 6 months or both for each violation.
- (b) Prosecutions for violations of any provision of this part shall be conducted in the Superior Court of the District of Columbia, by the Attorney General for the District of Columbia. It shall be sufficient to prove in any prosecution or hearing under this part only a single act prohibited by law or a single holding out, or any attempt thereof, without proving a general course of conduct in order to constitute a violation.
- (c) In addition to the remedy set forth in this section, application may be made to a court having competent jurisdiction over the parties and subject matter for a writ of injunction or other civil remedy to restrain violations of the provisions of this part. Such application may be made by the Attorney General for the District of Columbia.
- (d) Civil fines, penalties, and fees may be imposed as alternative sanctions for any infraction of the provisions of this part, or any rules or regulations issued under the authority of this part, pursuant to Chapter 18 of Title 2. Adjudication of any infraction of this chapter shall be pursuant to Chapter 18 of Title 2.

**§ 47-2885.21. Review**

Any person aggrieved by an adverse action of the Mayor may file a request for a hearing with the Office of Administrative Hearings. The Office of Administrative Hearings shall provide the aggrieved person with an opportunity for a hearing and shall sustain, modify, or vacate such action by the Mayor as is appropriate in the case. Judicial review of the decision of the Office of Administrative Hearings shall be in accordance with § 2-1831.16.

**§ 47-2885.22. Severability**

If any provision of this part is for any reason held invalid by any court of competent jurisdiction, the provision shall be deemed a separate, distinct, and independent provision, and its invalidity shall not affect the validity of the remaining provisions.

**§ 47-2885.23. Effect of part on prior regulations**

The provisions of this part supplement all other regulations and laws applicable in the District of Columbia. Regulations heretofore in effect in the District of Columbia which are inconsistent with the provisions of this part are hereby superseded with respect to matters covered by this part.

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE II. PRESCRIPTION DRUGS**  
**CHAPTER 8. PRESCRIPTION DRUG PRICE INFORMATION**

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SUBCHAPTER I. PRESCRIPTION DRUG PRICE POSTING

- § 48-801.01. List of most commonly used prescription drugs
- § 48-801.02. Posters to be furnished pharmacies; contents
- § 48-801.03. Completion and display of posters
- § 48-801.04. Quotation of prices, services and charges
- § 48-801.05. Services and drugs to be furnished at prices posted; exception
- § 48-801.06. Consumer information to reflect actual charges

SUBCHAPTER II. ADVERTISING

- § 48-802.01. Interference with disclosure of price information prohibited

SUBCHAPTER III. SUBSTITUTION OF THERAPEUTICALLY EQUIVALENT DRUGS

- § 48-803.01. Publication of formulary; procedure for determining contents
- § 48-803.02. Dispensation of equivalent products by pharmacists -- Conditions under which authorized; prices for prescribed drugs
- § 48-803.03. Dispensation of equivalent products by pharmacists -- Conditions under which prohibited
- § 48-803.04. Dispensation of equivalent products by pharmacists -- Recording and labeling required
- § 48-803.05. Dispensation of equivalent products by pharmacists -- Consideration as practice of medicine or evidence of negligence; failure of physician to specify specific brand.

SUBCHAPTER IV. ENFORCEMENT

- § 48-804.01. Violations of posting provisions
- § 48-804.02. Restraints of trade
- § 48-804.03. Inspection of pricing records and practices; cease and desist orders

SUBCHAPTER IV-A. DEFINITIONS

- § 48-804.51. Definitions
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**SUBCHAPTER I. PRESCRIPTION DRUG PRICE POSTING**

**§ 48-801.01. List of most commonly used prescription drugs**

Thirty days prior to each issue date, the Department of Human Services shall furnish to the Office of Consumer Protection a list of the 100 most commonly used prescription drugs.

**§ 48-801.02. Posters to be furnished pharmacies; contents**

Ten days prior to each issue date, the Office of Consumer Protection shall furnish to each pharmacy in the District a poster suitable for display of a type style and size so as to be easily readable at a reasonable distance, which:

- (1) Lists the 100 most commonly used prescription drugs in 2 commonly prescribed quantities, with space for the current selling price of each quantity;
- (2) Lists professional and convenience services, with space for each pharmacy to indicate:
  - (A) Whether it offers each service; and
  - (B) The additional charge, if any, for that service;
- (3) Contains a heading stating "OUR CURRENT PRESCRIPTION PRICES" and containing spaces for the insertion of the name and address of each pharmacy;
- (4) Indicates in simple language that:
  - (A) The price of a prescription drug is often different at different pharmacies, and that the consumer may want to make a comparison on the cost of a prescription;
  - (B) The pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by the consumer's doctor, unless the consumer does not approve; and
  - (C) The consumer has the right to know the exact price of a prescription before it is filled; and
- (5) Provides space for each pharmacy to indicate the eligibility and terms of any discount it offers on legend drugs.

#### **§ 48-801.03. Completion and display of posters**

On and after each issue date, each pharmacy shall legibly post on the poster its current selling prices for the 100 most commonly used prescription drugs, the professional and convenience services it offers and the additional charges therefor, and the eligibility and terms of any discount it offers on prescription drugs. The completed poster shall be displayed prominently in the immediate vicinity of the prescription drug service area in such a manner as to be easily visible to consumers without having to obtain permission or assistance of an employee of the pharmacy.

#### **§ 48-801.04. Quotation of prices, services and charges**

The current selling price of all prescription drugs (including those not required to be

posted) dispensed by each pharmacy, and the pharmacy's discounts and professional and convenience services and charges therefor, shall be available and be quoted, correctly and free of charge, by the pharmacy upon request identifying the name, strength, and quantity prescribed by a physician, whether the request is made in person, in writing or by telephone.

**§ 48-801.05. Services and drugs to be furnished at prices posted; exception**

No pharmacy may fail to provide to any consumer the discounts and services stated on the poster, under the eligibility, price, and other terms there stated. Every sale of one of the 100 most commonly used prescription drugs, in a quantity and strength which requires the price of the drug to be posted, shall be at the posted price, unless a decrease in price is authorized by subchapter III of this chapter.

**§ 48-801.06. Consumer information to reflect actual charges**

A pharmacy may charge any current selling price, discount, service availability or service charge, at any time; provided, that the poster and sources of consumer information are adjusted accordingly.

**SUBCHAPTER II. ADVERTISING**

**§ 48-802.01. Interference with disclosure of price information prohibited**

No person may directly or indirectly prohibit, hinder or restrict or attempt to prohibit or restrict the disclosure by any pharmacy, government agency, or other person, of accurate price information regarding prescription drugs, including such disclosure made by means of advertisements in print or broadcast media, or by other means.

**SUBCHAPTER III. SUBSTITUTION OF THERAPEUTICALLY EQUIVALENT DRUGS**

**§ 48-803.01. Publication of formulary; procedure for determining contents**

The Department of Human Services shall publish a formulary of drug products, with the chemical or generic name of each, that are determined to be therapeutically equivalent to specified brand name drug products. The Department shall determine the contents of the formulary only after recommendations are made by a committee of 9 members appointed by the Director of that Department. The committee shall consist of one licensed physician and one licensed pharmacist employed by the Department, 2 licensed physicians and 3 licensed pharmacists in private practice in the District, and 2 pharmacologists on the faculty of a university in the District. The recommendations of the committee shall require concurrence of a majority of the members of the committee. The committee's recommendations shall be published

in the District of Columbia Register as proposed regulations of the Department. The Department's determinations shall be made in accordance with §§ 2-503, 2-504 and 2-505 and published in the District of Columbia Register as final regulations. The committee shall review the published formulary annually, or whenever an amendment to it appears necessary. The committee shall publish its 1st recommendations no later than 8 months after April 7, 1977.

**§ 48-803.02. Dispensation of equivalent products by pharmacists -- Conditions under which authorized; prices for prescribed drugs**

- (a) When a pharmacist receives a prescription for a brand name drug for which 1 or more equivalent drugs are listed in the formulary prepared by the Department of Human Services, the pharmacist may dispense any 1 of the listed equivalent products, and, if a listed equivalent product is dispensed, the pharmacist must dispense the product in stock having the lowest current selling price. The pharmacist shall do so if the purchaser so requests, except as provided in § 48-803.03.
- (b) When a pharmacist receives a prescription for a drug by generic name, the pharmacist shall dispense the listed product in stock having the lowest current selling price.
- (c) Until the first promulgation of the formulary by the Department of Human Services, pharmacists licensed in the District shall have the same power which they had prior to September 10, 1976, to exercise their professional judgment in selecting the drug product to be dispensed.

**§ 48-803.03. Dispensation of equivalent products by pharmacists -- Conditions under which prohibited**

The pharmacist shall not dispense an equivalent drug product under § 48-803.02 if:

- (1) The person purchasing the drug product or the patient for whom it is intended indicates a preference for the drug product actually prescribed;
- (2) The prescriber, in the case of a written prescription order signed by the prescriber, writes in the prescriber's own handwriting "dispense as written" or "D.A.W." or a similar notation. A procedure for checking or initialing a box, preprinted or stamped on a prescription form, will not constitute an acceptable notation;
- (3) The prescriber, in the case of a prescription communicated by telephone, expressly indicates the prescription is to be dispensed as communicated, and this indication is noted in the pharmacist's own handwriting in the manner provided in subsection [2] of this section.

**§ 48-803.04. Dispensation of equivalent products by pharmacists -- Recording and labeling required**

When a drug is substituted under § 48-803.02, the pharmacist shall record on the prescription form the drug substituted by name and manufacturer, and retain the form for inspection by District officials. The pharmacist shall also label the prescription container with the name of the drug substituted, unless the prescribing physician writes "do not label," or words of similar import, on the prescription, or, in communicating the prescription by telephone, orders that the container not be so labeled.

**§ 48-803.05. Dispensation of equivalent products by pharmacists -- Consideration as practice of medicine or evidence of negligence; failure of physician to specify specific brand**

- (a) The substitution of therapeutically equivalent drugs by a licensed pharmacist under § 48-803.02 shall not constitute the practice of medicine.
- (b) Substitution of drugs made in accordance with § 48-803.02 shall not constitute evidence of negligence or improper pharmacy practice if the substitution was made within reasonable and prudent pharmacy practice or if the prescribed and substituted drugs were therapeutically equivalent drugs as determined under this chapter.
- (c) Failure of a licensed physician to specify that a specific brand is necessary for the particular patient shall not constitute evidence of negligence unless the physician had reasonable cause to believe that the health of the patient required the use of that brand and no other.

**SUBCHAPTER IV. ENFORCEMENT****§ 48-804.01. Violations of posting provisions**

- (a) Any pharmacy which sells a legend drug in violation of § 48-801.03, § 48-801.04, or § 48-801.05 is liable to the buyer, or the provider or insurer of the buyer, for the full amount charged for the drug.
- (b) Civil fines, penalties, and fees may be imposed as alternative sanctions for any infraction of the provisions of this subchapter, or any rules or regulations issued under the authority of this subchapter, pursuant to Chapter 18 of Title 2. Adjudication of any infraction of this subchapter shall be pursuant to Chapter 18 of Title 2.

**§ 48-804.02. Restraints of trade**

Any person who, by any means, interferes with, prevents, discourages, or attempts to

interfere with, prevent, or discourage: (1) any disclosure of, or attempt to disclose, or action necessary to disclose, substantially accurate prices, discounts, services, or other information concerning any prescription drug, whether or not such disclosure is authorized or directed in this chapter, or is through any media or other form of communication, or is made or to be made by any publisher, broadcaster, pharmacy, pharmacist, advertiser, drug manufacturer, wholesaler, or chain, government agency, or any other person; or (2) any retail drug price-setting, substitution, or marketing policy or action required, encouraged or permitted by, or consistent with this chapter; has committed a restraint of trade, and has caused a tortious injury in the District of Columbia as described in § 13-423(a)(3) and (4), and shall be liable for treble civil damages to each and every person (including a pharmacy or pharmacist), health insurer, and government agency the object of or injured by such interference, prevention, discouragement, or attempt to interfere, prevent, or discourage. Any action which jeopardizes in any way, or raises the net price of, the supply from manufacturers or wholesalers of drugs to any pharmacy, government agency, health insurer, or person providing or paying for a drug in the District may comprise such an interference, prevention, discouragement, or attempt.

#### **§ 48-804.03. Inspection of pricing records and practices; cease and desist orders**

After reasonable notice, the Office of Consumer Protection may inspect the pricing records and practices of any pharmacy or other person, to assure compliance with this chapter. After appropriate notice and hearing, the Office may, if it finds that any person has violated this chapter, issue a cease and desist order against continued or future violation, and such other orders as may otherwise be within powers of that Office.

### **SUBCHAPTER IV-A. DEFINITIONS**

#### **§ 48-804.51. Definitions**

As used in this chapter, the term:

- (1) "Issue date" means the 1st day of the 4th full calendar month after April 7, 1977, and the day following the end of each year after the 1st such issue date.
- (2) "Most commonly used prescription drugs" means the prescription drug products which were most frequently paid for by the Medicaid program operated by the District of Columbia government under a state plan filed in accordance with § 1902 of the Social Security Act (§ 1396a of Title 42, United States Code), in the 3 consecutive months ending 60 days before an issue date.
- (3) "Pharmacy" means a shop or other place at which drugs, chemicals, or poisons, as those terms are used in part C of subchapter IV of Chapter 28 of Title 47, are sold at retail.
- (4) "Person" means any individual, partnership, corporation, organization, or association.

- (5) "Professional and convenience services" includes, but is not limited to:
- (A) Patient consultations;
  - (B) Patient profiles;
  - (C) Prescription charting;
  - (D) Emergency prescription service;
  - (E) Personal delivery;
  - (F) Mail delivery;
  - (G) Credit services; and
  - (H) Staying open 24 hours per day.
- (6) "Current selling price" means all charges of a particular pharmacy to a consumer with respect to a prescribed drug, except additional charges for professional and convenience services.

**DISTRICT OF COLUMBIA OFFICIAL CODE  
TITLE 48. FOOD AND DRUGS  
SUBTITLE III. ILLEGAL DRUGS  
CHAPTER 9. CONTROLLED SUBSTANCES  
UNIT A. CONTROLLED SUBSTANCES ACT**

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SUBCHAPTER I. DEFINITIONS

- § 48-901.01. [Reserved]
- § 48-901.02. Definitions

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- § 48-902.01. Administration
- § 48-902.02. Nomenclature
- § 48-902.03. Schedule I tests
- § 48-902.04. Schedule I enumerated
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- § 48-902.06. Schedule II enumerated
- § 48-902.07. Schedule III tests
- § 48-902.08. Schedule III enumerated
- § 48-902.09. Schedule IV tests
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- § 48-902.11. Schedule V tests
- § 48-902.12. Schedule V enumerated
- § 48-902.13. Revising and republishing of schedules
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SUBCHAPTER III. REGULATION OF MANUFACTURE, DISTRIBUTION, AND DISPENSING

- § 48-903.01. Rules and regulations; fees
- § 48-903.02. Registration -- Required; renewal; exceptions; waiver; inspection
- § 48-903.03. Registration -- Public interest; limitations
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- § 48-904.01. Prohibited acts A; penalties
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- § 48-904.03. Prohibited acts C; penalties
- § 48-904.03a. Prohibited acts D; penalties
- § 48-904.04. Penalties under other laws
- § 48-904.05. Effect of acquittal or conviction under federal law
- § 48-904.06. Distribution to minors
- § 48-904.07. Enlistment of minors to distribute
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#### SUBCHAPTER V. ENFORCEMENT AND ADMINISTRATIVE PROVISIONS

- § 48-905.01. Cooperative arrangements; confidentiality
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#### SUBCHAPTER VI. MISCELLANEOUS

- § 48-906.01. Pending proceedings
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#### SUBCHAPTER VII. DRUG INTERDICTION AND DEMAND REDUCTION FUND

- § 48-907.01. Establishment of Fund
- § 48-907.02. Funding and disbursements
- § 48-907.03. Grant Award Committee [Repealed]

### **SUBCHAPTER I. DEFINITIONS**

#### **§ 48-901.01. Reserved.**

#### **§ 48-901.02. Definitions**

As used in this chapter, the term:

(1) "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(A) A practitioner (or, in the practitioner's presence, by the practitioner's authorized agent); or

(B) The patient or research subject at the direction of and in the presence of the practitioner.

(2) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. The term "agent" does not include a common or contract carrier, a public warehouseman, or an employee of the carrier or warehouseman, when acting in the usual and lawful course of the carrier's or warehouseman's business.

(3) "Cannabis" means all parts of the plant genus Cannabis, including both marijuana and hashish defined as follows:

(A) "Marijuana" includes the leaves, stems, flowers, and seeds of all species of the plant genus Cannabis, whether growing or not. The term "marijuana" does not include the resin extracted from any part of the plant, nor any compound, manufacture, salt, derivative, mixture, or preparation from the resin, including hashish and does not include the mature stalks of the plant, fiber produced from such stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture or preparation of the mature stalks, fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

(B) "Hashish" includes the resin extracted from any part of the plant genus Cannabis, and every compound, manufacture, salt, derivative, mixture, or preparation from such resin.

(4) "Controlled substance" means a drug, substance, or immediate precursor, as set forth in Schedules I through V of subchapter II of this chapter.

(5) "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.

(6) "D.E.A." means the Drug Enforcement Administration of the United States Department of Justice or its successor agency.

(7) "Dispense" means to distribute a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(8) "Dispenser" means a practitioner who dispenses.

(9) "Distribute" means the actual, constructive, or attempted transfer from one person to another other than by administering or dispensing of a controlled substance, whether or not there is an agency relationship.

(10) "Distributor" means a person who distributes.

(11) "Drug" means: (A) substances recognized as drugs in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, or the official National Formulary, or any supplement to any of them; (B) active substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (C) substances (other than food) intended to affect the structure or any function of the body

of man or animals; and (D) substances intended for use as a component of any article specified in clause (A), (B), or (C) of this paragraph. The term "drug" does not include devices or their components, parts, or accessories.

(12) "Immediate precursor" means a substance which the Mayor has found to be, and by rule designates as being, the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(13) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term "manufacture" does not include the preparation or compounding of a controlled substance by an individual for his or her own use or the preparation, compounding, packaging, or labeling of a controlled substance:

(A) By a practitioner as an incident to administering or dispensing a controlled substance in the course of the practitioner's professional practice; or

(B) By a practitioner, or by his or her authorized agent under supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(14) "Mayor" means the Mayor as provided for in § 1-204.21, or the Mayor's designated agent.

(15) "Narcotic drug" means 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 a combination of extraction and chemical synthesis:

(A) Opium, its phenanthrene alkaloids, and their derivatives (except isoquiniline alkaloids of opium);

(B) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent to or identical with any of the substances referred to in subparagraph (A) of this paragraph;

(C) Opium poppy and poppy straw;

(D) Cocaine, its salts, optical and geometric isomers, and salts of isomers;

(E) Ecgonine, its derivatives, their salts, isomers, and salts of isomers; and

(F) Any compound, mixture, or preparation that contains any of the substances referred to in this paragraph.

(16) "Opiate" means any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability and includes its racemic and levorotatory forms. The term "opiate" does not include, unless specifically designated as controlled under § 48- 902.01, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan).

(17) "Opium poppy" means the plant of the species *Papaver somniferum* L., except its seeds.

(18) "Person" means an individual, corporation, government, or governmental subdivision or agency, business trust, estate, trust, partnership, or association, or unincorporated business, or any other legal entity.

(19) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(20) "Practitioner" means:

(A) A physician, dentist, advanced practice registered nurse, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in the District of Columbia; or

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of its professional practice or research in the District of Columbia.

(21) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(22) "State" when applied to a part of the United States, includes any state, the District of Columbia, commonwealth, territory, insular possession thereof, and any area subject to the legal authority of the United States government.

(23) "Ultimate user" means a person who lawfully possesses a controlled substance for that person's own use or for the use of a member of that person's household or for administering to an animal owned by him or her or by a member of that person's household.

(24) "Addict" means any individual who habitually uses any narcotic drug or abusive drug so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such narcotic drug or abusive drug as to have lost the power of self-control with reference to his addiction.

(25) "Retail value" means the value in the market in which the substance was being distributed, manufactured or possessed, or the amount which the person possessing such controlled substance reasonably could have expected to receive upon the sale of the controlled substance at the time and place where the controlled substance was distributed, manufactured or possessed.

(26) "Abusive drug" means 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 a combination of extraction and chemical synthesis:

(A) Phencyclidine or a phencyclidine immediate precursor;

(B) Methamphetamine, its salts, isomers, and salts of its isomers; and

(C) Phenmetrazine and its salts.

(27) "Isomer" means the optical isomer, except as used in § 48-902.04(3) and § 48-902.06(1)(D). As used in § 48-902.04(3), "isomer" means any optical, positional, or geometric isomer. As used in § 48-902.06(1)(D), "isomer" means any optical or geometric isomer.

(28) "Real property" means any right, title, or interest in any tract of land, or any appurtenance or improvement on a tract of land.

(29) "Playground" means any facility intended for recreation, open to the public, and with any portion of the facility that contains one or more separate apparatus intended for the recreation of children, including, but not limited to, sliding boards, swingsets, and teeterboards.

(30) "Video arcade" means any facility legally accessible to persons under 18 years of age, intended primarily for the use of pinball and video machines for amusement, and which contains a minimum of 10 pinball or video machines.

(31) "Youth center" means any recreational facility or gymnasium, including any parking lot appurtenant thereto, intended primarily for use by persons under 18 years of age, which regularly provides athletic, civic, or cultural activities.

**SUBCHAPTER II. STANDARDS AND SCHEDULES****§ 48-902.01 Administration.**

- (a) The Mayor shall administer this chapter and, with provision for public notice and comment, may add substances to or delete or reschedule all substances enumerated in the schedules in § 48-902.04, § 48-902.06, § 48-902.08, § 48-902.10, or § 48-902.12 pursuant to subchapter I of Chapter 5 of Title 2 and pursuant to the procedures set forth in this chapter. In making a determination regarding a substance, the Mayor shall consider the following:
- (1) The actual or relative potential for abuse;
  - (2) The scientific evidence of its pharmacological effect, if known;
  - (3) The state of current scientific knowledge regarding the substance;
  - (4) The history and current pattern of abuse;
  - (5) The scope, duration, and significance of abuse;
  - (6) The risk to the public health;
  - (7) The potential of the substance to produce psychological or physiological dependence;  
and
  - (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

- (b) After considering the factors enumerated in subsection (a) of this section and after complying with subchapter I of Chapter 5 of Title 2, the Mayor shall make findings with respect to the factors and issue a rule either controlling the substance if the Mayor finds that the substance has a potential for abuse or deleting the substance if the Mayor finds that the substance does not have a potential for abuse.
- (c) If the Mayor designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.
- (d) If any substance is designated, rescheduled, or deleted as a controlled substance under federal law, the Mayor may similarly propose to control or delete the substance under this chapter pursuant to subsections (a) and (b) of this section.
- (e) Authority to control under this section does not extend to tobacco or to distilled spirits, wine, or malt beverages, as those terms are defined or used in § 25-103.

#### **§ 48-902.02 Nomenclature.**

The controlled substances listed or to be listed in the schedules in §§ 48-902.04, 48-902.06, 48-902.10 and 48-902.12 are included by whatever official, common, usual, chemical, or trade name designated.

#### **§ 48-902.03 Schedule I tests.**

The Mayor shall place a substance in Schedule I if the Mayor finds that the substance:

- (1) Has high potential for abuse; and
- (2) Has no accepted medical use in treatment in the United States or in the District of Columbia or lacks accepted safety for use in treatment under medical supervision.

#### **§ 48-902.04 Schedule I enumerated.**

The controlled substances listed in this section are included in Schedule I, unless and until removed therefrom pursuant to § 48-902.01:

- (1) 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:
- (A) Acetylmethadol;
  - (B) Allylprodine;
  - (C) Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alphaacetylmethadol, levomethadyl, acetate, or LAAM);
  - (D) Alphameprodine;
  - (E) Alphamethadol;
  - (F) Benzethidine;
  - (G) Betacetylmethadol;
  - (H) Betameprodine;
  - (I) Betamethadol;
  - (J) Betaprodine;
  - (K) Clonitazene;
  - (L) Dextromoramide;
  - (M) Diampromide;
  - (N) Diethylthiambutene;
  - (O) Difenoxin;
  - (P) Dimenoxadol;
  - (Q) Dimepheptanol;
  - (R) Diamethylthiambutene;
  - (S) Dioxaphetylbutyrate;
  - (T) Dipipanone;

- (U) Ethylmethylthiambutene;
- (V) Etonitazene;
- (W) Etoxidine;
- (X) Furethidine;
- (Y) Hydroxypethidine;
- (Z) Ketobemidone;
- (AA) Levomoramide;
- (BB) Levophenacymorphan;
- (CC) Morpheridine;
- (DD) Noracymethadol;
- (EE) Norlevorphanol;
- (FF) Normethadone;
- (GG) Norpipanone;
- (HH) Phenadoxone;
- (II) Phenampromide;
- (JJ) Phenomorphan;
- (KK) Phenoperidine;
- (LL) Piritramide;
- (MM) Propheptazine;
- (NN) Properidine
- (OO) Propiram;
- (PP) Racemoramide;
- (QQ) Thiopene;
- (RR) Trimeperidine;

(SS) Acetyl-Alpha-Methylfentanyl;

(TT) Alphe-methylfentanyl;

(UU) Alpha-Methylthiofentanyl;

(VV) Beta-hydroxyfentanyl;

(WW) Beta-hydroxy-3-Methylfentanyl;

(XX) 3-Methylfentanyl;

(YY) 3-Methylthiofentanyl;

(ZZ) MPPP;

(AAA) Para-fluorofentanyl;

(BBB) PEPAP;

(CCC) Thiofentanyl; and

(DDD) Tilidine;

(2) 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:

(A) Acetorphine;

(B) Acetyldihydrocodeine;

(C) Benzylmorphine;

(D) Codeine methylbromide;

(E) Codeine-N-Oxide;

(F) Cyprenorphine;

(G) Desomorphine;

(H) Dihydromorphine;

(I) Drotepanol;

- (J) Etorphine (except hydrochloride salt);
  - (K) Diacetylated morphine (heroin);
  - (L) Hydromorphenol;
  - (M) Methyldesorphine;
  - (N) Methyldihydromorphine;
  - (O) Morphine methylbromide;
  - (P) Morphine methylsulfonate;
  - (Q) Morphine-N-Oxide;
  - (R) Myrophine;
  - (S) Nicocodeine;
  - (T) Nicomorphine;
  - (U) Normorphine;
  - (V) Pholcodine; and
  - (W) Thebacon;
- (3) Unless specifically excepted 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 purposes of this paragraph only, the term "isomer" includes the optical, position, and geometric isomers):
- (A) 4-bromo-2, 5-dimethoxyamphetamine;
  - (B) 2, 5 dimethoxyamphetamine;
  - (C) 4-methoxyamphetamine;
  - (D) 5-methoxy-3, 4-methylenedioxy and amphetamine;
  - (E) 4-methyl-2, 5-dimethoxyamphetamine;
  - (F) 3,4-methylenedioxyamphetamine[MDA];

- (G) 3, 4, 5-trimethoxy amphetamine;
  - (H) Bufotenine;
  - (I) Diethyltryptamine;
  - (J) Dimethyltryptamine;
  - (K) Ethylamide analog of phencyclidine, PCE;
  - (L) Ibogaine;
  - (M) Lysergic acid diethylamide;
  - (N) Mescaline;
  - (O) Peyote;
  - (P) N-ethyl-3-piperidyl benzilate;
  - (Q) N-methyl-3-piperdyl benzilate;
  - (R) Psilocybin;
  - (S) Psilocyn;
  - (T) Pyrrolidine analog of phenycyclidine, PCPY;
  - (U) Thiophene analog of phencyclidine;
  - (V) Repealed;
  - (W) Parahexyl;
  - (X) 4-bromo-2, 5-dimthoxyphenthylamine; and
  - (Y) 3,4-methylenedioxyamphetamine [MDMA]
- (4) 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:

(A) Mecloqualone; and

(B) Methaqualone; and

(5) 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 stimulate effect on the central nervous system, including its salts, isomers, and salts of isomers:

(A) Fenethyline; and

(B) N-ethylamphetamine.

#### **§ 48-902.05 Schedule II tests.**

The Mayor shall place a substance in Schedule II if the Mayor finds that:

- (1) The substance has high potential for abuse;
- (2) The substance has currently accepted medical use in treatment in the United States or the District of Columbia, or currently accepted medical use, with severe restrictions; and
- (3) The abuse of the substance may lead to severe psychological or physical dependence.

#### **§ 48-902.06 Schedule II enumerated.**

The controlled substances listed in this section are included in Schedule II unless and until removed therefrom pursuant to § 48-902.01:

- (1) 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:
  - (A) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, naltrexone, and their respective salts, but including the following:
    - (i) Raw opium;
    - (ii) Opium extracts;
    - (iii) Opium fluid extracts;
    - (iv) Powdered opium;

- (v) Granulated opium;
  - (vi) Tincture of opium;
  - (vii) Codeine;
  - (viii) Ethylmorphine;
  - (ix) Etorphine Hydrochloride;
  - (x) Hydrocodone;
  - (xi) Metopon;
  - (xii) Morphine;
  - (xiii) Oxycodone;
  - (xiv) Oxymorphone;
  - (xv) Thebaine;
  - (xvi) Hydromorphone;
  - (xvii) Dihydrocodeine;
  - (xviii) Sufentanil;
  - (xix) Alfentanil; and
  - (xx) Carfentanil;
- (B) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (A) of this paragraph, but not including the isoquinoline alkaloids of opium;
- (C) Opium poppy and poppy straw;
- (D) 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, and salts of isomers; or any compound, mixture, or preparation that contains any substance referred to in this paragraph;
- (E) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy);

- (F) Hashish; and
- (G) 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:
  - (i) Delta 1 cis or trans tetrahydrocannabinol, and their optical isomers;
  - (ii) Delta 6 cis or trans tetrahydrocannabinol, and their optical isomers; or
  - (iii) Delta 3, 4 cis or trans tetrahydrocannabinol, and its optical isomers (compounds of these structures, regardless of numerical designation of atomic positions covered);
- (2) Unless specifically excepted or unless 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, dextrorphan excepted:
  - (A) Alphaprodine;
  - (B) Anileridine;
  - (C) Bezitramide;
  - (D) Biphentamine;
  - (E) Diphenoxylate;
  - (F) Eskatrol;
  - (G) Fentanyl;
  - (H) Fetamine;
  - (I) Isomethadone;
  - (J) Levo-alpha-acetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM;
  - (K) Levomethorphan;
  - (L) Levorphanol;
  - (M) Metazocine;

- (N) Methadone;
  - (O) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
  - (P) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;
  - (Q) Pethidine (meperidine);
  - (R) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;
  - (S) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;
  - (T) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
  - (U) Phenazocine;
  - (V) Piminodine;
  - (W) Racemethorphan; and
  - (X) Racemorphan;
- (1) 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 stimulate effect on the central nervous system:
- (A) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
  - (B) Methamphetamine, its salts, isomers, and salts of its isomers;
  - (C) Phenmetrazine and its salts;
  - (D) Methylphenidate and its salts;
  - (E) Repealed;
  - (F) Amphetamine/methamphetamine immediate precursor: Phenyl acetone (Phenyl-2-propanone), P2P; and
- (4) 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 specific chemical designation:

- (A) Methagualone;
- (B) Amobarbital;
- (C) Secobarbital;
- (D) Pentobarbital;
- (E) Phencyclidine;
- (F) Phencyclidine immediate precursors:
  - (i) 1-phenylecyclohexylamine
  - (ii) 1-piperidinocyclohexanecarbonitrile (PCC);
- (G) Dronabianol;
- (H) Nabilone; and
- (I) Glutethimide.

**§ 48-902.07 Schedule III tests.**

The Mayor shall place a substance in Schedule III if the Mayor finds that:

- (1) The substance has a potential for abuse less than the substances listed in Schedules I and II;
- (2) The substance has currently accepted medical use in treatment in the United States or the District of Columbia; and
- (3) The abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

**§ 48-902.08 Schedule III enumerated.**

- (a) The controlled substances listed in this section are included in Schedule III, unless and until removed therefrom pursuant to § 48-902.01:
  - (1) 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 stimulate 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) Those compounds, mixtures, or preparations in dosage unit form containing any stimulate 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, and any other drug of the quantitative composition shown in that list for those drugs or which is the same excepted that it contains a lesser quantity of controlled substances;
  - (B) Benzphetamine;
  - (C) Chlorphentermine;
  - (D) Mazindol; and
  - (E) Phendimetrazine;
- (2) Unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:
- (A) Any compound, mixture, or preparation containing:
    - (i) Amobarbital;
    - (ii) Secobarbital; or
    - (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; and
  - (x) Vinbarbital;
- (3) Nalorphine;
- (4) 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:
- (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 of dihydrocodeinone 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 100 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 with or not more than 25 milligrams per dosage unit, with 1 or more active, nonnarcotic ingredients in recognized therapeutic amounts; and
  - (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;
- (5) 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) Fluoxymesterone;
  - (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 salt, 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; and
- (6) Cannabis.

(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 vitiate the potential for abuse of the substances which have a stimulate or depressant effect on the central nervous system.

**§ 48-902.09 Schedule IV tests.**

The Mayor shall place a substance in Schedule IV if the Mayor finds that:

- (1) The substance has a low potential for abuse relative to substances in Schedule III;
- (2) The substance has currently accepted medical use in treatment in the United States or the District of Columbia; and
- (3) The abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in Schedule III.

**§ 48-902.10 Schedule IV enumerated.**

- (a) The controlled substances listed in this section are included in Schedule IV, unless and until removed therefrom pursuant to § 48-902.01:
  - (1) 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) Peterichloral;
- (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) 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, such as Fenfluramine;
- (3) 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 stimulate 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 organomeallic complexes and chelates thereof);
  - (D) Cathine;

- (E) Fencamfimin;
  - (F) Fenproporex;
  - (G) Mefenorex;
  - (H) Pipradrol; and
  - (I) SPA;
- (4) 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:
- (A) Dextropropoxyphene (Alpha-(+)-4-dimethylamino-1), 2-diphenyl-1-3-methyl-2 propionoxybutane; and
  - (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.

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

#### **§ 48-902.11 Schedule V tests.**

The Mayor shall place a substance in Schedule V if the Mayor finds that:

- (1) The substance has low potential for abuse relative to the controlled substances listed in Schedule IV;
- (2) The substance has currently accepted medical use in treatment in the United States or the District of Columbia; and
- (3) The substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in Schedule IV.

#### **§ 48-902.12 Schedule V enumerated.**

The controlled substances listed in this section are included in Schedule V unless and until removed therefrom pursuant to § 48-902.01.

- (1) Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or salts thereof, which also contains 1 or more nannarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:
  - (A) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
  - (B) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;
  - (C) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
  - (D) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
  - (E) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit; and
  - (F) Not more than 0.5 milligrams of difenopin and not less than 25 micrograms of atropine sulfate per dosage unit;
- (2) Repealed;
- (3) Deleted upon adoption of rule in 34 DCMR 4370 on July 10, 1987;
- (4) 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:
 

Buprenorphine;
- (5) Prophylhexedrine; and
- (6) Pyrovalerone.

**§ 48-902.13 Revising and republishing of schedules.**

The Mayor shall revise and republish the schedules semiannually for 2 years from August 5, 1981, and thereafter annually. The published schedules may include the brand or trade names of the substances controlled:

**§ 48-902.14 Treatment of controlled substance analogues.**

- (a) A controlled substances analogue shall, to the extent intended for human consumption, be treated for the purposes of any District of Columbia law as a controlled substance in Schedule I.
- (b) Except as provided in subsection (c) of this section, the term “controlled analogue” means:
- (1) A substance with a chemical structure that is substantially similar to the chemical structure of a controlled substance in Schedule I or II;
  - (2) A substance that has a stimulate, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I and II; or
  - (3) A substance that, with respect to a particular person, is represented to have or is intended to have a stimulate, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to, or greater than the stimulate, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II.
- (c) Such term does not include:
- (1) A controlled substance;
  - (2) Any substance for which there is an approved new drug application;
  - (3) With respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under § 505 of the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938 (52 Stat. 1052, 21 U.S.C. § 355) to the extent conduct with respect to such substance is pursuant to such exemption; or
  - (4) Any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

### **SUBCHAPTER III. REGULATION OF MANUFACTURE, DISTRIBUTION, DISPENSING**

#### **§ 48-903.01. Rules and regulations; fees**

The Mayor may issue rules and regulations and may charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within the District of Columbia.

**§ 48-903.02. Registration -- Required; renewal; exceptions; waiver; inspection**

- (a) Every person who manufactures, distributes, or dispenses any controlled substance within the District of Columbia, or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance within the District of Columbia, must obtain annually a registration issued by the Mayor in accordance with the rules. Applications to renew a registration must be filed in a timely manner, not less than 60 days prior to the expiration of the registration, or the registration shall abate.
- (b) Persons registered with the Mayor under this chapter to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this subchapter. Any person registered under this subchapter whose authority to possess, distribute, dispense, or conduct research with controlled substances is limited or otherwise restricted by any federal, state, or District of Columbia law, shall use such registration only to the extent authorized by said federal, state, or District of Columbia law unless otherwise specified.
- (c) The following persons need not register and may lawfully possess controlled substances under this chapter:
- (1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance acting in the usual course of business or employment;
  - (2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;
  - (3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a Schedule V substance; and
  - (4) A designated civilian employee of the Metropolitan Police Department, or a law-enforcement official or agent of the District of Columbia or the United States if he or she is on duty and is acting in the performance of officially authorized functions.
- (d) The Mayor may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if the Mayor finds it consistent with the public health and safety.
- (e) A separate registration is required for each principal place of business or professional

practice where the applicant manufactures, distributes, or dispenses controlled substances.

- (f) The Mayor may inspect the establishment of a registrant or applicant for registration in accordance with subsections (a) and (b) of this section.

**§ 48-903.03. Registration -- Public interest; limitations**

- (a) The Mayor shall register an applicant to manufacture, distribute, or dispense controlled substances included in Schedules I, II, III, IV, and V unless the Mayor determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Mayor shall consider the following factors:
- (1) Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
  - (2) Compliance with applicable District of Columbia law;
  - (3) Any convictions of the applicant under any federal, state, or District of Columbia laws relating to any controlled substance;
  - (4) Past experience in the manufacture, distribution, or dispensing of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
  - (5) Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
  - (6) Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
  - (7) Any other factors relevant to and consistent with the public health and safety.
- (b) Registration under subsection (a) of this section does not entitle a registrant to:
- (1) Manufacture or distribute controlled substances in Schedule I or II other than those specified in the registration; or
  - (2) Manufacture, distribute, or dispense Cannabis unless specified in the registration.
- (c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in Schedules II through V if they are authorized to dispense or conduct research under the provisions of § 48-903.02. Separate registration shall be required for practitioners engaging in research with narcotic controlled substances set forth in Schedules II through V. The Mayor need not require separate

registration under this subchapter for practitioners engaging in research with nonnarcotic controlled substances in Schedules II through V where the registrant is already registered under this subchapter in another capacity. Practitioners 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 Mayor evidence of that federal registration.

(d) Compliance by manufacturers and distributors with the provisions of the federal law respecting registration entitles them to be registered under this chapter.

(e) Any registration issued pursuant to this section shall be issued as a Public Health: Pharmacy and Pharmaceuticals endorsement to a basic business license under the basic business license system as set forth in subchapter I-A of Chapter 28 of Title 47.

#### **§ 48-903.04. Registration -- Suspension; revocation; forfeiture of substances**

- (a) A registration issued under § 48-903.03 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Mayor upon a finding that the registrant:
- (1) Has been convicted of a felony under any District of Columbia, state, or federal law relating to any controlled substance;
  - (2) Has had his or her federal or state registration suspended or revoked to manufacture, distribute, or dispense controlled substances;
  - (3) Has had his or her practitioner's license suspended or revoked in the District of Columbia by the appropriate authority; or
  - (4) Has violated any provisions of this chapter.
- (b) A registration issued under § 48-903.03 to manufacture, distribute, or dispense a controlled substance may be suspended by the Mayor upon a finding that the registrant has been convicted of a misdemeanor under any District of Columbia, state, or federal law relating to any controlled substance.
- (c) The Mayor may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.
- (d) If the Mayor suspends or revokes a registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation order may be placed under seal. 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 orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances may be forfeited in accordance

with the provisions of § 48-905.03(d).

- (e) The Mayor shall promptly notify the D.E.A. of all orders suspending or revoking registration and all forfeitures of controlled substances.

### **§ 48-903.05. Registration -- Procedural rights involving suspension or revocation**

- (a) If it appears to the Mayor that an application for registration should be denied or that an existing registration should be suspended or revoked, the Mayor shall notify the applicant or registrant of the proposed denial, suspension, or revocation, briefly stating the reasons therefor. In the case of a denial of renewal of registration, notice shall be served not later than 30 days before the expiration of the registration. Service may be made by delivering a copy of the notice to the applicant or registrant personally, or by leaving a copy thereof at the place of residence identified on the application or registration with some person of suitable age and discretion then residing therein, or by mailing a copy of the notice by certified mail to the residence address identified on the application or certificate, in which case service shall be complete as of the date the return receipt was signed. In the case of an organization, service may be made upon the president, chief executive, or other officer, managing agent, or person authorized by appointment or law to receive such notice as described in the preceding sentence at the business address of the organization identified in the application or registration certificate. The person serving the notice shall make proof thereof with the Mayor in a manner prescribed by the Mayor. In the case of service by certified mail, the signed return receipt shall be filed with the Mayor together with a signed statement showing the date such notice was mailed and if the return receipt does not purport to be signed by the person named in the notice, then specific facts from which the Mayor can determine that the person who signed the receipt meets the appropriate qualifications for receipt of such notice set out in this subsection. The applicant or registrant shall have 30 days from the date the notice was served in which to request a hearing before the Mayor to contest the proposed action to be taken by the Mayor; provided, that if the applicant or registrant does not request a hearing within 30 days after the serving 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 become final. Within 30 days of the date upon which any contest is noted, the Mayor shall convene a hearing. Within 10 days of the close of the hearing, the Mayor shall notify the applicant or registrant of the decision in the case. All proceedings, including the right to judicial review of the Mayor's decision, shall be in accordance with the District of Columbia Administrative Procedure Act. Where the application for renewal of registration has been timely filed, proceedings to refuse renewal of registration shall not abate the existing registration, which shall remain in effect pending the outcome of the administrative hearing. With regard to summary suspension of any registrant or the denial of renewal to any registration pursuant to subsection (b) of this section, a hearing shall be convened within 5 days of the institution of proceedings in this section; except, that a registrant who has been summarily suspended or denied a renewal under this section shall be entitled upon

request to a postponement of such hearing.

(b) (1) The Mayor may suspend, without prior notice and hearing, any registration simultaneously with the institution of proceedings under § 48-903.04, or where renewal of registration is refused, if the Mayor finds that there is an imminent danger to the public health or safety which warrants this action, including, but not limited to, the danger that would be created by the outbreak of a serious fire on the business premises of a registrant on which controlled substances are stored, resulting in heat in excess of 110 degrees Fahrenheit; grossly inadequate security measures; or while proceedings under § 48-903.04 are pending, continued and flagrant violations of the same sort which led to the institution of the pending proceedings.

(2) The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the Mayor or dissolved by a court of competent jurisdiction.

#### **§ 48-903.06. Records and inventories of registrants**

Persons registered to manufacture, distribute, or dispense controlled substances under this chapter shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law, laws of the District of Columbia, and with any additional rules which the Mayor issues.

#### **§ 48-903.07. Order forms**

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 respecting order forms shall be deemed compliance with this section.

#### **§ 48-903.09. Civil infractions**

Civil fines, penalties, and fees may be imposed as alternative sanctions for any infraction of the provisions of this subchapter, or any rules or regulations issued under the authority of this subchapter, pursuant to Chapter 18 of Title 2. Adjudication of any infraction of this subchapter shall be pursuant to Chapter 18 of Title 2.

Chapter 5. Drug Control §§ 22-500 to 22-599: Repealed

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

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- § 22-1100. HEARING OFFICER
  - § 22-1101. HEARINGS AND NOTICES
  - § 22-1102. SUMMARY SUSPENSSION AND DENIAL OR RENEWAL
  - § 22-1103. HEARING PROCEDURES
  - § 22-1104. EXHIGITS AND OTHER DOCUMENTARY EVIDENCE
  - § 22-1105. OFFICIAL NOTICE
  - § 22-1106. DISPOSITION OF CASES
  - § 22-1107. TRANSCRIPTS
  - § 22-1108. BURDEN OF PROOF
  - § 22-1109. DECISIONS
  - § 22-1110. MOTION FOR REHEARING OR RECONSIDERATION
  - § 22-1111. JUDICIAL REVIEW
  - § 22-1112. DEFINITIONS
- 

§ 22-1100. 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.

**§ 22-1101. 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 ed<sup>5</sup>, 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;

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<sup>5</sup> 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.<sup>6</sup>

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).

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<sup>6</sup> 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.

## **§ 22-1102. 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.<sup>7</sup>, 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.

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<sup>7</sup> 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.)<sup>8</sup>.
- 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.

### § 22-1103. 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; an
  - (d) The right to have subpoenas, pursuant to § 507 of the Act, § 33-457, D.C. Code, 1981 ed.<sup>9</sup>, 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.<sup>10</sup>;
  - (c) To take testimony to examine witnesses; and
  - (d) To direct continuance of any case for good cause shown.

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<sup>8</sup> Section 33-435(b)(1) no longer appears in the Code, See, D.C. Official Code §§ 48-903.04 and 48-903.05.

<sup>9</sup> Section 33-457 no longer appears in the Code, See, D.C. Official Code §§ 48-905.07.

<sup>10</sup> 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.)<sup>11</sup>.
- 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.)<sup>12</sup>
- 1103.10 All testimony shall be taken under oath.

#### **§ 22-1104. 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

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<sup>11</sup> The District of Columbia Administrative Procedure Act is now cited as D.C. Official Code 2-501 et. seq. (2001).

<sup>12</sup> 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.

#### **§ 22-1105. 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.

#### **§ 22-1106. 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.

#### **§ 22-1107. 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.

### **§ 22-1108. 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.

### **§ 22-1109. 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 ed<sup>13</sup>, 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.

#### **§ 22-1110. 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

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<sup>13</sup> 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.

**§ 22-1111. 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.)<sup>14</sup>.

**§ 22-1199. 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.

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<sup>14</sup> 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**

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- § 22-1200. PURPOSE
  - § 22-1201. SCHEDULE I ENUMERATED
  - § 22-1202. SCHEDULE II ENUMERATED
  - § 22-1203. SCHEDULE III ENUMERATED
  - § 22-1204. SCHEDULE IV ENUMERATED
  - § 22-1205. SCHEDULE V ENUMERATED
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**§ 22-1200. 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).

**§ 22-1201. 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) Hydromorphinol;
- (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.

## § 22-1202. 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-Phenylecyclohexylamine; and

(B) 1-Piperidinocyclohexanecarbonitrile (PCC);

(7) Dronabinol;

(8) Nabilone; and

(9) Glutethimide.

**§ 22-1203. 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) Clortermine;

(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) Dehydrochloromethyltestosterone;

(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.

#### **§ 22-1204. 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-1-3-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.

#### § 22-1205. 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.

**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

- 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 is written; except as follows:

- (a) A pharmacist may fill a prescription for a controlled substance listed in Schedule II that was submitted to the pharmacy more than thirty (30) days after the date on which it was written, if it is clear on the face of the prescription that the individual practitioner issued multiple prescriptions authorizing the patient to receive a total of up to a ninety (90)-day supply of the Schedule II controlled substance and:
  - (i) Each separate prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
  - (ii) The individual practitioner provided written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription; and
  - (iii) The prescription is presented to the pharmacy for filling not more than ninety (90) days after the date on which the prescription was written.

- 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 a label meeting the requirements set forth in § 1912.2 of this title.
- 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, IV, or V may not be filled or refilled more than six (6) months after the date on which the prescription was issued.

1310.1 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 meeting the requirements set forth in § 1912.2 of this title.

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 DELIVERY OF PRESCRIPTION MEDICATION BY MAIL OR CARRIER**

1315.1 This section shall apply to a pharmacy's delivery of filled prescriptions for individual patients by United States Postal Service, common carrier, employee or courier service to an address within the District of Columbia. Where a delivery is to an address outside of the District of Columbia, the pharmacy shall be governed by the laws of the state to which the prescription is being delivered.

1315.2 A licensed pharmacist shall supervise the dispensing of prescription drugs or devices by mail, common carrier, employee or courier service.

1315.3 The prescription shall contain all requirements specified for prescriptions as listed within this chapter and shall be packaged and sent 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.

- 1315.4 A pharmacy may deliver the following by employee or courier, but shall not dispense the following by mail or common carrier:
- (a) Antibiotics that have been reconstituted;
  - (b) Prescription drugs generally recognized to be subject to significant deterioration due to heat, cold, fermentation, or prolonged agitation unless it can be documented that the drug was shipped according to industry recognized shipping standards; or
  - (c) Any other drug or device which federal or District law prohibits dispensing by mail.
- 1315.5 A Prescription drug or device shall be shipped by U.S. Postal Service, common carrier, employee, or courier service unless the purchaser agrees in advance to another means of delivery that does not violate the provisions of this chapter.
- 1315.6 Prescription drugs and medical devices dispensed by any method shall be packaged and sent in conformance with the applicable federal and District laws and regulations and standards pertaining to temperature, light, and humidity and in containers that are resistant to breaking, denting, and tampering.
- 1315.7 A prescription medication may be delivered to:
- (a) The patient for whom the prescription is prescribed;
  - (b) Wherever the patient is located;
  - (c) An agent authorized by the patient; or
  - (d) The residence of the patient, regardless of whether the patient is present at the residence at the time of delivery.
- 1315.8 If a patient authorizes delivery of a prescription medication or device to an agent at a location other than the pharmacy or the patient's residence, the pharmacy shall document in a readily retrievable record:
- (a) The patient's authorization;
  - (b) The identity of the agent to whom the medication is sent; and
  - (c) The date, time; and location where the medication was sent.

**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 A DISPENSER TO ANOTHER PRACTITIONER OR A REVERSE DISTRIBUTOR**

1320.1 A practitioner who is authorized to dispense a controlled substance may distribute (without being registered to distribute) a quantity of the substance to:

- (a) A reverse distributor who is registered to receive controlled substances under federal and District law; or
- (b) Another practitioner for the purpose of general dispensing by the practitioner to his or her patients, provided that the following conditions are satisfied:

- (1) The practitioner to whom the controlled substance is to be distributed is registered appropriately to dispense that controlled substance;
- (2) The distribution is recorded by the distributing practitioner and by the receiving practitioner in accordance with 21 CFR § 1304.22(c);
- (3) If the substance is listed in Schedule I or II, an order form shall be used as required by 21 CFR § 1305; and
- (4) 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 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 section 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 DISTRIBUTION TO SUPPLIER**

1321.1 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, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained containing the following:

- (a) The date of the transaction;
- (b) The name, form, and quantity of the substance;
- (c) The name, address, and controlled substance registration number(s), if any, of the person making the distribution; and
- (d) The name, address, and controlled substance registration number(s), if known, of the supplier or manufacturer.

1321.2 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. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Federal Act 21 USC § 822(c) or 957(b)(1) shall be exempt from maintaining the records required by this section.

1321.3 Distributions referred to in this section may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

## **1322 DISTRIBUTION UPON DISCONTINUANCE OR TRANSFER OF BUSINESS**

1322.1 A registrant desiring to discontinue business activities altogether or with respect to controlled substances (without transferring such business activities to another person) shall:

- (a) Return for cancellation his or her District of Columbia certificate of registration to the Director;
- (b) Return for cancellation his or her federal registration certificate and any unexecuted order forms in his or her possession to the DEA; and
- (c) Dispose of any controlled substances in his or her possession in accordance with 21 CFR § 1307.21.

1322.2 A registrant desiring to discontinue business activities altogether or 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 Director, 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, controlled substance registration number(s), and authorized business activity of the registrant discontinuing the business (registrant-transferor);
- (b) The name, address, controlled substance registration number(s), 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 shall be listed); and

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

1322.3

Unless the registrant-transferor is informed by the Director, before the date on which the transfer was stated to occur, that the transfer shall not be permitted to 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 following:

- (a) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with 21 CFR § 1304.11. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Director unless requested by the Director. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with CFR § 1305;
- (b) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under 21 CFR § 1304, shall be transferred to the registrant-transferee. Responsibility for the accuracy of the records prior to the date of transfer shall remain with the transferor. Responsibility for the custody and maintenance of the records after the date of the transfer shall be upon the transferee; and
- (c) In the case of registrants required to make reports pursuant to 21 CFR § 1304, a report marked "Final" shall be prepared and submitted by the registrant-transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him or her, if no further transactions involving controlled substances are consummated by him or her. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him or her shall be reported as recipients in his or her initial report.

**1323**

**MANUFACTURE AND DISTRIBUTION OF CONTROLLED  
SUBSTANCE SOLUTIONS AND COMPOUNDS BY A PHARMACIST**

1323.1

A pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion that shall not exceed twenty (20%) of the complete solution, compound, or mixture.

**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                   ISSUANCE OF NON-CONTROLLED SUBSTANCES**

1325.1           A pharmacist shall dispense a non-controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or medical device pursuant to a valid written, oral, facsimile, or electronic prescription issued in compliance with this chapter by a licensed practitioner authorized to prescribe the substance or medical device.

1325.2           A prescription issued by a prescribing 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 applicable federal and District of Columbia laws and regulations and this chapter.

1325.3           A prescription order shall be issued or dispensed only for a legitimate medical purpose by a prescribing practitioner acting in the usual course of his or her professional practice.

1325.4           The prescribing practitioner and the pharmacist shall be jointly responsible for compliance with this chapter in prescribing and dispensing a prescribed substance or medical device.

1325.5           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.

1325.6           Non-controlled substance prescriptions shall have a label affixed to the package meeting the requirements as set forth in § Chapter 19 of this Title.

1325.7           The label required in § 1325.6 does not apply to a prescription for a non-controlled substance that is prescribed for administration to a patient who is institutionalized if the following limitations are observed:

- (a) Not more than a thirty (30) day supply or one hundred (100) dosage units, whichever is less, of the prescription is dispensed at one time;
- (b) The prescription controlled substance is not in the possession of the patient prior to administration;

- (c) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the prescription substance; and
- (d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and sets forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

1325.8 A prescription for a non-controlled substance shall not be filled if presented for dispensing more than one (1) year after the date on which the prescription was issued.

1325.9 The total amount dispensed under one prescription order for a non-controlled substance, including refills, shall be limited to a one (1) year supply, not to exceed other applicable federal or District laws.

1325.10 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 medication record. The following information must be retrievable by the prescription number:

- (a) The name of the drug or the name and manufacturer of the substituted drug if different than the originally prescribed or filled drug;
- (b) The dosage form of the drug dispensed;
- (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.

1325.11 If the pharmacist merely initials and dates the back of a prescription or in the electronic record, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.

1325.12 The prescribing practitioner may authorize additional refills of a non-controlled substance on the original prescription 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 extend beyond one year from the date of issuance 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.

1325.13 Additional quantities of prescription non-controlled substances beyond the one year limitation, shall only be authorized by a prescribing practitioner through the issuance of a new and separate prescription.

1325.14 As an alternative to the procedures provided under § 1325.10 of this chapter, an automated data processing system may be used for the storage and retrieval of refill information for prescription drug orders and prescription records.

1325.15 The partial filling of a prescription for a non-controlled substance is permissible, if the pharmacist is unable to supply the full quantity called for in the prescription, and he or she makes a notation of the quantity supplied on the face of the written or facsimile prescription (or written record of the oral prescription), provided that:

- (a) Each partial filling is recorded in the same manner as a refilling;
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
- (c) No dispensing occurs beyond one year after the date on which the prescription was issued.

1325.16 A pharmacist shall notify the prescribing physician if:

- (a) The pharmacist is unable to dispense the remaining portion of a partially filled prescription for a prescription non-controlled substance within a reasonable period of time;
- (b) The inability to do so lies with the pharmacy; and
- (c) In the professional judgment of the pharmacist the delay may jeopardize or alter the drug therapy of the patient.

## 1326 **GENERIC SUBSTITUTION**

1326.1 A pharmacist may dispense a generically equivalent drug product if:

- (a) The generic product costs the patient less than the prescribed drug product;

- (b) The patient does not refuse the substitution; and
- (c) The prescribing practitioner does not indicate on the written, facsimile, or electronic prescription form that the specific prescribed brand is to be dispensed by marking “DISPENSE AS WRITTEN,” “BRAND NECESSARY,” “NO SUBSTITUTION,” or other similar language.

1326.2 If a prescription is transmitted orally, the prescribing practitioner or the practitioner’s authorized agent shall prohibit substitution by specifying “BRAND NECESSARY,” “NO SUBSTITUTION,” or other similar language.

1326.3 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. This drug formulary is incorporated by reference as a part of this chapter.

1326.4 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, DC 20402. The electronic version may be accessed on line at <http://www.fda.gov/cder/ob/default.htm> This URL is subject to change.

## **1327 SUBSTITUTION OF DOSAGE FORMS**

1327.1 A pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided that:

- (a) The pharmacist notifies the patient of the dosage form substitution prior to filling the prescription;
- (b) The pharmacist documents the substitution on the prescription record;
- (c) The pharmacist notifies the practitioner of the dosage form substitution prior to dispensing or as soon as is reasonably possible thereafter; and
- (d) The dosage form dispensed contains the identical amount of the active ingredients as the dosage prescribed for the patients, is not an enteric-coated or time release product; and does not alter desired clinical outcomes.

1327.2 The notification required in § 1327.1(c) shall not apply to those circumstances where the dosage form substitution is made in order to comply with the prescriber’s intent, (i.e. physician prescribed tablets but the medication only comes in capsules.)

1327.3 Substitution of dosage form shall not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

## **1328 THERAPEUTIC INTERCHANGE**

1328.1 This section shall not apply to generic drug substitutions. For generic drug substitutions, see the requirements of § 1326 of this chapter.

1328.2 As used in this section, “therapeutic interchange” means the dispensing of chemically different drugs that are considered to be therapeutically equivalent.

1328.3 A therapeutic interchange shall not be made without the prior approval of the prescribing practitioner.

1328.4 The approval required pursuant to § 1328.3 may be in the form of a readily retrievable, written, documented policy maintained by the pharmacy which clearly indicates that the provider has intended to approve the therapeutic interchange.

1328.5 The patient shall be notified of the therapeutic interchange prior to, or upon delivery, of the dispensed prescription to the patient. The notification shall include:

- (a) A description of the change;
- (b) The reason for the change; and
- (c) Contact information indicating who the patient may contact with questions concerning the change.

## **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.

**1329 RETURN OF PRESCRIPTION DRUGS**

1329.1 In the interest of the public health of the District of Columbia and the possible adverse effects which the resale of drugs may have upon the health of the public, it shall be unlawful for any licensed pharmacist to accept any unused prescription or drug, in whole or part, after it has been dispensed or sold, for the purpose of re-dispensing or resale to any person.

**1330-1331 REPEALED**

**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

**1333 PRESCRIPTION REQUIREMENTS FOR MEDICAID COVERED SERVICES**

1333.1 Effective April 1, 2008, a written prescription for any drug, including over-the-counter drugs, for a Medicaid fee for service beneficiary shall only be written on

- (a) The prescription pad contains one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- (b) The prescription pad contains one or more industry-recognized features designed to prevent erasure or modification of information written on the prescription by the prescriber; or
- (c) The prescription pad contains one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

1333.2 Beginning April 1, 2009, a written prescription for any drug, including over-the-counter drugs, for a Medicaid beneficiary shall only be written on tamper resistant prescription pads meeting all of the following characteristics:

- (a) The prescription pad contains one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- (b) The prescription pad contains one or more industry-recognized features designed to prevent erasure or modification of information written on the prescription by the prescriber; and
- (c) The prescription pad contains one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

1333.3 The requirements of this section shall apply whether Medicaid is the primary or secondary payor of the prescription being filled.

1333.4 Prescription orders transmitted to a pharmacy via telephone, telephone facsimile, or electronic prescription order are exempt from the tamper resistant requirements set forth in §§ 1331.1 and 1333.2 of this chapter.

1333.5 The tamper resistant requirements in § 1333.1 of this chapter do not apply to refill prescriptions of an original written prescription that was presented to a pharmacy before April 1, 2008.

1333.6 The exceptions set forth under Section 1927(k)(3) of the Social Security Act (42 U.S.C.S. § 1396r-8(k)(3)) concerning nursing facilities, hospitals, and other institutional and clinical settings, shall also be an exception to the requirements of this section.

1333.7 In the event a prescription is not submitted on a tamper resistant prescription form meeting the requirements set forth in §§ 1331.1 and 1333.2, a pharmacy may fill the prescription in full as written on an emergency basis as long as the pharmacy receives a verbal, telephone facsimile, electronic, or compliant written prescription within seventy-two (72) hours after the date on which the prescription was filled.

1333.8 Effective April 1, 2008, the Medical Assistance Administration (MAA) shall only reimburse providers for covered Medicaid outpatient drugs when the written, non-electronic, prescription is executed on a tamper resistant pad meeting the requirements of this section.

## 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.

**Automated medication system**— A robotic, computerized, or mechanical device and its components that distributes medications in a licensed health care facility, or prepares medications for final dispensing by a licensed pharmacist to a patient or a patient's agent, and maintains related transaction information.

**Board**—The District of Columbia Board of Pharmacy established by the District of Columbia Health Occupations Revision of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01.)

**Centralized automated medication system**— An automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient.

**Common carrier**— An organization that transports persons or goods according to defined routes and schedules and offers its services to the general public such as FedEx and UPS.

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

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- § 22-1500. AUTHORITY TO MAKE INSPECTIONS
  - § 22-1501. INSPECTIONS
  - § 22-1502. RECORDS AND REPORTS
  - § 22-1503. ACCOUNTABILITY AUDITS
  - § 22-1504. ORDER FORMS
  - § 22-1505. RETENTION OF RECORDS
  - § 22-1506. DEFINITIONS
- 

**§ 22-1500. 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.<sup>15</sup>), 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.<sup>16</sup>) and in situations described in § 505(a)(4) of the Act (§ 33-555(a)(4), D.C. Code, 1981 ed.<sup>17</sup>).

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.<sup>18</sup>); 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.<sup>19</sup>

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<sup>15</sup> Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

<sup>16</sup> Section 33-557, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.07(2001).

<sup>17</sup> Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

<sup>18</sup> Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

<sup>19</sup> Section 33-555, D.C. Code, 1981 ed. is now cited as D.C. Official Code § 48-905.05(2001).

**§ 22-1501. 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.

#### **§ 22-1502. 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.

#### **§ 22-1503. 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.

#### **§ 22-1504. 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.

**§ 22-1505. RETENTION OF RECORDS**

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

**§ 22-1599. 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**

**CHAPTER 19. PHARMACIES**

**Sec**

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**1900 GENERAL PROVISIONS**

1900.1 It shall be unlawful for any person to operate, maintain, open, or establish a pharmacy within the District of Columbia without a valid license or registration from the Mayor.

1900.2 It shall be unlawful for an establishment or institution, or any part thereof, that does not provide services of the practice of pharmacy, as defined within, to use or have upon it, or displayed within it, or affixed to, or used in connection with it, a sign bearing the word or words “pharmacy,” or “apothecary,” “drug store,” “druggist,” or any word or words of similar or like import which would tend to indicate that the practice of pharmacy is being conducted in the establishment or institution.

1900.3 No drugs shall be permitted within a pharmacy until a license is obtained from the Director.

1900.4 A pharmacy shall maintain written policies and procedures regarding appropriate cleanliness and hygiene practices and ensure that its employees comply with the established policies and procedures.

1900.5 A pharmacy shall:

- (a) Review its written policies and procedures, as necessary but at least biennially,
- (b) Revise them as necessary, and
- (c) Document the review.

**1901 GENERAL OPERATING STANDARDS**

1901.1 A pharmacy shall be operated only by pharmacist holding a valid license in the District of Columbia to practice pharmacy or, if a non-resident pharmacy, a valid license in the state in which the pharmacy is physically located.

1901.2 A licensed pharmacist shall be on duty at all times that a pharmacy is open for business. Where only one pharmacist is on duty, the pharmacy shall be closed for business during the pharmacist’s meal period and breaks.

- 1901.3 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 Registrations;
  - (d) Professional licenses of pharmacists on duty;
  - (e) Certificates of registration of pharmacy interns; and
  - (f) The hours that the pharmacy is open for business.
- 1901.4 A pharmacy shall stock, maintain, sell, compound, dispense, and distribute only FDA registered drugs, medical devices, and chemicals for compounding.
- 1901.5 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.
- 1901.6 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.
- 1901.7 A pharmacy shall only obtain a drug or medical device from a pharmacy, manufacturer, distributor, or wholesaler that is registered or exempted from registration in the District of Columbia pursuant to § 302 (c) of the Uniform Controlled Substances Act or, if a non-resident pharmacy, be registered or exempted from registration by the federal government or the state in which the pharmacy, manufacturer, distributor, or wholesaler is located.
- 1901.8 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.
- 1901.9 Neither drugs nor other merchandise shall be dispensed, sold, held for sale, or given away in any pharmacy damaged by fire, flood, or other causes until the Director or designee has determined that the merchandise is not adulterated or otherwise unfit for sale, use, or consumption. Damaged premises shall be inspected by the Director or designee to determine their continued suitability for pharmacy operations.
- 1901.10 Chapter 65 (Pharmacists) of Title 17 DCMR and Chapter 13 of Title 22 DCMR

supplement this chapter.

## **1902 NEW LICENSURE OF PHARMACIES**

1902.1 Licenses shall be issued for the following categories of pharmacies as defined in this chapter, except for non-resident pharmacies, which shall be required to register with the Department:

- (a) Retail pharmacy/community pharmacy;
- (b) Nuclear pharmacy;
- (c) Institutional pharmacy;
- (d) Special or limited use pharmacy; and
- (e) Non-resident pharmacy.

1902.2 A retail chain pharmacy with locations both in and outside of the District of Columbia shall obtain:

- (a) A license for each location within the District of Columbia; and
- (b) A registration pursuant to § 1903 for each location outside the District of Columbia which dispenses, distributes, ships, mails, or delivers, in any manner, prescription drugs or prescription medical devices directly or indirectly to a patient in the District of Columbia.

1902.3 The Director shall not license or register a pharmacy, person, or entity, which serves as a storefront, broker, agent, dealer, or in any way exists to facilitate the dispensing, shipping, mailing, delivery, or distribution of prescription drugs or devices from Canada, or any other jurisdiction outside of the United States, to District of Columbia residents.

1902.4 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 of Consumer and Regulatory Affairs, 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 the application.

1902.5 It shall be unlawful for any person to furnish false or fraudulent information on an application for a license or registration.

1902.6 The application for a pharmacy license shall be made on a form to be prescribed by the Director and shall include the required fee. No license fee shall be required for the operation of a pharmacy by the United States government or by the District of Columbia government.

1902.7 The application for a pharmacy license shall include the name and license number of the licensed pharmacist who shall be responsible for ensuring that the pharmacy complies with all applicable laws and regulations pertaining to the operation of the respective pharmacy and practice of pharmacy. The pharmacist shall be known as:

- (a) The “pharmacist-in-charge” for a retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy;
- (b) The “Director of Pharmacy” for an institutional pharmacy; and
- (c) The “Responsible Nuclear Pharmacist” for a nuclear pharmacy.

1902.8 The proprietor of a pharmacy, or other appropriate individual, shall notify the Director within thirty (30) days after a change in the pharmacist-in-charge, Director of Pharmacy, or Responsible Nuclear Pharmacist.

1902.9 Prior to issuing a license, the Director shall make an inspection of a pharmacy to determine compliance with the Act and this chapter.

1902.10 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.

1902.11 The Director shall issue a license to a pharmacy that the Director determines is in compliance with the Act and this chapter.

1902.12 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.

- 1902.13 A license is valid only for the proprietor, the premises, and the pharmacy name designated on the license and the location for which it is issued.
- 1902.14 A pharmacy license is not transferable.
- 1902.15 The pharmacy license shall be issued in the name of the proprietor whether or not the proprietor of a pharmacy is a pharmacist.
- 1902.16 A license is the property of the District of Columbia 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;
  - (d) Change in proprietorship of the pharmacy;
  - (e) Death of the proprietor;
  - (f) Failure of the pharmacy to open for business within thirty (30) days after the license has been issued, except that the Director may grant an extension at his or her discretion for good cause shown;
  - (g) Failure of the pharmacy to operate for any reason for more than ninety (90) consecutive days after it has opened for business; or
  - (h) Closure of the pharmacy.
- 1902.17 The term of a license issued or renewed pursuant to this chapter is two (2) years and shall expire on May 31 of each odd numbered year regardless of the issuance date unless the Director changes the renewal system pursuant to § 1902.18.
- 1902.18 The Director may change the renewal system to another system for the administrative convenience of the Director.
- 1902.19 If the Director changes the renewal system pursuant to § 1902.18 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.

### **1903 REGISTRATION OF NONRESIDENT PHARMACIES**

- 1903.1 The purpose of these rules is to provide standards for the operation of nonresident pharmacies, which dispense or distribute prescription drugs or medical devices,

directly or indirectly such as through the use of an agent or intermediary, to persons located within the District of Columbia. The Department has determined that these rules are necessary to protect the health and welfare of the citizens of the District of Columbia.

- 1903.2 Nonresident pharmacies which dispense, distribute, ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, directly or indirectly, shall, in addition to complying with all applicable federal laws, be registered by the Department and comply with the pharmacy and drug laws and regulations of the District of Columbia, unless and unto the extent that compliance would violate the pharmacy or drug laws or regulations in the state in which the nonresident pharmacy is located.
- 1903.3 No person or entity required to be registered shall ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, directly or indirectly, until a Certificate of Registration is issued by the Department.
- 1903.4 A nonresident pharmacy shall:
- (a) Register with the Department on a form provided by the Department and pay the required fee (no registration fee shall be required for the registration of a nonresident pharmacy operated by the United States government or any other state government); and
  - (b) Biennially renew the registration and pay the required fee.
- 1903.5 The term of a registration issued or renewed pursuant to this chapter is two (2) years, or the balance of the registration period, whichever is shorter, and shall expire on May 31 of each odd numbered year regardless of the issuance date unless the Director changes the renewal system pursuant to § 1903.6.
- 1903.6 The Director may change the renewal system to another system for the administrative convenience of the Director.
- 1903.7 If the Director changes the renewal system pursuant to § 1903.6 of this chapter, the term of a registration 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.
- 1903.8 As part of the application for registration or renewal of registration, a nonresident pharmacy shall:
- (a) Submit evidence to the Department that the nonresident pharmacy holds a pharmacy license, registration, or permit, in good standing, issued by the state in which the pharmacy is located;

- (b) Submit evidence to the Department that the nonresident pharmacy holds a valid DEA registration number, if the pharmacy dispenses prescription controlled substances listed in any Schedule into the District of Columbia;
- (c) Submit evidence that the pharmacist in charge holds a valid license in good standing in the state in which the nonresident pharmacy is located;
- (d) Provide the name, address, and title of its:
  - (1) Owner or proprietor;
  - (2) Pharmacist-in-charge, along with his or her license number and state of licensure;
  - (3) Principal corporate officers;
  - (4) Pharmacists who are dispensing prescription drugs or medical devices to citizens of the District of Columbia, along with their license numbers and state of licensure; and
  - (5) Resident agent located within the District of Columbia designated to accept service of process;
- (e) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agent of the state in which the nonresident pharmacy is located;
- (f) Submit an affidavit by the pharmacist-in-charge certifying that the pharmacist-in-charge has read and understands the pharmacy and drug laws and regulations of the District of Columbia, and that the pharmacist-in-charge has made the pharmacy and drug laws and regulations of the District of Columbia available to all pharmacists working in the nonresident pharmacy;
- (g) Provide evidence of the nonresident pharmacy's ability to provide to the Department a record of a prescription order dispensed to a resident of the District of Columbia not later than three (3) business days after the time the Department requests the record; and
- (h) Provide all website address(es) and domain registration(s) to the Department, if applicable;
- (i) If the nonresident pharmacy is solely internet-based or operates primarily as an internet-based pharmacy, the pharmacy shall also:
  - (1) Submit proof acceptable to the Department of certification by the Verified

Internet Pharmacy Practice Sites Program (VIPPS) of the National Association of Boards of Pharmacy, or other national certification program for internet pharmacies acceptable to the Department, for each website and domain registration; and

(2) Submit proof of registration in good standing in the District of Columbia as a foreign corporation.

- 1903.9 The Director shall deny an application for registration if the applicant fails to provide the required information or documentation.
- 1903.10 A nonresident pharmacy shall report a change in the name or address of the resident agent in writing to the Department within thirty (30) days after the change.
- 1903.11 A nonresident pharmacy shall report a change in the pharmacist-in-charge, or corporate officers within thirty (30) days after the change.
- 1903.12 A nonresident pharmacy which changes proprietorship or ownership, its name, or location shall notify the Department within ten (10) days after the change and apply for a new registration.
- 1903.13 A nonresident pharmacy shall notify the Department within ten (10) days after closing.
- 1903.14 A nonresident pharmacy shall, during its regular hours of operation, but not less than six (6) days per week, and a minimum of forty (40) hours per week, provide toll-free telephone communication consultation between patients in the District of Columbia and a licensed pharmacist at the pharmacy who has access to the patient's prescription records. This toll-free number shall be disclosed on a label affixed to each container of drugs or medical device dispensed to patients in the District of Columbia.
- 1903.15 A nonresident pharmacy shall immediately communicate to a patient or prescribing practitioner any expected delay in delivering the prescribed drug or device which might jeopardize or alter the drug therapy of the patient.
- 1903.16 A nonresident pharmacy shall maintain, at all times:
- (a) A license, registration, or permit in good standing issued in the state in which it is located;
  - (b) Its records of prescription drugs and devices dispensed to patients in the District of Columbia so that the records are readily retrievable, in hardcopy or electronically, for a period of five (5) years from the date of first dispensing. Records which are more than two (2) years old may be stored offsite as long

as they can be retrieved within three (3) business days of a request;

- (c) Compliance with the laws and regulations regarding confidentiality of prescription records in the state in which it is located, and if there are no such laws in that state, then the pharmacy shall comply with the confidentiality laws and regulations of the District of Columbia;
- (d) Compliance with all requests for information made by the Department pursuant to this section; and
- (e) If the pharmacy is internet-based or primarily internet-based:
  - (1) Certification by the Verified Internet Pharmacy Practice Sites Program (VIPPS) of the National Association of Boards of Pharmacy, or other national certification program for internet pharmacies acceptable to the Department, for each website and domain registration; and
  - (2) Registration in good standing in the District of Columbia as a foreign corporation.

1903.17 By applying for and being granted registration as a nonresident pharmacy in the District of Columbia, a nonresident pharmacy shall be deemed to have given its consent to provide to the Department, not later than three (3) business days after the time the Department requests the record:

- (a) All Information and records concerning a prescription drug or medical device order dispensed to a resident of the District of Columbia;
- (b) Any inspection reports, warning notices, notice of deficiency reports, disciplinary actions or any other related reports from the state in which it is located concerning the operation of the nonresident pharmacy for review of compliance with state and federal drug laws; and
- (c) All information requested by the Department.

1903.18 If a nonresident pharmacy fails to comply with any provision of § 1903.17 the Department may summarily suspend the registration. The Department may lift a summary suspension imposed under this section if the Department determines that the nonresident pharmacy has provided the requested information or records.

1903.19 In addition to any other appropriate remedies or actions, the Director shall withdraw the registration of a registrant that:

- (a) Loses licensure in good standing in the state in which it is located;
- (b) Loses registration in good standing in the District of Columbia as a foreign

corporation; or

(c) Is conducted in a manner that endangers the public health, welfare and safety.

- 1903.20 When withdrawing a registration pursuant to § 1903.19 of this chapter, the Director shall give written notice to the registrant citing the basis for withdrawal. The effective date of withdrawal shall be thirty (30) calendar days from the date of service of the notice, or immediately, in the case of danger to the public health, safety, or welfare.
- 1903.21 The notice required in § 1903.20 of this chapter shall state that the registration shall be automatically withdrawn unless, prior to the effective date, the registrant submits proof satisfactory to the Director that the registrant has the licensure or registration required pursuant to § 1903.16.
- 1903.22 In the case of a withdrawal that is effective immediately, the registrant may seek reinstatement of the registration by submitting proof satisfactory to the Director that the registrant no longer poses a danger to the public health, safety, or welfare.
- 1903.23 In addition to any other appropriate remedies or actions, the Director may fine, suspend, or withdraw the registration of a registrant that violates the pharmacy or drug laws or regulations of the state in which it is located, the District of Columbia, or the United States; or causes harm or injury to a person in the District of Columbia.
- 1903.24 A registrant shall be afforded notice and, upon written request received by the Director within thirty (30) days of the receipt of the notice, an opportunity to be heard prior to the Director taking action pursuant to § 1903.19 against the registrant.
- 1903.25 Once a registration has been withdrawn, a registrant shall not ship, mail, or deliver in any manner, prescription drugs or medical devices into the District of Columbia, whether directly or indirectly.
- 1903.26 Upon receipt of a complaint against the nonresident pharmacy, the Department shall forward the complaint to the state where the nonresident pharmacy is located.
- 1903.27 The Department will extend reciprocal cooperation to any state that licenses or registers nonresident pharmacies for the purpose of investigating complaints against pharmacies located in the District of Columbia or the sharing of information and investigative reports, as long as the other state will extend the same reciprocal cooperation to the Department.

**1904 RENEWAL OF PHARMACY LICENSE**

- 1904.1 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.
- 1904.2 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.
- 1904.3 A licensee applying for renewal of a license shall submit the application for renewal not less than thirty (30) days prior to its expiration, to avoid lapse.
- 1904.4 If the Director does not receive the application for renewal of a license at least thirty (30) days prior to the expiration date, the license shall lapse on the expiration date. The licensee may be reinstated within thirty (30) days of expiration upon receipt of a completed renewal application and the payment of a late fee.
- 1904.5 Upon receipt of the required late fee and final processing of the renewal application, the licensee shall be deemed to have possessed a valid license during the period between the expiration of the license and the reinstatement date.
- 1904.6 Reinstatement of a license that has been expired for over thirty (30) days shall be at the discretion of the Director. Otherwise, a licensee that fails to submit the completed renewal application or required late fee within thirty (30) days after the expiration of the applicant's license shall be required to apply for new licensure pursuant to § 1902 of this chapter.
- 1904.7 Prior to the renewal of a license, the Director shall make an inspection of a pharmacy to determine compliance with the Act and this chapter.
- 1904.8 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.

**1905 CHANGE IN PHARMACY NAME, PROPRIETORSHIP, 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 § 1902 of this Chapter.
- 1905.3 If the change of name or location is 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 proprietorship 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 § 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.

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 § 1902.9 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 proprietor shall, in addition to the requirements of this section, comply with the provisions of § 1323 of this Title, and notify the Director of the closing of the pharmacy not later than fifteen (15) days prior to the anticipated date of closing. The notice shall be submitted to the Director in writing and shall contain the following information:

- (a) The date the pharmacy will close;
- (b) The names, addresses, and telephone numbers 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, addresses, DEA registration numbers, and District registration numbers 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 A pharmacy that dispenses prescription drugs shall, at least fifteen (15) days prior to the closing date of the pharmacy, post a closing notice sign in a conspicuous place in the front of the prescription department and at all public entrance doors to the pharmacy. The closing notice sign shall contain the following information:

- (a) The date of closing; and

- (b) The name, address, and telephone number of the pharmacy acquiring the prescription drug orders, refill information, and patient medication records of the pharmacy.

1906.3 On the date of closing, the pharmacy shall, in addition to complying with all other District and federal requirements:

- (a) Transfer the prescription drug files, refill information, and patient medication records to a licensed pharmacy within a reasonable distance of the closing pharmacy. The pharmacy shall be the same pharmacy which was identified in the closing notice sign; and
- (b) Remove all signs and symbols indicating the presence of a pharmacy, or any representation that would tend to mislead the public that pharmacy is located at the address.

1906.4 Not later than fifteen (15) days after the pharmacy has closed, the proprietor shall submit to the Director the following:

- (a) The pharmacy license;
- (b) The District of Columbia certificate of registration; and
- (c) A written statement containing the following information:
  - (1) The actual date of closing;
  - (2) 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;
  - (3) If controlled substances were transferred, a list of the names, addresses, DEA registration numbers, and District 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;
  - (4) Confirmation that the DEA registration and all unused DEA 222 forms (order forms) were returned to the DEA;
  - (5) Confirmation that all pharmacy labels with addresses and blank prescription pads with addresses which were in the possession of the pharmacy were destroyed;
  - (6) If controlled substances were transferred, confirmation that an inventory

has been conducted; and

- (7) Confirmation that all signs and symbols indicating the presence of the pharmacy have been removed.

1906.5 If a pharmacy is closed suddenly due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances the pharmacy shall notify the Director immediately or as far in advance of the closing as allowed by the circumstances.

1906.6 The pharmacist-in-charge and the proprietor of the pharmacy shall be jointly responsible for ensuring the pharmacy's compliance with the provisions of this section.

## **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 to operate 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 one hundred fifty (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) Shall contain an area which is suitable for confidential patient counseling, if the pharmacy serves the public;
- (d) Be separated from other areas by a barrier which renders the area inaccessible to unauthorized persons;
- (e) Provide an unobstructed view of the pharmacist on duty;
- (f) Be properly lighted and ventilated;

- (g) Have a sink and goose-neck faucet with hot and cold running water within the dispensing and compounding area, for the immediate access and use of all pharmacy personnel, maintained in a sanitary condition and shall include:
  - (1) Soap or detergent; and
  - (2) Air-driers or single-use towels.
- (h) Maintain the temperature of the pharmacy within a range compatible with the proper storage of drugs; and
- (i) 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 degrees Fahrenheit (36°F) and forty-six degrees Fahrenheit (46°F).

1907.5 All areas where drugs and medical devices are stored, shall be dry, well lighted, well ventilated, 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) and maintained in a clean and orderly condition.

1907.6 Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their dispensing as stipulated by the United States Pharmacopoeia /National Formulary (USP/NF) and/or the manufacturer's or distributor's labeling unless otherwise indicated by the Bureau of Food, Drug & Radiation Protection, Pharmaceutical Control Division.

## **1908 SANITATION STANDARDS**

1908.1 The sanitary standards contained in this section shall apply to all pharmacies and drug and medical device storage areas, unless otherwise exempted by this chapter or the Director.

1908.2 A pharmacy and all areas under the control of the pharmacy, including storage areas and restrooms, shall be maintained in a clean and sanitary condition free of infestation by rodents, birds, insects, and other vermin.

1908.3 All pharmacy and storage areas shall be dry and well ventilated.

1908.4 All pharmacy equipment shall be kept clean and in good operating condition.

1908.5 Trash shall be kept in opaque trash bags and covered waste receptacles.

1908.6 Trash, sewage, and other refuse shall be removed from a pharmacy in a timely

and sanitary manner.

- 1908.7 Restroom facilities shall be located in an area reasonably accessible to pharmacy personnel and supplied with a hand washing sink, soap or detergent, toilet paper, and air driers or single-service towels.
- 1908.8 The pharmacy's plumbing facilities shall be kept in good repair.
- 1908.9 Animals shall not be permitted in the pharmacy or areas immediately adjacent to and under the control of the pharmacy except for guide dogs accompanying disabled persons.
- 1908.10 All persons working in a pharmacy in any capacity shall follow hygienic work practices, including the washing of hands thoroughly as often as is necessary to remove soil and contamination.

## **1909 REQUIRED EQUIPMENT AND REFERENCES**

- 1909.1 The equipment and references requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.
- 1909.2 The pharmacist-in-charge shall be responsible for maintaining the following:
- (a) Current dispensing information reference source consistent with the scope of pharmacy practice at the location of the permitted pharmacy;
  - (b) A set of prescription balances, sensitive to 15 milligrams, and weights or an electronic scale if the pharmacy engages in dispensing activities that require the weighing of components;
  - (c) Other equipment, supplies, and references consistent with the pharmacy's scope of practice and with the public safety; and
  - (d) All other items required by federal and District of Columbia laws and regulations.
- 1909.3 A pharmacy may apply to the Director for a waiver of any of the equipment required under § 1909.2 where the equipment would be inapplicable to the services provided by the pharmacy.
- 1909.4 A pharmacy shall be equipped to provide emergency information about reactions to poisons from a current source.
- 1909.5 In addition to the requirements set forth under § 1909.2, a nuclear pharmacy shall maintain the following items, in hard copy or electronic format, in its reference

library:

- (a) A reference on the safe handling of radioactive materials;
- (b) A minimum of three texts dealing with nuclear medicine science;
- (c) A reference on sterile product preparation; and
- (d) Code of Federal Regulations, Title 49, Parts 106-199, with recent amendments.

**1910 SECURITY AND SAFEGUARDS AGAINST DRUG DIVERSION**

- 1910.1 The security and safeguards requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.
- 1910.2 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.
- 1910.3 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 authorized access.
- 1910.4 Any controlled substance stored outside of the prescription drug compounding and dispensing area shall be kept in a locked storage area.
- 1910.5 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.
- 1910.6 Each pharmacist, while on duty, shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of drugs or devices.
- 1910.7 A pharmacy shall be secured by either a physical barrier with a suitable lock, or by an electronic barrier to detect entry, and protected by an alarm at all times while a pharmacist is not on duty.

1910.8 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.

1910.9 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;
- (c) Over-the-counter medicine that contains a controlled substance; and
- (d) Over-the-counter medicines that have been identified by the Food and Drug Administration or the Director as having a potential for misuse or abuse.

## **1911 PACKAGING AND HANDLING OF DRUGS AND MEDICAL DEVICES**

1911.1 The packaging and handling requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1911.2 A pharmacy shall dispense drugs or medical devices in new and clean containers or in the manufacturer's original container or package.

1911.3 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.

1911.4 A pharmacy shall not reuse a manufacturer's bottle or container.

1911.5 A pharmacy shall not reuse a bottle or container that has held toxic, adulterated, or misbranded substances.

1911.6 A pharmacy shall obtain drugs only from suppliers licensed or registered as required by federal and District law.

1911.7 A pharmacy shall obtain only drugs that are in the original manufacturer's or distributor's container.

1911.8 A pharmacist shall direct and supervise the compounding, repackaging,

or prepackaging of drugs and make the final verification of the prepackaged product and document the verification.

1911.9 A pharmacy shall keep a log of drugs that have been compounded, repackaged, or 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 manufacturer or distributor's lot or control number of the drug;
- (d) The strength of the drug;
- (e) The expiration date;
- (f) The date of prepackaging or repackaging;
- (g) The quantity of drugs prepared; and
- (h) The name or initials of the pharmacist supervising the packaging.

1911.10 A pharmacy shall keep the log required under § 1911.09 of this chapter for five (5) years from the date of packaging. Records that are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request.

1911.11 All drugs and medical devices held by a pharmacy shall be stored:

- (a) In a proper and safe manner;
- (b) In an appropriate container or package that provides for protection of the product;
- (c) To insure complete and accurate identification of the product; and
- (d) As required by the manufacturer, this chapter, and other applicable federal and District of Columbia laws or regulations.

## **1912 LABELING OF DISPENSED DRUGS**

1912.1 The labeling requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1912.2 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, or if the ultimate user is an animal, the name of the owner, the first name of the animal, and the species of the animal;
- (c) The name of the prescribing practitioner;
- (d) The date of filling;
- (e) The generic, chemical, or brand name of the drug 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 §§ 48-801 et al);
- (f) The strength, dosage, and quantity of the drug dispensed;
- (g) The directions for use and cautionary statements, if any, contained in the prescription or required by law;
- (h) The serial number of the prescription or prescription number; and
- (i) 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.

1912.3 If a prescription order is for a controlled substance, the label shall also include a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

1912.4 A pharmacy shall be responsible for labeling each prepackaged or repackaged 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 or distributor's control or lot number; and
- (e) The expiration date of the product according to the manufacturer or on one (1) year from the date the drug or medical device is prepackaged, 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.

1912.5 When the size of the label required pursuant to this section requires a reduction in type, the reduction shall not be made to a size smaller than is necessary and under no circumstances shall the size be less than six (6) point type.

1912.6 Once opened, a multi-dose container shall be labeled with the expiration date of the product according to the manufacturer or on one (1) year from the date the drug or medical device is prepackaged, 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 RECORDKEEPING**

1913.1 The recordkeeping requirements of this section shall apply to all pharmacies, unless otherwise exempted by this chapter or the Director.

1913.2 A pharmacy shall maintain on a current basis a complete and accurate record of all prescription drugs and devices received, sold, compounded, dispensed, or otherwise disposed of by the pharmacy for a period of five (5) years.

1913.3 For purposes of this section, the requirement may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.

1913.4 A pharmacy shall keep a chronological record, for a period of five (5) years from the date of first dispensing, of each prescription that is filled or refilled including the following information:

- (a) The name and address of the patient;
- (b) The name and address of the prescriber and date prescribed;
- (c) The name, strength, dosage form, and quantity of the drug prescribed, and quantity dispensed if different from the quantity prescribed;
- (d) The name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially;
- (e) Directions for use;
- (f) The date the prescription was compounded, dispensed, or refilled;

- (g) The name or initials of the pharmacist responsible for final verification of the prescription order;
- (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;
- (j) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, a change in quantity, directions, number of refills, or authorization to substitute a drug; and
- (k) Any other information required by District of Columbia or federal law or regulations.

1913.5 The pharmacist performing the final verification of a prescription shall be identified on the prescription record by name or initial, and shall be fully responsible for the accuracy of the processing, compounding, and dispensing of the prescription order.

1913.6 A pharmacy shall put in place systems to assign a secure identification code to each pharmacist for use on verification records, or require manual signatures of pharmacists performing final verifications to ensure that only the actual verifying pharmacist can place his or her name or initials on the verification records.

1913.7 All prescriptions orders shall be maintained for a period of five (5) years from the date of first dispensing.

1913.8 Prescription orders for controlled substances in Schedules I and II shall be maintained in a file separate from all other records of the pharmacy.

1913.9 Prescription orders for controlled substance 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. However, if a pharmacy employs an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

1913.9 All prescription orders shall be in compliance with requirements under this

section, the Act and Title 21, CFR Part 1306, where applicable.

1913.10 There shall be maintained in each pharmacy a bound volume, which shall be available for inspection by the Director, in which shall be recorded information required by federal or District of Columbia law or regulation concerning each sale of:

- (a) Over-the-counter (OTC) Schedule V controlled substances;
- (b) Hypodermic syringes, needles, or other medical devices which may be used in the administration of controlled substances;
- (c) Gelatin capsules and glassine envelopes in quantities sufficient to indicate an intention to use such substances for the illegal distribution or dispensing of any controlled substance; and
- (d) Diluents or adulterants, such as lactose or quinine, in quantities sufficient to indicate an intention to use such substances for the illegal distribution or dispensing of any controlled substance.

1913.11 A pharmacy shall maintain a patient record system in an automated data processing system or manual record system which shall provide for the immediate retrieval of patient information during the pharmacy's normal operating hours which may include:

- (a) Full name of the patient for whom the drug is intended;
- (b) Street address and telephone number of the patient;
- (c) Patient's age or date of birth;
- (d) Patient's gender, height and weight;
- (e) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the (5) years immediately preceding the most recent entry showing the name of the drug, prescription number, name and strength of the drug, the quantity and date received, and the name of the practitioner;
- (f) The pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug;
- (g) Patient allergies, drug reactions, current medications and relevant prior medications including non-prescription medications and relevant devices, or medication conditions which are communicated by the patient or the patient's agent; and

- (h) Any other information which the pharmacist, in his or her professional judgment, deems appropriate.

1913.12 A patient record shall be maintained for a period of not less than five (5) years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

1913.13 Prescription records, patient records, and any other individually identifiable health care information shall be maintained, used, and disclosed only in a manner that protects the integrity and confidentiality of the information, and that is in compliance with the requirements of HIPPA, and all applicable federal and District of Columbia laws and regulations.

1913.14 Authorized agents of the Director shall have immediate and unimpeded access to all pharmacy patient records and the pharmacist-in-charge shall be responsible for informing their superiors.

#### **1914            COMPUTERIZED RECORDKEEPING**

1914.1 A pharmacy may use an automated data processing system to meet the recordkeeping requirements under § 1913 of this Title if the system meets the requirements of this section.

1914.2 The automated data processing system shall have:

- (a) Adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records. A pharmacy shall document any alterations in the prescription drug order, occurring after the prescription has been dispensed, and identify the pharmacist responsible for the alteration;

(b) The capability of producing:

- (1) Readable required documentation and information on all original and refilled prescriptions through on-line retrieval, or, from the cathode ray tube (CRT), microfiche, microfilm, printout, or other method acceptable to the Board of Pharmacy; and
- (2) A refill-by-refill audit trail for any specified strength and dosage form of any drug. The audit trail shall be by printout, and include the name of the prescribing practitioner, name and location of the patient, quantity dispensed on each refill, dispensing date of each refill, name or identification code of the pharmacist performing the final verification, and unique identifier of the prescription drug order.

- (c) The capability to print all information entered into the system on paper within three (3) business days; and
- (d) Adequate safeguards to ensure security and confidentiality of patient records pursuant to the applicable federal and District of Columbia laws and regulations.

- 1914.3 A pharmacist shall be responsible for the completeness and accuracy of the information he or she enters into the automated data processing system.
- 1914.4 All entries made into the automated data processing system shall include the initials or identification code of the dispensing pharmacist responsible for the transaction giving rise to the entry.
- 1914.5 The pharmacist-in-charge shall maintain a record keeping system in which each pharmacist involved in dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. The log book or file shall be maintained at the pharmacy for a period of five (5) years from the date of dispensing. Records which are more than two (2) years old may be stored offsite as long as they can be retrieved within three (3) business days of a request.
- 1914.6 Any facility maintaining centralized prescription records shall be capable of sending a requested printout to the Pharmacy within seventy-two (72) hours.
- 1914.7 The pharmacist-in-charge, Director of Pharmacy, or Responsible Nuclear Pharmacist, as applicable, shall develop and implement a policy and procedure manual for the operational aspects of the automated data processing system which shall:
- (a) Identify the required output documentation stored and provided by the system;
  - (b) Identify the procedures for when the system is not operational;
  - (c) Outline the regular and routine backup file and file maintenance procedures;
  - (d) Outline the audit procedures;
  - (e) Identify personnel responsibilities; and
  - (f) Provide a quality assurance mechanism for data entry validation.
- 1914.8 A pharmacy shall maintain sufficient patient data and prescription drug order data, in hard copy format, to permit reconstruction of the data and proper dispensing of prescription orders, within two (2) hours of an unscheduled system interruption or malfunction of the automated data processing system.

- 1914.9 A pharmacy shall have an auxiliary system or procedures in place to ensure that all refills are authorized and that the maximum number of refills is not exceeded, if the automated data processing system is inoperative for any reason. In the event the actual number of remaining authorized refills cannot be determined and the pharmacist is unable to contact the prescribing provider for a new prescription, the pharmacist may use his or her professional judgment to dispense not more than a seven (7) day supply to cover or prevent a medical emergency.
- 1914.10 The auxiliary system set forth in § 1914.9 shall be capable of meeting the requirements of this chapter and functioning in the place of the automated data processing system until the automated data processing system is again operational.
- 1914.11 All prescription drug order information shall be entered into the automated data processing system not more than ninety-six (96) hours after the automated data processing system is again operational.
- 1914.12 A pharmacy shall implement routine backup file and file maintenance procedures to prevent loss of patient data.
- 1914.13 A pharmacy shall notify the Board of Pharmacy of a permanent loss of prescription drug order information or patient information due to a system failure, not more than twenty-four hours (24) after the discovery.
- 1914.14 A pharmacy shall be responsible for continuity in the maintenance of prescription records if the relationship with its data processing services supplier terminates.
- 1914.15 A pharmacy using an automated data processing system shall comply with all applicable federal and District of Columbia laws and regulations.

## **1915 AUTOMATED MEDICATION DISPENSING SYSTEMS**

- 1915.1 An automated medication dispensing system may be utilized in a licensed pharmacy or health care facility if the requirements of this section are being met.
- 1915.2 An automated medication dispensing system shall be used only in settings where there is an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice.
- 1915.3 The recordkeeping requirements of this section may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.

- 1915.4 A pharmacy shall provide the Director written notice of the installation of an automated medication dispensing system prior to utilizing an automated medication dispensing system. The notice shall include:
- (a) The name and address of the pharmacy;
  - (b) The location of the automated equipment;
  - (c) The identification of the responsible pharmacist; and
  - (d) The type of system, manufacturer's name, make, and model.
- 1915.5 An automated medication dispensing system shall have adequate security and procedures to:
- (a) Prevent unauthorized access;
  - (b) Comply with federal and District of Columbia laws and regulations; and
  - (c) Maintain patient confidentiality.
- 1915.6 An automated medication dispensing system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.
- 1915.7 The pharmacy, or provider pharmacy providing remote pharmacy services, shall:
- (a) Maintain records regarding the automated medication dispensing system in a readily retrievable manner for at least five (5) years. The records shall include:
    - (1) Maintenance records and service logs;
    - (2) System failure reports;
    - (3) Accuracy audits and system performance audits;
    - (4) Copies of reports and analyses generated as part of the quality assurance program;
    - (5) Reports or databases related to level of access and changes in the level of access to the system; and
    - (6) Training records including the training content, date, and identity of those attending the training program.

- (b) Maintain dispensing records for all prescription drugs or devices dispensed or distributed from the automated medication system for a period of five (5) years and shall include:
  - (1) Identity of the system accessed;
  - (2) Identification of the individual accessing the system;
  - (3) Date of transaction;
  - (4) Name, strength, dosage form, and quantity of drug accessed; and
  - (5) Name of the patient for whom the drug was accessed.
- (c) Maintain stocking and removal records of all drugs stored in and removed from the system for a period of five (5) years, which shall include identification of the person stocking or removing drugs from the system and identification of the pharmacist who verified that the system was accurately filled;
- (d) Maintain records, including records of drugs discarded through the use of a reverse distributor, of all drugs discarded as waste for a period of five (5) years, which shall include identification of the person discarding the drugs and the identification of the pharmacist who verified that the drugs were properly discarded in accordance with federal and District law and regulations;
- (e) Ensure that the automated medication dispensing system maintains the integrity of the information in the system and protects patient confidentiality;
- (f) Ensure that a comprehensive program of quality assurance for the automated medication dispensing system is in place;
- (g) Ensure that the system complies with this chapter;
- (h) Maintain policies and procedures related to:
  - (1) The operation of the system;
  - (2) Training of personnel using the system; and
  - (3) Operations during system down time;
- (i) Establish a process to:
  - (1) Ensure the security of the system;
  - (2) Account for medication added to and removed from the system; and

(3) Minimize the potential for misidentification of medications, dosages, and dosage forms by those accessing the automated medication system; and

(j) Ensure that authorized individuals working with the automated medication dispensing system receive initial and annual training regarding:

(1) The capabilities and limitations of the system;

(2) The operation of the system; and

(3) Procedures for system downtime.

1915.8 The records which are required to be maintained pursuant to § 1915.7 shall be stored on site where the automated medication dispensing system is located.

1915.9 The Director of Pharmacy or pharmacist-in-charge shall:

(a) Control access to the automated medication dispensing system;

(b) Designate in writing the individuals who are authorized to access the system;

(c) Establish criteria and a process for determining which drugs may be stored in the automated medication system;

(d) Develop policies and procedures regarding the automated medication system; and

(e) Be responsible for all pharmacy operations involving the automated medication dispensing system.

1915.10 Access to the automated medication dispensing system shall be limited to individuals that have completed documented training concerning the automated pharmacy system and who are one of the following:

(a) Licensed pharmacist;

(b) Qualified pharmacy personnel under a licensed pharmacist's supervision; or

(c) Individuals permitted by law to administer medication.

1915.11 Where a centralized automated medication dispensing system is being used, a licensed pharmacist shall perform a final check of each medication that is removed from the system prior to distribution or dispensing, unless:

- (a) A licensed pharmacist utilizing a centralized automated medication dispensing system distributes patient specific medications within the licensed health care facility and the medication is distributed for subsequent administration by a health care professional permitted by law to administer medication; or
  - (b) A licensed pharmacist performs a daily quality assurance check of the integrity of the system that includes random sampling of the output.
- 1915.12 Where a decentralized automated medication dispensing system is being used:
- (a) A licensed pharmacist shall perform a review of each order for medication before the medication is removed from the system, except if the order is for a starter dose; and
  - (b) A licensed pharmacist shall perform a review of each order for a starter dose within twenty-four (24) hours of removal of the starter does from the remote or decentralized automated medication system, if the patient is still under the care of the facility when the review is to be performed.
- 1915.13 Only a licensed pharmacist may fill an automated medication dispensing system, unless otherwise specifically permitted by this section.
- 1915.14 Automated medication dispensing systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by:
- (a) Authorized personnel pursuant to § 1915.9(b), supervised by a licensed pharmacist with a pharmacist performing the final verification; or
  - (b) Health care professionals licensed under the Act, and authorized to access an automated medication dispensing system due to the health care professionals' privileges to administer medication.
- 1915.15 Only a licensed pharmacist may return medication to the automated medication dispensing system, unless otherwise specifically permitted by this section.
- 1915.16 Automated medication dispensing systems that possess sufficient safeguards to ensure accuracy of the replenishment may allow for medication to be returned to those systems by:
- (a) Authorized personnel pursuant to § 1915.9(b), supervised by a licensed pharmacist; or
  - (b) Health care professionals licensed under the Act, and authorized to access an automated medication dispensing system due to the health care professionals' privileges to administer medication.

- 1915.17 Medication which is returned to an automated medication dispensing system may be used for subsequent administration provided that:
- (a) The drugs are in sealed, tamper evident packaging which has not been opened;
  - (b) The medication is in an unadulterated form;
  - (c) If in a unit of use package, the medication is in the intact package that the medication was in when initially removed from the system;
  - (d) The return of medication is documented within the system or in other records maintained by a licensed pharmacist; and
  - (e) The return of medication is conducted in accordance with written procedures.
- 1915.18 Drugs for use in an automated medication dispensing system shall be packaged in the original manufacturer's container or be prepackaged and labeled in compliance with the requirements of this chapter, and applicable federal and District laws and regulations.
- 1915.19 Controlled dangerous substances shall only be dispensed and distributed in accordance with applicable federal and District of Columbia laws and regulations.

## **1916 REMOTE AUTOMATED PHARMACY SERVICES**

- 1916.1 The purpose of this section is to provide standards for the provision of remote pharmacy services by a provider pharmacy in a facility that is not at the same location as the provider pharmacy through an automated pharmacy system.
- 1916.2 A provider pharmacy may provide remote pharmacy services directly or through the use of a Board-approved subcontractor using an automated pharmacy system to a health care facility or other appropriate facility located in the District of Columbia if:
- (a) The provider pharmacy submits an application to the Director for permission to provide remote pharmacy services using an automated medication dispensing system. The application shall include:
    - (1) The name, address, and license number of the provider pharmacy;
    - (2) The name and address of the facility where the remote pharmacy services will be provided;
    - (3) The name and address of the subcontractor who will provide after-hours remote pharmacy services, if applicable;
    - (4) An affidavit with the notarized signatures of the pharmacist-in-charge, and

the medical director or the person responsible for the on-site operation of the facility affirming that the provider pharmacy and the facility have entered into a written agreement outlining the responsibilities of each party in complying with this chapter and the applicable federal and District laws and regulations; and

(5) Documentation that the automated medication dispensing system is located where medications are administered by authorized health care professions.

(b) The Director approves the application. Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

1916.3 A provider pharmacy may only utilize a subcontractor for the provision of after-hours and weekend remote pharmacy services, or in the case of an emergency situation caused by forces majeure, i.e. acts of God.

1916.4 A provider pharmacy shall notify the Director in writing within ten (10) days of a change of location, discontinuance of service, or closure of a remote site or remote pharmacy service.

1916.5 The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

1916.6 The following duties shall be performed only by a licensed pharmacist at the provider pharmacy:

(a) Receiving an oral, facsimile, or electronic prescription drug order;

(b) Interpreting the prescription drug order;

(c) Verifying the accuracy of the prescription data entry;

(d) Selecting the drug product;

(e) Interpreting the patient's medication records and conducting a drug regimen review;

(f) Authorizing the telepharmacy system to print a prescription label at the remote site; and

(g) Performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed. The final check shall be accomplished through a visual check using electronic methods.

- 1916.7 Patient counseling of an inpatient of a health care facility may be performed by either a pharmacist or a licensed health care professional authorized to administer drugs.
- 1916.8 Drugs shall only be dispensed at a remote site through an automated prescription medication dispensing system if:
- (a) An original prescription drug order has been received, or reviewed electronically, by a pharmacist at the provider pharmacy;
  - (b) A pharmacist at the provider pharmacy has approved the release of the initial dose of a prescription drug order; and
  - (c) A pharmacist at the provider pharmacy has conducted a drug regimen review prior to releasing a prescription drug order to the automated pharmacy system.
- 1916.9 Non-sterile drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a registered pharmacy technician or an authorized licensed healthcare provider reconstitutes the product.
- 1916.10 Subsequent doses from an approved prescription drug order may be removed from the automated medication system by, authorized personnel, after the initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.
- 1916.11 A provider pharmacy shall only store drugs at a remote site within an automated medication dispensing system that is locked by key or combination so as to prevent access by unauthorized personnel.
- 1916.12 A pharmacist from the provider pharmacy shall be accessible at all times to respond to a patient's or other health professional's questions and needs pertaining to drugs dispensed through an automated medication dispensing system at a remote site. The access may be by telephone or through a twenty-four (24) hour pager service.
- 1916.13 The provider pharmacy shall be responsible for ensuring that the requirements set forth under §§ 1914 and 1915 of this Title are met, and for maintaining all required records.
- 1916.14 The pharmacist-in-charge of the provider pharmacy shall be responsible for ensuring that the remote site and automated medication dispensing system comply with all applicable federal and District laws and regulations.
- 1916.15 Nothing in this section shall be construed to permit a pharmacy, or provider pharmacy, located within the District of Columbia to provide remote pharmacy services to a facility or individual located outside of the District of Columbia

without legal authorization under the laws of the recipient state or jurisdiction.

## **1917 TELEPHARMACY SERVICES**

1917.1 The purpose of this section is to provide standards for the provision of remote pharmacy services by a provider pharmacy in a facility that is not at the same location as the provider pharmacy through a telepharmacy system.

1917.2 Telepharmacy systems may only be used in institutional settings.

1917.3 A provider pharmacy may provide remote pharmacy services directly, or through the use of a Director-approved subcontractor, using a telepharmacy system to a health care facility or other appropriate facility located in the District of Columbia if:

(a) The provider pharmacy submits an application to the Director for permission to provide remote pharmacy services using a telepharmacy system. The application shall include:

- (1) The name, address, and license number of the provider pharmacy;
- (2) The name and address of the facility where the remote pharmacy services will be provided;
- (3) The name and address of the subcontractor who will provide after-hours remote pharmacy services; and
- (4) An affidavit with the notarized signatures of the pharmacist-in-charge or Director or Pharmacy, and the medical director or the person responsible for the on-site operation of the facility affirming that the provider pharmacy and the facility have entered into a written agreement outlining the responsibilities of each party in complying with this chapter and the applicable federal and District laws and regulations.

(b) The Director approves the application. Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

1917.4 A provider pharmacy may only utilize a subcontractor for the provision of after-hours and weekend remote pharmacy services; or as emergency staffing where the President of the United States or the Mayor has declared a disaster or bio-terrorism related event in the District of Columbia.

1917.5 A provider pharmacy and the facility shall notify the Director in writing within ten (10) days of a change of location, discontinuance of service, or closure of a remote

site or remote pharmacy service.

- 1917.6 The pharmacist-in-charge or director of pharmacy, of the provider pharmacy is responsible for all pharmacy operations involving the telepharmacy system located at the remote site including supervision of the telepharmacy system and compliance with this section.
- 1917.7 The following duties shall be performed only by a licensed pharmacist at the provider pharmacy:
- (a) Receiving an oral prescription drug order;
  - (b) Interpreting the prescription drug order;
  - (c) Verifying the accuracy of the prescription data entry;
  - (d) Interpreting the patient's medication records and conducting a drug regimen review;
  - (e) Authorizing the telepharmacy system to print a prescription label at the remote site;
  - (f) Performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed. The final check shall be accomplished through a visual check using electronic methods; and
  - (g) Counseling the patient. This counseling may be performed using electronic methods such as telephone, email, video conferencing, and webcam.
- 1917.8 Nonsterile drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a registered pharmacy technician or an authorized licensed healthcare provider reconstitutes the product.
- 1917.9 Drugs shall only be dispensed at a remote site through a telepharmacy system if:
- (a) An original prescription drug order has been received, or reviewed electronically, by a pharmacist at the provider pharmacy;
  - (b) A pharmacist at the provider pharmacy has approved the release of the initial dose of a prescription drug order;
  - (c) A pharmacist at the provider pharmacy has conducted a drug regimen review prior to releasing a prescription drug order to the telepharmacy system; and

(d) A pharmacist is able to electronically supervise the telepharmacy system and the dispensing of the prescription drug order.

1917.10 Drugs may be dispensed by the provider pharmacy through a telepharmacy system at a remote site only in unit-of-use or unit dose containers that are:

(a) Prepackaged in suitable containers at the provider pharmacy and appropriately labeled as required under this Title; or

(b) In original manufacturer's or distributor's containers.

1917.11 A provider pharmacy shall only store drugs at a remote site within an area that is locked by key or combination so as to prevent access by unauthorized personnel.

1917.12 A pharmacist from the provider pharmacy shall be accessible at all times to respond to a patient's or other health professional's questions and needs pertaining to drugs dispensed through a telepharmacy system at a remote site. The access may be by telephone or through a twenty-four (24) hour pager service.

1917.13 The provider pharmacy shall be responsible for ensuring that the requirements set forth under §§ 1913 and 1914 of this Title are met and for maintaining all required records.

1917.14 The pharmacist-in-charge or Director of Pharmacy of the provider pharmacy shall be responsible for ensuring that the remote site and telepharmacy system comply with all applicable federal and District laws and regulations.

1917.15 Nothing in this section shall be construed to permit a pharmacy, or provider pharmacy, located within the District of Columbia to provide remote pharmacy services to a facility or individual located outside of the District of Columbia without legal authorization under the laws of the recipient state or jurisdiction.

## **1918 PROSPECTIVE DRUG REGIMEN REVIEW**

1918.1 For purposes of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record and each prescription drug order presented for dispensing. The review shall include screening for the following, if available:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contra-indications;

(d) Drug-drug interactions;

- (e) Incorrect drug dosage or duration of drug treatment;
- (f) Drug-allergy interactions;
- (g) Reasonable dose and route of administration;
- (h) Clinical abuse/misuse;
- (i) Proprietary or over-the-counter drugs;
- (j) Natural or herbal products; and
- (k) Homeopathic products.

1918.2 Upon identifying any of the above, the pharmacist shall take appropriate steps to avoid or resolve any problem or potential problem including consultation with the practitioner. The pharmacist shall document such occurrences.

1918.3 The pharmacy must maintain the patient profile in a readily retrievable manner meeting the requirements of § 1913.11 of this Chapter.

## **1919 PATIENT COUNSELING**

1919.1 Following review of a patient's medical record and prior to dispensing a drug or medical device, a pharmacist shall make a verbal offer to counsel, or his designee shall notify the patient or the patient's agent of the opportunity to receive an oral consultation from the pharmacist:

- (a) Whenever a prescription drug or device has not previously been dispensed to a patient;
- (b) Whenever a prescription drug or device has not previously been dispensed to a patient in the same dosage form, strength, or with the same written directions;
- (c) Once yearly on maintenance medications; or
- (d) Whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

1919.2 The pharmacy shall post a sign in a conspicuous manner informing patients of their right to receive an oral consultation from the pharmacist regarding their prescriptions.

- 1919.3 The consultation shall be face to face, whenever practicable, or by telephone and shall include appropriate elements of patient counseling which may include the following:
- (a) The name and description of the drug or device;
  - (b) The dosage form, dosage, route of administration, and duration of drug therapy;
  - (c) Intended use of the drug or device and expected action;
  - (d) Special directions and precautions for preparation, administration, and use by the patient;
  - (e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
  - (f) Techniques for self-monitoring of drug therapy;
  - (g) Proper storage;
  - (h) Prescription refill information;
  - (i) Action to be taken in the event of a missed dose; and
  - (j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient, drug, or device.
- 1919.4 The consultation shall be reinforced with the provision of written information which may include:
- (a) Information leaflets;
  - (b) Pictogram labels; or
  - (c) Video programs.
- 1919.5 When the patient or patient's agent is not present, as in the case of prescription deliveries, the pharmacist shall ensure that the patient receives written notice:
- (a) Of his or her right to request consultation; and
  - (b) A telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

- 1919.6 Only a pharmacist may counsel a patient or the patient's agent and answer questions concerning prescription drugs or devices.
- 1919.7 A pharmacist shall assess to the best of his or her ability that the patient or agent understands the counseling information provided.
- 1919.8 A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses consultation. The pharmacist shall document such refusal for consultation.
- 1919.9 A pharmacist shall not be required to counsel an inpatient of a health care facility, where other licensed health care professionals are authorized to administer drugs, except upon request.

**1920 PHARMACIST-IN-CHARGE**

- 1920.1 A retail/community pharmacy, special or limited use pharmacy, or non-resident pharmacy shall be managed by a pharmacist (hereafter referred to as "Pharmacist-in-charge"). The pharmacist-in-charge shall be licensed to practice pharmacy in the District of Columbia, except that the pharmacist-in-charge of a non-resident pharmacy shall be licensed in the state in which the pharmacy is located.
- 1920.2 A pharmacist may not serve as a pharmacist-in-charge unless he is physically present in the pharmacy a sufficient amount of time to provide supervision and control. A pharmacist may not serve as a pharmacist-in-charge for more than one (1) pharmacy at a time except upon obtaining written permission from the Director.
- 1920.3 In addition to any other responsibilities set forth under this Title, the pharmacist-in-charge or proprietor of a pharmacy shall have the following responsibilities:
- (a) Ensuring that quality assurance programs are in place for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. Quality assurance programs shall be designed to prevent and detect drug diversion;
  - (b) Developing or adopting, implementing, and maintaining a training manual and program for the training of all individuals employed in the pharmacy who are legally authorized to assist in the practice of pharmacy. The pharmacist-in-charge shall be responsible for supervising the training program;
  - (c) Developing or ensuring the establishment of policies and procedures for the procurement, storage, security, and disposition of drugs and devices;

- (d) Developing or ensuring the establishment of policies and procedures for the provision of pharmacy services;
- (e) Ensuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;
- (f) Implementing an ongoing quality assurance program that monitors performance of the automated pharmacy system, which is evidenced by written policies and procedures;
- (g) Ensuring that all pharmacists employed at the pharmacy are currently licensed in the District of Columbia, or if it is a non-resident pharmacy, in the state in which the pharmacy is located;
- (h) Ensuring that all pharmacy interns employed at the pharmacy are currently registered in the District of Columbia;
- (i) Ensuring the making or filing any reports required by federal or District of Columbia laws or regulations, which shall include but not be limited to, notifying the Director of the occurrence of any of the following:
  - (1) Permanent closing;
  - (2) Change of proprietorship, management, location, or pharmacist-in-charge;
  - (3) Any theft or loss of prescription drugs or medical devices;
  - (4) Conviction of any employee of any federal, state, or District of Columbia drug laws;
  - (5) Disasters, accidents, or any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;
  - (6) Occurrences of significant adverse drug reactions;
  - (7) Illegal use or disclosure of protected patient health information;
- (j) Developing or ensuring the establishment of policies and procedures for preventing the illegal use or disclosure of protected health information, or verifying the existences thereof and ensuring that all employees of the pharmacy read, sign, and comply with the established polices and procedures; and

- (k) Developing or ensuring the establishment of a procedure for proper management of drug recalls which may include, where appropriate, contacting patients to whom the recalled drug product(s) have been dispensed.

1920.4 The pharmacist-in-charge may be assisted by a sufficient number of pharmacists, pharmacy interns, and pharmacy technicians as may be required to competently and safely provide pharmacy services.

1920.5 The pharmacist-in-charge or proprietor of a pharmacy shall assure the development and implementation of written policies and procedures to specify the duties to be performed by pharmacy interns and pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum:

- (a) Specify that pharmacy interns and pharmacy technicians are to be personally and directly supervised by a pharmacist stationed within the same work area who has the ability to control and who is responsible for the activities of the pharmacy interns and pharmacy technicians; and
- (b) Specify that pharmacy interns and pharmacy technicians shall not be assigned duties that may be performed only by a pharmacist, which shall include but not be limited to:
  - (1) Drug utilization review;
  - (2) Clinical conflict resolution;
  - (3) Prescriber contact concerning prescription drug order clarification;
  - (4) Patient counseling on prescription, over-the-counter, and herbal products;
  - (5) Dispensing process validation;
  - (6) Receiving new oral prescription drug orders, or refill authorizations;
  - (7) Prescription transfers; and
  - (8) Independent compounding.

## **1921 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.

- 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 recordkeeping requirements of this section may be met by maintaining the most recent two years of records on site and the remaining three years of records off site as long as the records can be retrieved within three (3) business days of a request.
- 1921.4 The Director of Pharmacy shall be responsible for, at a minimum, the following:
- (a) Developing or ensuring that the institutional pharmacy meets all requirements set forth under applicable federal and District of Columbia laws and regulations;
  - (b) Developing or adopting, and maintaining, and making available written policies and procedures that delineate the operation and activities of the provision of pharmacy services for the institution that ensure compliance with all applicable federal and District of Columbia laws and regulations;
  - (c) Ensuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and in patient care areas, as well as current antidote information, telephone numbers of regional poison control centers, and other emergency assistance organizations, and other materials and information as may be deemed necessary by the appropriate committee of the institutional facility, if any;
  - (d) Ensuring the provision of the appropriate level of pharmaceutical care services to patients of the institutional facility;
  - (e) Ensuring that drugs and devices are prepared for distribution safely, and accurately as prescribed;
  - (f) Ensuring a sufficient supply of drugs and devices to meet the needs of the patients of the institutional facility, and other appropriate equipment for the preparation thereof;
  - (g) Developing or ensuring the establishment of a system for the compounding, sterility assurance, quality assurance, and quality control of sterile pharmaceuticals compounded within the institutional pharmacy;

- (h) Developing or ensuring the establishment of a system to assure that all pharmacy personnel responsible for compounding or for supervising the compounding of sterile pharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;
- (i) Ensuring the provision of written guidelines and approval of the procedures to assure that all pharmaceutical requirements are met when any part of preparing, sterilizing, and labeling of sterile pharmaceuticals is not performed under direct pharmacy supervision;
- (j) Developing or ensuring the establishment of a system for bulk compounding or batch preparation of drugs;
- (k) Ensuring that the pharmacy maintains records of all transactions of the institutional pharmacy as may be required by applicable federal or District of Columbia law or regulations, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;
- (l) Ensuring that the records in a data processing system are maintained in compliance with federal and District of Columbia laws and regulations;
- (m) Ensuring the automated medication dispensing system is operated and maintained in compliance with federal and District of Columbia laws and regulations;
- (n) Maintaining and making available metric-apothecaries weight and measure conversion tables and charts to applicable personnel;
- (o) Maintaining and making available current reference materials on toxicology, pharmacology, bacteriology, sterilization, and disinfection;
- (p) Preparation and sterilization of parenteral medications compounded within the institutional facility;
- (q) Ensuring the 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;
- (r) Developing or ensuring the establishment and implementation of policies and procedures to ensure 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 designees, make proper disposition of such drugs at the storage site;

- (s) Developing or ensuring the establishment of and implementation of 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;
- (t) Ensuring documentation of suspected and reported adverse drug reactions to the prescriber;
- (u) Ensuring the making and maintaining of reports of suspected reactions to the FDA, to the manufacturer, and to the United States Pharmacopoeia, and reporting of drug product defects accordingly; and
- (v) Developing or ensuring the establishment of 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.

1921.5 The Director of Pharmacy shall maintain the following records for a period of five (5) years:

- (a) Physician's orders;
- (b) Proofs of use of Schedule II controlled substances and any other drugs requested or required;
- (c) Reports of suspected adverse drug reactions;
- (d) Drug distribution records from night cabinets, automated medication dispensing systems, emergency kits, and similar systems;
- (e) Inventories of the pharmacy;
- (f) Inventories of controlled substances;
- (g) Alcohol and flammable reports; and
- (h) Any other records and reports as may be required by federal or District of Columbia law and regulations.

1921.6 In the event of an adverse drug reaction, an entry reflecting the reaction shall be made on the patient's pharmacy record.

1921.7 The Director of Pharmacy, at least once a month, shall inspect the pharmacy and all areas of the institution where drugs 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 all prescription 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 medication kits are adequate and in proper supply both within the pharmacy and at outside storage locations; and
- (g) Security and storage standards are met.

- 1921.8 The Director of Pharmacy shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the institutional pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.
- 1921.9 Trained technical and administrative personnel may be employed in a support capacity in institutional pharmacies, provided that the support activities are performed under the supervision of a pharmacist.
- 1921.10 Areas occupied by an institutional pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.
- 1921.11 An institutional pharmacy, or any part thereof, shall be locked in the absences of personal and direct supervision by authorized personnel.
- 1921.12 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.
- 1921.13 Authorized persons may have access to designated areas in the institutional pharmacy, and may remove drugs in compliance with the institution's established policies and procedures.
- 1921.14 Personnel authorized to have access to designated areas in the institutional pharmacy, shall receive thorough education and training in the proper methods of access, removal of drugs, and records and procedures required, prior to being permitted access to those areas of the pharmacy.

- 1921.15 The Director of Pharmacy or his or her designee shall administer the education and training required by § 1921.14 of this chapter.
- 1921.16 Removal of any drug from the pharmacy by an authorized person shall be recorded on a suitable form showing the patient's name, identification number, room number, name of the drug, strength, amount, date, time and the signature of the authorized person. The form shall be left with the container from which the drug was removed.
- 1921.17 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, automated medication dispensing systems, telepharmacy systems, 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. A pharmacist shall be "on call" during all absences.
- 1921.18 If night cabinets are used, the following procedures shall be used:
- (a) In the absence of a licensed pharmacist, drugs shall be stored in a locked cabinet or other enclosure constructed and located outside of the pharmacy area, to which only specifically authorized personnel may obtain access by key or combination, and which is 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 and shall ensure that:
    - (1) All drugs available in the cabinet or similar container are properly stored and labeled; and
    - (2) Only prepackaged drugs are available, in amounts sufficient for immediate therapeutic requirements;
    - (3) Whenever access to the cabinet occurs, written practitioners' orders and proofs-of-use are provided to the pharmacist by the start of the business the following business day;
    - (4) All drugs therein are inventoried no less than once per week;
    - (5) A complete audit of all activity concerning the cabinet is conducted no less than once per month; and

- (6) Written policies and procedures are established to implement the requirements of this subsection.

1921.19 Whenever any drug is not available from floor supplies, night cabinets, automated medication dispensing systems, telepharmacy systems, or by similar means, and the drug is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, the drug may 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 obtaining drugs from the pharmacy. The responsible nurse shall be designated in writing by the appropriate committee of the institutional facility. The responsible nurse may, in times of emergency, delegate this duty to another licensed registered nurse;
- (b) The responsible nurse 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; and
- (c) The Director of Pharmacy or his or her designee shall administer the education and training required in subsection (b) of this section.

1921.20 Removal of any drug from the pharmacy by an authorized nurse shall be recorded on a suitable form showing the patient's name, room number, name of the drug, strength, amount, date, time and the signature of the nurse. The form shall be left with the container from which the drug was removed.

1921.21 Investigational drugs shall be stored in and dispensed from the pharmacy only by a pharmacist. All information with respect to investigational drugs shall be maintained in the pharmacy.

1921.22 For an institutional facility that does not have an institutional pharmacy, drugs may be provided for use by authorized personnel by emergency kits located at the facility, provided the following requirements are met:

- (a) The pharmacist-in-charge at the provider pharmacy shall determine, in consultation with the medical and nursing staff of the facility, which drugs and what quantity of those drugs should be included in the emergency kit and prepare the kit for use only by those persons licensed or authorized to administer drugs;
- (b) The emergency kit shall contain the drugs 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 of harm to patients by delay resulting from obtaining such drugs from such other sources;

- (c) The emergency kit shall be sealed with a tamper evident seal, and stored in a secured area to prevent unauthorized access by force or otherwise, and to ensure a proper environment for preservation of the drugs inside the kit;
- (d) The exterior of the emergency kit shall be labeled so as to clearly indicate that it is an emergency drug kit and that it is for use in emergencies only. The label shall contain a listing of the drugs contained in the kit, including the name, strength, quantity, and expiration date of the contents, and the name, address, and telephone number of the pharmacy who prepared the kit;
- (e) All drugs contained in an emergency kit shall be labeled with the necessary information required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients;
- (f) Drugs shall be removed from emergency kits only pursuant to a valid written or verbal order by an authorized prescriber;
- (g) Whenever an emergency kit is opened, the provider pharmacist shall be notified and the pharmacist shall restock and reseal the kit as soon as possible, but not more than seventy-two (72) hours after notification. In the event the kit is opened in an unauthorized manner, the pharmacist and other appropriate personnel of the facility shall be notified;
- (h) The expiration date of an emergency kit shall be the earliest date of expiration of any drug supplied in the kit. Upon the occurrence of the expiration date, the provider pharmacist shall replace the expired drug; and
- (i) The provider pharmacist shall, in conjunction with the medical staff of the institutional facility, develop and implement written policies and procedures to ensure compliance with the provisions of this subsection, and other applicable federal and District of Columbia laws and regulations.

1921.23 Drugs shall be dispensed from the institutional pharmacy only pursuant to the valid prescription order of an authorized practitioner.

1921.24 The Director of Pharmacy shall maintain a listing, including signatures, of those practitioners who are authorized to issue orders to the institutional pharmacy.

1921.25 Drugs brought into an institutional facility by a patient shall not be administered unless they can be identified by the pharmacist and the quantity and quality of the drug assured.

- 1921.26 The Director of Pharmacy shall develop or ensure the establishment and implementation of policies and procedures to ensure that if drugs brought into an institutional facility by a patient are not to be administered, that they are properly returned to an adult member of the patient's immediate family.
- 1921.27 Prescription drug orders for use by inpatients of the facility shall contain the following information:
- (a) Patient name, identification number, and room number;
  - (b) Drug name;
  - (c) Drug strength;
  - (d) Directions for use and route of administration;
  - (e) Date and physician's signature, or signature of his or her authorized representative; and
  - (f) The words "Patient May Use Own Medications" when the prescription drug order is being written for drugs brought into the institution by the patient pursuant to § 1921.25.
- 1921.28 Prescription drug orders for use by outpatients shall, in addition to the information items required by § 1921.27, contain the patient's address, the facility's address, and DEA registration number, if applicable.
- 1921.29 Drugs dispensed for use by inpatients of an institutional facility, whereby the drug is not in the possession of the ultimate user prior to administration, shall be dispensed in appropriate containers and adequately labeled to meet the following requirements:
- (a) The label of a single-unit package of an individual-dose or unit-dose system of packaging of drugs shall include:
    - (1) The generic, chemical, or brand name of the drug;
    - (2) The route of administration, if other than oral;
    - (3) The strength and volume, where appropriate,
    - (4) The control number or lot number, and expiration date;
    - (5) Identification of the repackager by name or by license number and shall be clearly distinguishable from the rest of the label; and

- (6) Special storage conditions, if required.
- (b) When a multiple-dose drug distribution system (i.e. blister cards) is utilized, including dispensing of single unit packages, the drugs shall be dispensed in a container to which is affixed a label containing the following information:
  - (1) Identification of the dispensing pharmacy;
  - (2) The patient's name;
  - (3) The date of dispensing;
  - (4) The generic, chemical, or brand name of the drug dispensed; and
  - (5) The drug strength.

1921.30 All drugs dispensed to inpatients for self administration, and all drugs dispensed to ambulatory or outpatients, shall contain a label affixed to the container indicating:

- (a) The name and address of the pharmacy dispensing the drug;
- (b) The name of the patient for whom the drug is prescribed; or, if the patient is an animal, the name of the owner, name of the animal, and the species of the animal;
- (c) The name of the prescribing practitioner;
- (d) Such directions as may be stated on the prescription drug order;
- (e) The date of dispensing;
- (f) Any cautions which may be required by federal or District of Columbia law,
- (g) The serial number or prescription number of the prescription drug order;
- (h) The name or initials of the dispensing pharmacist;
- (i) The generic, chemical, or brand name of the drug dispensed;
- (j) The strength, dosage, and quantity of the drug dispensed;
- (k) The name of the manufacturer or distributor of the drug; and

(l) The expiration date.

1921.31 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 (5) 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.

1921.32 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 plenums 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 five (5) years.

- 1921.33 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".
- 1921.34 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.
- 1921.35 Gowns and gloves shall be worn when preparing cytotoxic agents.
- 1921.36 The Director of pharmacy 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.
- 1921.37 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.

1921.38 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.

1921.39 The quality assurance program required by section 1921.37 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.

1921.40 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.

1921.41 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.

## **1922 NUCLEAR PHARMACIES**

1922.1 A pharmacy, institution, or other establishment that provides radiopharmaceutical services shall obtain from the Director a nuclear pharmacy license. The license to

operate a nuclear pharmacy shall be conditioned upon approval of the United States Nuclear Regulatory Commission (NRC) where applicable.

1922.2 A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a qualified nuclear pharmacist as defined in § 1922.3.

1922.3 A qualified nuclear pharmacist shall:

- (a) Be a currently licensed pharmacist in the District of Columbia;
- (b) Have met the Nuclear Regulatory Commission standards of training for medically used or radioactive by-product material; and
- (c) Be currently certified as a nuclear pharmacist by a certification board recognized by the Board; or in lieu of certification:
  - (1) Submit proof acceptable to the Board that the individual has completed a minimum of two hundred (200) contact hours of didactic instruction in nuclear pharmacy and the safe handling and the use of radioactive material from a program recognized by the Board; and
  - (2) Submit proof acceptable to the Board that the individual has completed a minimum of five hundred (500) hours of supervised clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing nuclear pharmacy services or in a structured clinical nuclear pharmacy training program in an approved school of pharmacy.

1922.4 A qualified nuclear pharmacist shall be responsible for all operations of the nuclear pharmacy and shall be in personal attendance at all times that the nuclear pharmacy is open for business.

1922.5 A nuclear pharmacy shall be managed by a nuclear pharmacist (hereafter referred to “Responsible Nuclear Pharmacist”) who is licensed to practice pharmacy in the District of Columbia. A nuclear pharmacist shall not be the Responsible Nuclear Pharmacist for more than one nuclear pharmacy at a time.

1922.6 The Responsible Nuclear Pharmacist shall be assisted by a sufficient number of additional authorized nuclear pharmacists as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.

1922.7 All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a qualified nuclear pharmacist.

1922.8 The Responsible Nuclear Pharmacist shall designate in advance, one or more

other licensed pharmacists to have access to the licensed area in emergency situations when a qualified nuclear pharmacist is not present. These pharmacists may obtain single doses of radiopharmaceuticals for the immediate emergency and shall document such withdrawals in the control system.

1922.9 The Responsible Nuclear Pharmacist shall be responsible for, at a minimum, the following:

- (a) Ensuring that radiopharmaceuticals are dispensed and delivered safely and accurately as prescribed;
- (b) Developing a system to ensure that all personnel responsible for compounding or supervising the compounding of radiopharmaceuticals within the pharmacy receive appropriate education and training and competency evaluation;
- (c) Establishing policies for procurement of drugs and devices and storage of all pharmaceutical materials including radiopharmaceuticals, components, used in the compounding of radiopharmaceuticals, and drug delivery practices;
- (d) Developing a system for the disposal and distribution of drugs from the pharmacy;
- (e) Developing a system for the compounding, sterility assurance, and quality control of sterile radiopharmaceuticals;
- (f) Maintaining records of all transactions of the pharmacy necessary to maintain accurate control over and accountability for all pharmaceutical materials including radiopharmaceuticals, required by applicable federal and District of Columbia laws and regulations;
- (g) Developing a system to ensure maintenance of effective controls against the theft or diversion of prescription drugs, and prescription records;
- (h) Ensuring that the pharmacy has a system to dispose of radioactive and cytotoxic waste in a manner so as not to endanger the public health; and
- (i) Developing and implementing written policies and procedures to ensure compliance with the applicable provisions federal and District of Columbia laws and regulations.

1922.10 Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the District or as otherwise defined by the Director.

- 1922.11 The Nuclear Pharmacy area shall be secured from unauthorized personnel.
- 1922.12 In a nuclear pharmacy providing ordinary pharmacy services in addition to radiopharmaceutical services, the nuclear pharmacy area shall be separate from the pharmacy areas for non-radioactive drugs and shall be secured from unauthorized personnel.
- 1922.13 All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area, occupying at least twenty-five (25) square feet of space, separate from and exclusive of the hot laboratory, compounding, dispensing, quality assurance and office areas.
- 1922.14 Nuclear pharmacies shall maintain records of acquisition, inventory, and disposition of all radioactive drugs and other radioactive materials in accordance with all applicable federal and District of Columbia laws and regulations.
- 1922.15 A nuclear pharmacy shall have the equipment and reference material required under § 1909 of this Title as well as all other applicable federal and District of Columbia laws and regulations.
- 1922.16 Radiopharmaceuticals shall be dispensed only upon a prescription drug order from a practitioner authorized to possess, use, and administer radiopharmaceuticals.
- 1922.17 A nuclear pharmacy shall dispense only radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical quality assurance.
- 1922.18 The immediate outside container (shield) of a radioactive drug to be dispensed shall bear the following information:
- (a) The name and address of the nuclear pharmacy;
  - (b) The name of the prescriber (authorized user);
  - (c) The date of dispensing;
  - (d) The serial number, lot number, or prescription number assigned to the radiopharmaceutical order;
  - (e) The standard radiation symbol;
  - (f) The name of the diagnostic procedure;
  - (g) The words "Caution: Radioactive Material";
  - (h) The name of the radionuclide and chemical form;

- (i) The amount of radioactivity and the calibration date and time;
- (j) The expiration date and time;
- (k) In the case of a diagnostic radiopharmaceutical, the patient's name or the words "Per Physician's Order";
- (l) In the case of a therapeutic radiopharmaceutical, the patient's name;
- (m) The activity and date and time of assay;
- (n) The volume, if in liquid form; and
- (o) The requested activity and the calibrated activity.

1922.19 The immediate inner container shall be labeled with:

- (a) The standard radiation symbol;
- (b) The words "Caution-Radioactive Material"; and
- (c) The serial number or prescription number assigned to the order.

1922.20 Orders for radiopharmaceuticals, whether written or verbal, shall include at least the following information:

- (a) The name of the institution or facility and the name of the person transmitting the order;
- (b) The date that the radiopharmaceutical will be needed and the calibration time;
- (c) The name or generally recognized and accepted abbreviation of the radiopharmaceutical;
- (d) The dose or activity of the radiopharmaceutical at the time of calibration; and
- (e) In the case of a therapeutic radiopharmaceutical or a radiopharmaceutical blood product, the name of the patient shall be obtained prior to dispensing.

1922.21 The amount of radioactivity shall be determined by radiometric methods for each individual dose immediately prior to dispensing.

1922.22 A nuclear pharmacy shall comply with 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.

**1923 PHARMACY FEES**

1923.1 The fees related to pharmacies are as follows:

(a) Biennial License Fee	\$500.00
(b) Late Fee	\$125.00
(c) Non-Resident Pharmacy Registration Fee	\$400.00
(d) Duplicate certificate	\$35.00
(e) License validation	\$35.00

**1924 RESERVED**

**1925 INSPECTION AND INVESTIGATION**

1925.1 The Director, or his agent, shall have the right to enter upon and into the premises of any licensee, registrant, applicant for a license or registration, pharmacy or other location where prescription drugs or devices are stored, or reasonably believed to be stored:

- (a) At reasonable times,
- (b) After presenting proper identification; and
- (c) For the purpose of making compliance inspections or conducting complaint investigations concerning the laws and regulations applicable to the practice of pharmacy, operation of pharmacies, and handling of controlled and prescription drugs.

1925.2 An inspection or investigation conducted under this Title 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.

1925.3 The Director shall delegate pharmacists licensed in good standing under the Act to conduct inspections of pharmacy operations covered by these rules, which shall be conducted for a new license, at least annually thereafter, and as often as the Director deems necessary.

1925.4 The Director shall delegate staff to investigate complaints of violations of the Act, this chapter, and all other applicable laws and regulations regarding the practice of pharmacy and the operation of a pharmacy.

1925.5 The Director shall delegate pharmacists licensed in good standing under the Act to conduct compliance inspections, audits, and other inspections required under the Act to ensure accountability for all controlled substances and to ensure compliance with laws regulating the practice of pharmacy and the distribution of prescription drugs and devices in the District and all other applicable laws and regulations regarding the practice of pharmacy and the operation of a pharmacy.

## **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 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.<sup>1</sup>

1927.2                Except for a summary suspension undertaken pursuant to section 11(b) of the Act, D.C. Code § 2-2010(b),<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:

- (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.<sup>3</sup>

**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;
- (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.

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<sup>1</sup> Section 2-2010 of the D.C. Code is now cited as D.C. Official Code § 47-2885.10 (2001).

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

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

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 known 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),<sup>4</sup> 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 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

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<sup>4</sup> Section 2-2010 of the D.C. Code is now cited as D.C. Official Code § 47-2885.10 (2001).

(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);<sup>5</sup>

(b) Subpoena respondents, witnesses, books, papers, and documents pursuant to section 3 of D.C. Law 3-109, D.C. Code § 1-338 (1987);<sup>6</sup>

(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 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:

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<sup>5</sup> D.C. Code § 1-338.1 is now cited as D.C. Official Code § 1-301.21 (2001).

<sup>6</sup> D.C. Code § 1-338.1 is now cited as D.C. Official Code § 1-301.21 (2001).

- (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 secs. 2-2001 through 2-2023, as amended.

**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.

**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.

**Automated medication dispensing system**- a robotic, computerized, or mechanical device and its components that distributes or dispenses medications in a licensed health care facility, or prepares medications for final dispensing by a licensed pharmacist to a patient or a patient's agent, and maintains related transaction information.

**Board**—The District of Columbia Board of Pharmacy established by the District of Columbia Health Occupations Revision of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*)

**Centralized automated medication system**- an automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient.

**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.

**Compounding**—the preparation, mixing, assembling, packaging, or labeling 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** - 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, approved October 27, 1970 (Pub.L. 91-513, 21 USC § 801 *et seq.*) as amended; and 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 *et seq.*) as amended.

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

**Decentralized automated medication system**- an automated medication system that is located outside of the pharmacy in a health care facility with an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

**Department**—The District of Columbia Department of Health.

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

**Director of Pharmacy**—the licensed pharmacist in an institutional facility who is in direct charge of, and has overall responsibility for the operation and management of pharmacy services of that institution.

**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.

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

**Drug**—means:

- (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 does not include medical devices or their components, parts, or accessories.

**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.

**Final Verification-** The review of the final prescription prior to delivery to a patient to ensure that the ordered medication or medical device is properly prepared and placed in a suitable container with appropriate labeling.

**Hardware** - the fixed component parts of a computer.

**HIPAA**—The Federal Health Insurance Portability and Accountability Act of 1996, approved August 21, 1996 (42 U.S.C. §§ 1320d-1320d-8).

**Homeopathic Drug-** A substance that has known "homeopathic provings" and/or known effects which mimic the symptoms, syndromes or conditions which it is administered to treat, and is manufactured according to the specifications of the Homeopathic Pharmacopoeia of the United States (HPUS). Official homeopathic drugs are those that have been monographed and accepted for inclusion in the HPUS.

**HORA-** Health Occupation Revision Act of 1985 ("Act"), effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code §§ 3-1201.01 et seq.).

**Inspection-** a periodic on site review of places at which prescription drugs or devices may be produced, sold, or stored to determine compliance with applicable federal and District laws and regulations, including pre-licensure inspections performed to ensure a facility complies with applicable District law and regulations prior to receiving a license to operate in the District.

**Investigation-** the process of gathering and recording essential facts and observations with respect to the events and circumstances related to complaints, reported information, including interviews, reviewing records, and physical inspections to determine whether there is a violation of any applicable laws or regulations.

**Institutional Facility-** means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, including a(n):

- (1) Hospital;
- (2) Convalescent home;
- (3) Nursing home;
- (4) Extended care facility;
- (5) Mental health facility;
- (6) Rehabilitation center;
- (7) Psychiatric center;
- (8) Developmental disability center;
- (9) Drug abuse treatment center;
- (10) Family planning clinic;
- (11) Penal institution;
- (12) Hospice;

- (13) Public health facility;
- (14) Athletic facility.

**Institutional pharmacy**- means that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, distributed and pharmaceutical care is provided.

**Labeler**—an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 CFR § 207.20.

**Labeling**—the process of affixing a label to any drug container, but does not include the labeling by a manufacturer, packer, or distributor of an over-the-counter drug, packaged legend drug, or medical device.

**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 a human 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 a human 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

**Nonresident pharmacy**- A pharmacy, including an internet-based pharmacy, located outside the District of Columbia which ships, mails, or delivers, in any manner, prescription drugs or prescription medical devices into the District of Columbia, whether directly or through an intermediary, pursuant to a valid prescription.

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

**Over-the-counter drug (Proprietary)**—drugs which may be sold without a prescription and which are prepackaged 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.

**Person**—any individual, partnership, association, corporation, company, joint stock association, or any organized group of persons whether incorporated or not, or any trustee, receiver, or assignee thereof.

**Pharmaceutical Care**—the provision of drug therapy and other patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing of a disease process.

**Pharmacist**—a person who is licensed to engage in the practice of pharmacy in the jurisdiction in which he or she is practicing.

**Pharmacist-in-charge**—a licensed pharmacist who accepts responsibility for the operation of a pharmacy and who is personally in full and actual charge of the pharmacy and pharmacy personnel.

**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.

**Pharmacy intern**—any person who is registered in the District of Columbia to engage in the practice of pharmacy under the direct supervision of a pharmacist.

**Pharmacy technician**—an individual employed by a pharmacy who possesses appropriate education, training, and experience to assist in the practice of pharmacy, under the direct supervision of a pharmacist, by assisting in the technical services of preparing pharmaceuticals for final dispensing by a pharmacist.

**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**- a practitioner who is authorized by law to issue a prescription.

**Prescription (Legend)**—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**—means any of the following:

- (a) A drug which under federal law is required 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 order of, a licensed veterinarian. 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
- (b) A drug which is restricted to use by health professionals and allied practitioners for research.
- (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.

**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/retail pharmacy or the institutional pharmacy providing remote pharmacy services.

**Qualified nuclear pharmacist**—a licensed pharmacist, who is certified as a nuclear pharmacy by a certification board recognized by the Board and 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 or any applicable federal or District of Columbia laws or regulations.

**Radiopharmaceuticals**—radioactive drugs and chemicals within the classification of legend drugs as defined under the Federal Food, Drug, and Cosmetic Act , approved June 25, 1938 (21 USC §§ 301 et seq.).

**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.

**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.

**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.

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

**Still image capture**- A specific image captured electronically from a video or other image capture device.

**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.

**Store and forward**—A video or still image record which is saved electronically for future review.

**Systems backup** - (auxiliary records maintenance) hard copy, disk, tape, or equivalent used if the computer system becomes inoperative.

**Telepharmacy**—The practice of pharmacy through the use of a telepharmacy system.

**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.

**TITLE 29. PUBLIC WELFARE**  
**CHAPTER 9. MEDICAID PROGRAM**

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**§ 29-914. D.C. MEDICAID PRIOR APPROVAL REQUIRED FOR SELECTED PHARMACEUTICALS PROVIDED TO D.C. MEDICAID AMBULATORY CARE PATIENTS**

914.1 Prior authorization from the D.C. Medicaid program shall be required for the dispensing of the following prescribed drugs to D.C. Medicaid ambulatory care patients:

(a) Oxycodone HCl and Aspirin (more commonly known as Percodan);

(b) Flurazepam (more commonly known as Dalmane); and

(c) Oxycodone and Acetaminophen (more commonly known as Percocet and Tylox).

914.2 Pharmacists shall request authorization from the Department of Human Services Office of Health Care Financing prior to dispensing to D.C. Medicaid patients any of the prescribed drugs identified in subsection 914.1 of this rule.

914.3 For purposes of this section, the phrase "Ambulatory Care Patients" means a patient served through a system of primary care provided through outpatient facilities including services provided to patients who reside in intermediate care facilities for the mentally retarded. Ambulatory care does not include services provided in inpatient hospitals, skilled nursing facilities, intermediate care facilities or health maintenance organizations.

# **SECTION II.**



## **LICENSURE AND PRACTICE OF PHARMACISTS**

**TITLE 3. DISTRICT OF COLUMBIA BOARDS AND COMMISSIONS**  
**SUBTITLE I. GENERAL**  
**CHAPTER 12. HEALTH OCCUPATIONS BOARDS**  
**UNIT A. GENERAL**

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- § 3-1201.01. General definitions
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- § 3-1201.04. Persons licensed under prior law

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- § 3-1202.08. Board of Pharmacy

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- § 3-1205.15. Summary action
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- § 3-1213.01. Appropriations

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**SUBCHAPTER I. DEFINITIONS AND SCOPE**

**§ 3-1201.01. General definitions**

For the purposes of this chapter, the term:

- (1) "Board" means the Board of Chiropractic, the Board of Dentistry, the Board of

Dietetics and Nutrition, the Board of Marriage and Family Therapy, the Board of Medicine, the Board of Nursing, the Board of Nursing Home Administration, the Board of Occupational Therapy, the Board of Optometry, the Board of Pharmacy, the Board of Physical Therapy, the Board of Podiatry, the Board of Professional Counseling, the Board of Psychology, the Board of Respiratory Care, or the Board of Social Work, established by this chapter, as the context requires.

(2) "Collaboration" means the process in which health professionals jointly contribute to the health care of patients with each collaborator performing actions he or she is licensed or otherwise authorized to perform pursuant to this chapter.

(A)-(C) Repealed.

(3) "Attorney General" means the Attorney General of the District of Columbia.

(4) "Council" means the Council of the District of Columbia.

(5) "Day" means calendar day unless otherwise specified in this chapter.

(6) "District" means the District of Columbia.

(7) "Health occupation" means a practice that is regulated under the authority of this chapter.

(8) "Health professional" means a person licensed under this chapter or permitted by this chapter to practice a health occupation in the District.

(9) "Impaired health professional" means a health professional who is unable to perform his or her professional responsibilities reliably due to a mental or physical disorder, excessive use of alcohol, or habitual use of any narcotic or controlled substance or any other drug in excess of therapeutic amounts or without valid medical indication.

(10) "Mayor" means the Mayor of the District of Columbia.

(11) "Person" means an individual, corporation, trustee, receiver, guardian, representative, firm, partnership, society, school, or other entity.

(12) [Repealed].

(13) "State" means any of the several states, the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States.

(14) "Superior Court" means the Superior Court of the District of Columbia.

**§ 3-1201.02. Definitions of Health Occupations**

For the purposes of this chapter, the term:

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

(B) Within the meaning of this paragraph, the term:

- (i) "Pharmacy" means 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.
- (ii) "Prescription" means 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.

**§ 3-1201.03. Scope of Chapter**

(a) This chapter does not limit the right of an individual to practice a health occupation that he or she is otherwise authorized to practice under this chapter, nor does it limit the right of an individual to practice any other profession that he or she is authorized to practice under the laws of the District.

(b) The practices of health occupations regulated by this chapter are not intended to be mutually exclusive.

(c) This chapter shall not be construed to prohibit the practice of a health occupation by an individual enrolled in a recognized school or college as a candidate for a degree or certificate in a health occupation, or enrolled in a recognized postgraduate training program provided that the practice is:

- (1) Performed as a part of the individual's course of instruction;
- (2) Under the supervision of a health professional who is either licensed to practice in the District or qualified as a teacher of the practice of the health occupation by the board

charged with the regulation of the health occupation;

(3) Performed at a hospital, nursing home, or health facility operated by the District or federal government, a health education center, or other health-care facility considered appropriate by the school or college; and

(4) Performed in accordance with procedures established by the board charged with the regulation of the health occupation.

(d) Nothing in this chapter shall be construed to require licensure for or to otherwise regulate, restrict, or prohibit individuals from engaging in the practices, services, or activities set forth in the paragraphs of this subsection if the individuals do not hold themselves out, by title, description of services, or otherwise, to be practicing any of the health occupations regulated by this chapter. Nothing in this subsection shall be construed as exempting any of the following categories from other applicable laws and regulations of the District or federal government:

(1) Any minister, priest, rabbi, officer, or agent of any religious body or any practitioner of any religious belief engaging in prayer or any other religious practice or nursing practiced solely in accordance with the religious tenets of any church for the purpose of fostering the physical, mental, or spiritual well-being of any person;

(2) Any person engaged in the care of a friend or member of the family, including the domestic administration of family remedies, or the care of the sick by domestic servants, housekeepers, companions, or household aids of any type, whether employed regularly or because of an emergency or illness, or other volunteers;

(3) Any individual engaged in the lawful practice of audiology, speech pathology, X-ray technology, laboratory technology, or respiratory therapy;

(4) An orthotist or prosthetist engaged in fitting, making, or applying splints or other orthotic or prosthetic devices;

(5) Any individual engaged in the practice of cosmetology, the practice of nontherapeutic massage, or the operation of a health club;

(6) Any individual engaged in the commercial sale or fitting of shoes or foot appliances; or

(7) Marriage and family therapists, marriage counselors, art therapists, drama therapists, attorneys, or other professionals working within the standards and ethics of their respective professions.

(e) This chapter shall not be construed to prohibit the practice of a health occupation by an individual who has filed an initial application for licensure in the health occupation and is awaiting action on that initial application, provided the practice is performed:

(1) Under the supervision of a health professional licensed in the District;

- (2) At a hospital, nursing home, health facility operated by the District or federal government, or other health care facility considered appropriate by the Board; and
- (3) In accordance with any other requirements established by the Mayor.

#### **§ 3-1201.04. Persons licensed under prior law**

- (a) Except as expressly provided to the contrary in this chapter, any person licensed, registered, or certified by any agency of the District established or continued by any statute amended, repealed, or superseded by this act is considered for all purposes to be licensed, registered, or certified by the appropriate health occupations board established under this chapter for the duration of the term for which the license, registration, or certification was issued, and may renew that authorization in accordance with the appropriate renewal provisions of this chapter.
- (b) Except as provided to the contrary in this chapter, an individual who was originally licensed, registered, or certified under a provision of law that has been deleted by this act continues to meet the education and experience requirements as if that provision had not been deleted.
- (c) Each employee of the Commission on Mental Health Services who was employed at St. Elizabeths Hospital prior to October 1, 1987, and who accepted employment with the District government on October 1, 1987, without a break in service, shall, within 27 months of appointment by the District government, meet all licensure requirements. If the employee does not meet all licensure requirements, the employee shall be issued a limited license subject to the provisions, limitations, conditions, or restrictions that shall be determined by the appropriate board or commission. The limited license shall not exceed the term of employment with the Commission on Mental Health Services.

### **SUBCHAPTER II. ESTABLISHMENT OF HEALTH OCCUPATION BOARDS**

#### **§ 3-1202.08. Board of Pharmacy**

- (a) There is established a Board of Pharmacy to consist of 7 members appointed by the Mayor.
- (b) The Board shall regulate the practice of pharmacy.
- (c) Of the members of the Board, 5 shall be pharmacists licensed in the District and 2 shall be consumer members.
- (d) Except as provided in subsection (e) of this section, members of the Board shall be appointed for terms of 3 years.

(e) Of the members initially appointed under this section, 2 shall be appointed for a term of 1 year, 2 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years.

### **SUBCHAPTER III. ADMINISTRATION**

#### **§ 3-1203.01. Administration**

The boards established by this chapter shall be under the administrative control of the Mayor.

#### **§ 3-1203.02. Responsibilities of Mayor**

The Mayor shall be responsible for:

- (1) Planning, developing, and maintaining procedures to ensure that the boards receive administrative support, including staff and facilities, sufficient to enable them to perform their responsibilities;
- (2) Processing and providing licenses as required and approved by the boards;
- (3) Providing investigative and inspection services;
- (4) Holding hearings on cases pursuant to guidelines established in § 3-1205.19 when requested to do so by the board, and appointing hearing officers to enable the boards to hold hearings;
- (5) Furnishing expert services in noncompliance cases brought in an administrative or court proceeding;
- (6) Providing budgetary and personnel services;
- (7) Maintaining central files of records pertaining to licensure, inspections, investigations, and other matters requested by the boards;
- (8) Furnishing facilities and staff for hearings and other proceedings;
- (9) Providing information to the public concerning licensing requirements and procedures;
- (10) Publishing and distributing procedural manuals concerning licensing and inspections and other materials prepared by the boards;
- (11) Assisting, supplying, furnishing, and performing other administrative, clerical, and technical support the Mayor determines is necessary or appropriate;

(12) Issuing rules, as the Mayor may periodically determine to be necessary to protect the health and welfare of the citizens of the District, for the temporary licensure for a fixed period of time not to exceed 90 days and under conditions to be prescribed by the Mayor by rule, of applicants for licensure to practice a health occupation in the District, except the Mayor may provide for the issuance of temporary licenses to applicants for licensure to practice social work and marriage and family therapy for a period not to exceed 1 year, and to applicants for licensure to practice as anesthesiologist assistants for a period not to exceed 2 years;

(13) Making necessary rules relating to the administrative procedures of the boards; and

(14) Issuing all rules necessary to implement the provisions of this chapter.

#### **SUBCHAPTER IV. GENERAL PROVISIONS RELATING TO HEALTH OCCUPATION BOARDS**

##### **§ 3-1204.01. Qualifications of members**

(a) The members of each board shall be residents of the District at the time of their appointments and while they are members of the board.

(b) (1) Each professional member of a board, in addition to the requirements of subsection (a) of this section, shall have been engaged in the practice of the health occupation regulated by the board for at least 3 years preceding appointment.

(2) The dietitian and nutritionist members initially appointed to the Board of Dietetics and Nutrition, the nonphysician acupuncturist member initially appointed to the Advisory Committee on Acupuncture, the anesthesiologist assistant member initially appointed to the Advisory Committee on Anesthesiologist Assistants, the physician assistant member initially appointed to the Advisory Committee on Physician Assistants, the respiratory care members initially appointed to the Board of Respiratory Care, the social worker members initially appointed to the Board of Social Work, the professional counselor members initially appointed to the Board of Professional Counseling, the naturopathic physician member initially appointed to the Advisory Committee on Naturopathic Medicine, marriage and family therapist members initially appointed to the Board of Marriage and Family Therapy, and the massage therapy members initially appointed to the Board of Massage Therapy shall be eligible for and shall file a timely application for licensure in the District. The advanced registered nurse members initially appointed to the Board of Nursing shall be licensed in the District as registered nurses, shall meet the qualifications of this chapter to practice their respective specialties, shall have practiced their respective specialties for at least 3 years preceding appointment, and shall file a timely application for certification to practice their respective specialties shall file a timely application for certification to practice their respective specialties.

(c) Each consumer member of a board, in addition to the requirements of subsection (a) of this section, shall:

- (1) Be at least 18 years old;
  - (2) Not be a health professional or in training to become a health professional;
  - (3) Not have a household member who is a health professional or is in training to become a health professional; and
  - (4) Not own, operate, or be employed in or have a household member who owns, operates, or is employed in a business which has as its primary purpose the sale of goods or services to health professionals or health-care facilities.
- (d) Within the meaning of subsection (c) of this section, the term "household member" means a relative, by blood or marriage, or a ward of an individual who shares the individual's actual residence.
- (e) The office of a member of a board or advisory committee shall be forfeited upon the member's failure to maintain the qualifications required by this chapter.
- (f) Each professional member of a board or advisory committee shall disqualify himself or herself from acting on his or her own application for licensure or license renewal or on any other matter related to his or her practice of a health occupation.

#### **§ 3-1204.02. Terms of members; filling of vacancies**

- (a) The terms of members of a board or advisory committee, after the initial terms, shall expire on the 3rd anniversary of the date the 1st members constituting a quorum take the oath of office.
- (b) At the end of a term, a member shall continue to serve until a successor is appointed and sworn into office.
- (c) A vacancy on a board or advisory committee shall be filled in the same manner as the original appointment was made.
- (d) A member appointed to fill a vacancy shall serve only until the expiration of the term or until a successor is appointed and sworn into office.

#### **§ 3-1204.03. Limitation on consecutive terms**

No member of a board or advisory committee shall be appointed to serve more than 3 full consecutive 3-year terms.

#### **§ 3-1204.04. Removal**

(a) The Mayor may remove a member of a board or advisory committee for incompetence, misconduct, or neglect of duty, after due notice and a hearing.

(b) The failure of a member of a board or advisory committee to attend at least 1/2 of the regular, scheduled meetings of the board or advisory committee within a 12-month period shall constitute neglect of duty within the meaning of subsection (a) of this section.

#### **§ 3-1204.05. Officers; meetings; quorum**

(a) From among the members of each board and advisory committee, the Mayor shall designate a chairperson.

(b) Each board and advisory committee shall determine the times and places of its meetings and shall publish notice of regular meetings at least 1 week in advance in the District of Columbia Register.

(c) A majority of the members of each board and advisory committee shall constitute a quorum.

#### **§ 3-1204.06. Compensation**

Members of each board and advisory committee shall be entitled to receive compensation in accordance with § 1-611.08, and in addition shall be reimbursed for reasonable travel and other expenses incurred in the performance of their duties.

#### **§ 3-1204.07. Staff**

For each board, the Mayor may set the compensation of personnel he or she deems advisable, subject to available appropriations, in accordance with Chapter 6 of Title 1.

#### **§ 3-1204.08. General powers and duties**

Each board shall:

(1) Administer and enforce the provisions of this chapter, and rules and regulations issued pursuant to this chapter, related to the health occupation regulated by the board;

(2) Evaluate the qualifications and supervise the examinations of applicants for licenses, either personally or through the use of consultant services;

(3) Make recommendations to the Mayor, upon request by the Mayor or when the board determines it necessary, for standards and procedures to be used in determining the acceptability of foreign education and training programs as substantially equivalent to the

requirements of this chapter;

- (4) Issue licenses to qualified applicants;
- (5) Issue subpoenas, examine witnesses, and administer oaths;
- (6) Receive and review complaints of violations of this chapter or rules and regulations issued pursuant to this chapter;
- (7) Request the Mayor, on its own initiative or on the basis of a complaint, to conduct investigations of allegations of practices violating the provisions of this chapter with respect to the health occupation regulated by the board; and
- (8) Conduct hearings and keep records and minutes necessary to carry out its functions.
- (9) Issue advisory opinions regarding compliance with acceptable standards of practice.

#### **§ 3-1204.09. Fees**

The Mayor is authorized to establish a fee schedule for all services related to the regulation of all health occupations under this chapter, in accordance with the requirements of District law.

#### **§ 3-1204.10. Disposition of funds**

All fees, civil fines, and other funds collected pursuant to this chapter shall be deposited to the General Fund of the District.

#### **§ 3-1204.11. Annual report**

Each board shall, before January 1 of each year, submit a report to the Mayor and the Council of its official acts during the preceding fiscal year.

### **SUBCHAPTER V. LICENSING OF HEALTH PROFESSIONALS**

#### **§ 3-1205.01. License required**

A license issued pursuant to this chapter is required to practice medicine, acupuncture, chiropractic, registered nursing, practical nursing, dentistry, dental hygiene, dietetics, marriage and family therapy, massage therapy, naturopathic medicine, nutrition, nursing home administration, occupational therapy, optometry, pharmacy, physical therapy, podiatry, psychology, social work, professional counseling, and respiratory care or to practice as an

anesthesiologist assistant, physician assistant, or occupational therapy assistant in the District, except as provided in this chapter. A certification issued pursuant to this chapter is required to practice advanced practice registered nursing.

### **§ 3-1205.02. Exemptions**

The provisions of this chapter prohibiting the practice of a health occupation without a license shall not apply:

- (1) To an individual who administers treatment or provides advice in any case of emergency;
- (2) To an individual employed in the District by the federal government, while he or she is acting in the official discharge of the duties of employment;
- (3) To an individual, licensed to practice a health occupation in a state, who is called from the state in professional consultation by or on behalf of a specific patient to visit, examine, treat, or advise the specific patient in the District, or to give a demonstration or clinic in the District, provided that the individual engages in the consultation, demonstration, or clinic in affiliation with a comparable health professional licensed pursuant to this chapter;
- (4) To a health professional who is authorized to practice a health occupation in any state adjoining the District who treats patients in the District if:
  - (A) The health professional does not have an office or other regularly appointed place in the District to meet patients;
  - (B) The health professional registers with the appropriate board and pays the registration fee prescribed by the board prior to practicing in the District; and
  - (C) The state in which the individual is licensed allows individuals licensed by the District in that particular health profession to practice in that state under the conditions set forth in this subsection.
  - (D) Notwithstanding the provisions of subparagraphs (A), (B), and (C) of this paragraph, a health professional practicing in the District pursuant to this paragraph shall not see patients or clients in the office or other place of practice of a District licensee, or otherwise circumvent the provisions of this chapter.

### **§ 3-1205.03. General qualifications of applicants**

(a) An individual applying for a license under this chapter shall establish to the satisfaction of the board regulating the health occupation that the individual:

- (1) Has not been convicted of an offense which bears directly on the fitness of the individual to be licensed;
- (2) Is at least 18 years of age;
- (3) Has successfully completed the additional requirements set forth in § 3-1205.04 and subchapters VI, VII, VIII and VIII-A of this chapter, as applicable;
- (4) Has passed an examination, administered by the board or recognized by the Mayor pursuant to § 3-1205.06, to practice the health occupation; and
- (5) Meets any other requirements established by the Mayor by rule to assure that the applicant has had the proper training, experience, and qualifications to practice the health occupation.

(b) The board may grant a license to an applicant whose education and training in the health occupation has been successfully completed in a foreign school, college, university, or training program if the applicant otherwise qualifies for licensure and if the board determines, in accordance with rules issued by the Mayor, that the education and training are substantially equivalent to the requirements of this chapter in assuring that the applicant has the proper training, experience, and qualifications to practice the health occupation.

(c) The board may deny a license to an applicant whose license to practice a health occupation was revoked or suspended in another state if the basis of the license revocation or suspension would have caused a similar result in the District, or if the applicant is the subject of pending disciplinary action regarding his or her right to practice in another state.

(d) The references in § 3-1205.04 and subchapters VI, VII, VIII and VIII-A of this chapter to named professional organizations and governmental entities for purposes of accreditation or the administration of national examinations shall be considered to refer to successor organizations or entities upon a determination by the Mayor that the successor is substantially equivalent in standards and purposes as the organization or entity named in this chapter.

#### **§ 3-1205.04. Additional qualifications of applicants**

- (i) An individual applying for a license to practice pharmacy under this chapter shall establish to the satisfaction of the Board of Pharmacy that the individual:

- (1) Has earned a degree in pharmacy from a college or school of pharmacy accredited by the American Council of Pharmaceutical Education; and
- (2) Has worked as a pharmacy intern in a pharmacy for the period of time required by the Mayor or has gained other equivalent experience the Mayor may permit by rule.

### **§ 3-1205.05. Application for license**

(a) An applicant for a license shall:

- (1) Submit an application to the board regulating the health occupation on the form required by the board; and
- (2) Pay the applicable fees established by the Mayor.

(b) The social security number of each applicant for a license issued pursuant to this chapter shall be recorded on the application. If a number other than the social security number is used on the face of the license, the issuing agency or entity shall keep the applicant's social security number on file and the applicant shall be so advised.

### **§ 3-1205.06. Examinations**

(a) An applicant who otherwise qualifies for a license is entitled to be examined as provided by this chapter.

(b) (1) Each board that administers examinations shall give examinations to applicants at least twice a year at times and places to be determined by the Board.

(2) When the Mayor, pursuant to subsection (e)(2) of this section, determines that a national examination is acceptable, then the frequency, time, and place that the national examination is given shall be considered acceptable and in accordance with this chapter.

(c) Each board shall notify each qualified applicant of the time and place of examination.

(d) Except as otherwise provided by this chapter, each board shall determine the subjects, scope, form, and passing score for examinations to assess the ability of the applicant to practice effectively the health occupation regulated by the board.

(e) Each board, in its discretion, may waive the examination requirements:

- (1) For any applicant who meets the requirements of § 3-1205.07 for licensure by reciprocity or endorsement; or

(2) For any person who has been certified by a national examining board if the Mayor determines by rule that the examination was as effective for the testing of professional competence as that required in the District.

### **§ 3-1205.07. Reciprocity and endorsement**

Each board shall issue a license by reciprocity or endorsement to an applicant:

(1) Who is licensed or certified and in good standing under the laws of another state with requirements which, in the opinion of the Board, were substantially equivalent at the time of licensure to the requirements of this chapter, and which state admits health professionals licensed by the District in a like manner; or

(2) Who is certified or accredited by a recognized national accrediting association, acceptable to the Board, as a qualified professional according to standards that were the substantial equivalent at the time of the certification or accreditation to the standards for that profession as set forth in this chapter and who has continually remained in good standing with the certifying or accrediting association from the date of certification or accrediting until the date of licensing; and

(3) Who pays the applicable fees established by the Mayor.

### **§ 3-1205.08. Issuance of license**

Each board shall issue a license to an applicant who meets the requirements of this chapter and rules and regulations issued pursuant to this chapter to practice the health occupation regulated by the board.

### **§ 3-1205.09. Scope of license**

(a) (1) A person licensed under this chapter to practice a health occupation is authorized to practice that occupation in the District while the license is effective.

(2) A person certified to practice advanced registered nursing is authorized to practice the specialty for which he or she has been certified by the Board of Nursing.

(b) An individual who fails to renew a license to practice a health occupation shall be considered to be unlicensed and subject to the penalties set forth in this chapter and other applicable laws of the District, if he or she continues to practice the health occupation.

**§ 3-1205.10. Term and renewal of licenses**

(a) A license expires 1 year from the date of its first issuance or renewal unless renewed by the board that issued it as provided in this section, except that the Mayor, by rule, may provide for a period of licensure of not more than 3 years.

(b) The Mayor may establish by rule continuing education requirements as a condition for renewal of licenses under this section.

(c) At least 30 days before the license expires, or a greater period as established by the Mayor by rule, each board shall send to the licensee, by first class mail to the last known address of the licensee, a renewal notice that states:

- (1) The date on which the current license expires;
- (2) The date by which the renewal application must be received by the board for renewal to be issued and mailed before the license expires; and
- (3) The amount of the renewal fee.

(d) Before the license expires, the licensee may renew it for an additional term, if the licensee:

- (1) Submits a timely application to the board;
- (2) Is otherwise entitled to be licensed;
- (3) Pays the renewal fee established by the Mayor; and
- (4) Submits to the board satisfactory evidence of compliance with any continuing education requirements established by the board for license renewal.

(e) Each board shall renew the license of each licensee who meets the requirements of this section.

**§ 3-1205.11. Inactive status**

(a) Upon application by a licensee and payment of the inactive status fee established by the Mayor, each board shall place a licensee on inactive status.

(b) While on inactive status, the individual shall not be subject to the renewal fee and shall not practice, attempt to practice, or offer to practice the health occupation in the District.

(c) Each board shall issue a license to an individual who is on inactive status and who desires to resume the practice of a health occupation if the individual:

- (1) Pays the fee established by the Mayor;
- (2) Complies with the continuing education requirements in effect when the licensee seeks to reactivate the license; and
- (3) Complies with the current requirements for renewal of licenses.

### **§ 3-1205.12. Reinstatement of expired licenses**

(a) If a health professional fails for any reason to renew the license issued under this subchapter, the board regulating the health occupation shall reinstate the license if the health professional:

- (1) Applies to the board for reinstatement of the license within 5 years after the license expires;
- (2) Complies with current requirements for renewal of a license as set forth in this subchapter;
- (3) Pays a reinstatement fee established by the Mayor; and
- (4) Submits to the board satisfactory evidence of compliance with the qualifications and requirements established under this subchapter for license reinstatements.

(b) The board shall not reinstate the license of a health professional who fails to apply for reinstatement of a license within 5 years after the license expires. The health professional may become licensed by meeting the requirements then in existence for obtaining an initial license under this subchapter.

### **§ 3-1205.13. Display of licenses; change of address**

(a) Each licensee shall display the license conspicuously in any and all places of business or employment of the licensee.

(b) Each licensee shall notify the board of any change of address of the place of residence or place of business or employment within 30 days after the change of address.

(c) Each licensee shall be subject to the penalties provided by this chapter for failure to comply with the requirements of this section.

**§ 3-1205.14. Revocation, suspension, or denial of license or privilege; civil penalty; reprimand**

(a) Each board, subject to the right of a hearing as provided by this subchapter, on an affirmative vote of a majority of its members then serving, may take 1 or more of the disciplinary actions provided in subsection (c) of this section against any applicant, licensee, or person permitted by this subchapter to practice the health occupation regulated by the board in the District who:

- (1) Fraudulently or deceptively obtains or attempts to obtain a license for an applicant or licensee or for another person;
- (2) Fraudulently or deceptively uses a license;
- (3) Is disciplined by a licensing or disciplinary authority or convicted or disciplined by a court of any jurisdiction for conduct that would be grounds for disciplinary action under this section;
- (4) Has been convicted in any jurisdiction of any crime involving moral turpitude, if the offense bears directly on the fitness of the individual to be licensed;
- (5) Is professionally or mentally incompetent or physically incapable;
- (6) Is addicted to, or habitually abuses, any narcotic or controlled substance as defined by Unit A of Chapter 9 of Title 48;
- (7) Provides, or attempts to provide, professional services while under the influence of alcohol or while using any narcotic or controlled substance as defined by Unit A of Chapter 9 of Title 48, or other drug in excess of therapeutic amounts or without valid medical indication;
- (8) Willfully makes or files a false report or record in the practice of a health occupation;
- (9) Willfully fails to file or record any medical report as required by law, impedes or obstructs the filing or recording of the report, or induces another to fail to file or record the report;
- (10) On proper request in accordance with law, fails to provide details of a patient's medical record to a hospital or another health professional licensed under this chapter or under the laws of another jurisdiction;
- (11) Willfully makes a misrepresentation in treatment;

- (12) Willfully practices a health occupation with an unauthorized person or aids an unauthorized person in the practice of a health occupation;
- (13) Submits false statements to collect fees for which services are not provided or submits statements to collect fees for services which are not medically necessary;
- (14) Pays or agrees to pay anything of value to, or to split or divide fees for professional services with, any person for bringing or referring a patient;
- (15) Fails to pay a civil fine imposed by a board, other administrative officer, or court;
- (16) Willfully breaches a statutory, regulatory, or ethical requirement of confidentiality with respect to a person who is a patient or client of the health professional, unless ordered by a court;
- (17) Refuses to provide service to a person in contravention of Chapter 14 of Title 2;
- (18) Violates any of the conditions of an agreement between the licensee and the board to voluntarily limit the practice of the licensee made pursuant to § 3-1205.18;
- (19) Prescribes, dispenses, or administers drugs when not authorized to do so;
- (20) Practices without a protocol when required by subchapter VI of this chapter;
- (21) Performs, offers, or attempts to perform services beyond the scope of those authorized by the license held by the health professional;
- (22) Maintains an unsanitary office or performs professional services under unsanitary conditions;
- (23) Engages in sexual harassment of a patient or client;
- (24) Violates any provision of this chapter or rules and regulations issued pursuant to this chapter;
- (25) Violates any District of Columbia or federal law, regulation, or rule related to the practice of a health profession or drugs;
- (26) Fails to conform to standards of acceptable conduct and prevailing practice within a health profession;

(27) Violates an order of the board or the Mayor, or violates a consent decree or negotiated settlement entered into with a board or the Mayor;

(28) Demonstrates a willful or careless disregard for the health, welfare, or safety of a patient, regardless of whether the patient sustains actual injury as a result; or

(29) Fails to pay the applicable fees established by the Mayor.

(b) (1) A board may require a health professional to submit to a mental or physical examination whenever it has probable cause to believe the health professional is impaired due to the reasons specified in subsection (a)(5), (6), and (7) of this section. The examination shall be conducted by 1 or more health professionals designated by the board, and he, she, or they shall report their findings concerning the nature and extent of the impairment, if any, to the board and to the health professional who was examined.

(2) Notwithstanding the findings of the examination commissioned by the board, the health professional may submit, in any proceedings before a board or other adjudicatory body, the findings of an examination conducted by 1 or more health professionals of his or her choice to rebut the findings of the examination commissioned by the board.

(3) Willful failure or refusal to submit to an examination requested by a board shall be considered as affirmative evidence that the health professional is in violation of subsection (a)(5), (6), or (7) of this section, and the health professional shall not then be entitled to submit the findings of another examination in disciplinary or adjudicatory proceedings related to the violation.

(c) Upon determination by the board that an applicant, licensee, or person permitted by this subchapter to practice in the District has committed any of the acts described in subsection (a) of this section, the board may:

(1) Deny a license to any applicant;

(2) Revoke or suspend the license of any licensee;

(3) Revoke or suspend the privilege to practice in the District of any person permitted by this subchapter to practice in the District;

(4) Reprimand any licensee or person permitted by this subchapter to practice in the District;

(5) Impose a civil fine not to exceed \$ 5,000 for each violation by any applicant, licensee, or person permitted by this subchapter to practice in the District;

- (6) Require a course of remediation, approved by the board, which may include:
  - (A) Therapy or treatment;
  - (B) Retraining; and
  - (C) Reexamination, in the discretion of and in the manner prescribed by the board, after the completion of the course of remediation;
- (7) Require a period of probation; or
- (8) Issue a cease and desist order pursuant to § 3-1205.16.

(d) Nothing in this subchapter shall preclude prosecution for a criminal violation of this chapter regardless of whether the same violation has been or is the subject of 1 or more of the disciplinary actions provided by this subchapter. Criminal prosecution may proceed prior to, simultaneously with, or subsequent to administrative enforcement action.

(e) A person licensed to practice a health occupation in the District of Columbia is subject to the disciplinary authority of the board although engaged in practice elsewhere. Subsection (a) of this section shall not be construed to limit the disciplinary authority of the board only to conduct or activities engaged in outside of the District that result in the imposition of discipline by a licensing or disciplinary authority where the conduct occurred.

### **§ 3-1205.15. Summary action**

- (a) If the Mayor determines, after investigation, that the conduct of a licensee presents an imminent danger to the health and safety of the residents of the District, the Mayor may summarily suspend or restrict, without a hearing, the license to practice a health occupation.
- (b) The Mayor, at the time of the summary suspension or restriction of a license, shall provide the licensee with written notice stating the action that is being taken, the basis for the action, and the right of the licensee to request a hearing.
- (c) A licensee shall have the right to request a hearing within 72 hours after service of notice of the summary suspension or restriction of license. The Mayor shall hold a hearing within 72 hours of receipt of a timely request, and shall issue a decision within 72 hours after the hearing.
- (d) Every decision and order adverse to a licensee shall be in writing and shall be accompanied by findings of fact and conclusions of law. The findings shall be supported by, and in accordance with, reliable, probative, and substantial evidence. The Mayor shall provide a copy of the decision and order and accompanying findings of fact and conclusions of law to each party to a case or to his or her attorney of record.

(e) Any person aggrieved by a final summary action may file an appeal in accordance with subchapter I of Chapter 5 of Title 2.

### **§ 3-1205.16. Cease and desist orders**

(a) When a board or the Mayor, after investigation but prior to a hearing, has cause to believe that any person is violating any provision of this chapter and the violation has caused or may cause immediate and irreparable harm to the public, the board or the Mayor may issue an order requiring the alleged violator to cease and desist immediately from the violation. The order shall be served by certified mail or delivery in person.

(b) (1) The alleged violator may, within 15 days of the service of the order, submit a written request to the board or the Mayor to hold a hearing on the alleged violation.

(2) Upon receipt of a timely request, the board or the Mayor shall conduct a hearing and render a decision pursuant to § 3-1205.19.

(c) (1) The alleged violator may, within 10 days of the service of an order, submit a written request to the board or the Mayor for an expedited hearing on the alleged violation, in which case he or she shall waive his or her right to the 15-day notice required by § 3-1205.19(d).

(2) Upon receipt of a timely request for an expedited hearing, the board or the Mayor shall conduct a hearing within 10 days of the date of receiving the request and shall deliver to the alleged violator at his or her last known address a written notice of the hearing by any means guaranteed to be received at least 5 days before the hearing date.

(3) The board or the Mayor shall issue a decision within 30 days after an expedited hearing.

(d) If a request for a hearing is not made, the order of the board or the Mayor to cease and desist is final.

(e) If, after a hearing, the board determines that the alleged violator is not in violation of this chapter, the board or the Mayor shall revoke the order to cease and desist.

(f) If any person fails to comply with a lawful order of a board or the Mayor issued pursuant to this section, the board or the Mayor may petition the court to issue an order compelling compliance or take any other action authorized by this chapter.

**§ 3-1205.17. Voluntary surrender of license**

(a) Any health professional who is the subject of an investigation into, or a pending proceeding involving, allegations involving misconduct may voluntarily surrender his or her license or privilege to practice in the District, but only by delivering to the board regulating the health occupation an affidavit stating that the health professional desires to surrender the license or privilege and that the action is freely and voluntarily taken, and not the result of duress or coercion.

(b) Upon receipt of the required affidavit, the board shall enter an order revoking or suspending the license of the health professional or the privilege to practice.

(c) The voluntary surrender of a license shall not preclude the imposition of civil or criminal penalties against the licensee.

**§ 3-1205.18. Voluntary limitation or surrender of license by impaired health professional**

(a) (1) Any license issued under this chapter may be voluntarily limited by the licensee either:

(A) Permanently;

(B) For an indefinite period of time to be restored at the discretion of the board regulating the health occupation; or

(C) For a definite period of time under an agreement between the licensee and the board.

(2) During the period of time that the license has been limited, the licensee shall not engage in the practices or activities to which the voluntary limitation of practice relates.

(3) As a condition for accepting the voluntary limitation of practice, the board may require the licensee to do 1 or more of the following:

(A) Accept care, counseling, or treatment by physicians or other health professionals acceptable to the board;

(B) Participate in a program of education prescribed by the board; and

(C) Practice under the direction of a health professional acceptable to the board for a specified period of time.

(b) (1) Any license issued under this chapter may be voluntarily surrendered to the board by the licensee either:

(A) Permanently;

(B) For an indefinite period of time to be restored at the discretion of the board regulating the health occupation; or

(C) For a definite period of time under an agreement between the licensee and the board.

(2) During the period of time that the license has been surrendered, the individual surrendering the license shall not practice, attempt to practice, or offer to practice the health occupation for which the license is required, shall be considered as unlicensed, and shall not be required to pay the fees for the license.

(c) All records, communications, and proceedings of the board related to the voluntary limitation or surrender of a license under this section shall be confidential.

### **§ 3-1205.19. Hearings**

(a) Before a board denies an applicant a license, revokes or suspends a license or privilege to practice, reprimands a licensee, imposes a civil fine, requires a course of remediation or a period of probation, or denies an application for reinstatement, it shall give the individual against whom the action is contemplated an opportunity for a hearing before the board except where the denial of the license is based solely on an applicant's failure to meet minimum age requirements, hold a required degree, pass a required examination, pay the applicable fees established by the Mayor, or where there are no material facts at issue.

(b) A board, at its discretion, may request the applicant or licensee to attend a settlement conference prior to holding a hearing under this section, and may enter into negotiated settlement agreements and consent decrees to carry out its functions.

(c) Except to the extent that this chapter specifically provides otherwise, a board shall give notice and hold the hearing in accordance with subchapter I of Chapter 5 of Title 2.

(d) The hearing notice to be given to the individual shall be sent by certified mail to the last known address of the individual at least 15 days before the hearing.

(e) The individual may be represented at the hearing by counsel.

(f) (1) A board may administer oaths and require the attendance and testimony of witnesses and the production of books, papers, and other evidence in connection with any proceeding under this section.

(2) A board shall require the attendance of witnesses and the production of books, papers, and other evidence reasonably requested by the person against whom an action is contemplated.

(3) In case of contumacy by or refusal to obey a subpoena issued by the board to any person, a board may refer the matter to the Superior Court of the District of Columbia, which may by order require the person to appear and give testimony or produce books, papers, or other evidence bearing on the hearing. Refusal to obey such an order shall constitute contempt of court.

(g) If, after due notice, the individual against whom the action is contemplated fails or refuses to appear, a board may nevertheless hear and determine the matter.

(h) A board shall issue its final decision in writing within 90 days after conducting a hearing.

(i) A board may delegate its authority under this chapter to hold hearings and issue final decisions to a panel of 3 or more members of the board in accordance with rules promulgated by the Mayor. Final decisions of a hearing panel shall be considered final decisions of the board for purposes of appeal to the District of Columbia Court of Appeals.

### **§ 3-1205.20. Judicial and administrative review of actions of board**

Any person aggrieved by a final decision of a board or the Mayor may appeal the decision to the District of Columbia Court of Appeals pursuant to § 2-510.

### **§ 3-1205.21. Reinstatement of suspended or revoked license**

(a) Except as provided in subsection (b) of this section, a board may reinstate the license or privilege of an individual whose license or privilege has been suspended or revoked by the board only in accordance with:

(1) The terms and conditions of the order of suspension or revocation; or

(2) A final judgment or order in any proceeding for review.

(b) (1) If an order of suspension or revocation was based on the conviction of a crime which bears directly on the fitness of the individual to be licensed, and the conviction subsequently is overturned at any stage of an appeal or other post conviction proceeding, the suspension or revocation shall end when the conviction is overturned.

(2) After the process of review is completed, the clerk of the court issuing the final disposition of the case shall notify the board or the Mayor of that disposition.

## **SUBCHAPTER X. PROHIBITED ACTS; PENALTIES; INJUNCTIONS**

### **§ 3-1210.01. Practicing without license**

No person shall practice, attempt to practice, or offer to practice a health occupation licensed or regulated under this chapter in the District unless currently licensed, or exempted from licensing, under this chapter.

### **§ 3-1210.02. Misrepresentation**

Unless authorized to practice a health occupation under this chapter, a person shall not represent to the public by title, description of services, methods, or procedures, or otherwise that the person is authorized to practice the health occupation in the District.

### **§ 3-1210.03. Certain representations prohibited**

(l) Unless authorized to practice pharmacy under this chapter, a person shall not use the words or terms "pharmacy," "pharmacist," "druggist," "registered pharmacist," "R.Ph.," "Ph.G.," or any similar title or description of services with the intent to represent that the person practices pharmacy.

### **§ 3-1210.04. Filing false document or evidence; false statements**

(a) No person shall file or attempt to file with any board or the Mayor any statement, diploma, certificate, credential, or other evidence if the person knows, or should know, that it is false or misleading.

(b) No person shall knowingly make a false statement that is in fact material under oath or affirmation administered by any board or hearing officer.

**§ 3-1210.05. Fraudulent sale, obtaining, or furnishing of documents**

No person shall sell or fraudulently obtain or furnish any diploma, license, certificate or registration, record, or other document required by this chapter, by any board, or by the Mayor.

**§ 1210.06. Restrictions relating to pharmacies**

(a) Nothing in this chapter regulating the practice of pharmacy shall be construed as altering or affecting in any way District or federal laws requiring a written prescription for controlled substances or other dangerous drugs.

(b) (1) No pharmacist shall supervise more than 1 pharmacy intern at a time without prior approval of the Board of Pharmacy.

(2) No one other than a licensed pharmacist shall receive an oral prescription for Schedule II controlled substances.

(3) It shall be unlawful for a pharmacy intern to compound or dispense any drug by prescription in the District except while in the presence of and under the immediate supervision of a pharmacist.

(4) Any person engaging in the practice of pharmacy as a pharmacy intern shall register with the Mayor and shall comply with the applicable provisions of this chapter and subpart C of subchapter IV of Chapter 28 of Title 47.

**§ 3-1210.06a. Pharmacist consultation with medical assistance recipient or caregivers; records**

(a) A pharmacist who provides prescription services to medical assistance recipients shall offer to discuss with each medical assistance recipient or caregiver who presents a prescription order for outpatient drugs any matter which, in the exercise of the pharmacist's professional judgment, the pharmacist deems significant, which may include the following:

(1) The name and description of the medication;

(2) The dosage form, dosage, route of administration, and duration of drug therapy;

(3) Special directions, precautions for preparation, administration, and use by the patient;

- (4) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
  - (5) Techniques for self-monitoring drug therapy;
  - (6) Proper storage;
  - (7) Prescription refill information; and
  - (8) Action to be taken in the event of a missed dose.
- (b) The offer to discuss may be made in the manner determined by the professional judgment of the pharmacist, which may include any 1 or a combination of the following:
- (1) A face-to-face communication with the pharmacist or the pharmacist's designee;
  - (2) A sign posted in such a manner that it can be seen by patients;
  - (3) A notation affixed to or written on the bag in which the prescription is to be dispensed;
  - (4) A notation contained on the prescription container;
  - (5) Communication by telephone; or
  - (6) Any other manner prescribed by rule.
- (c) Nothing in this section shall be construed as requiring a pharmacist to provide consultation if the medical assistance recipient or caregiver refuses the consultation. These refusals shall be noted in the profile maintained in accord with subsection (d) of this section for a medical assistance recipient.
- (d) A pharmacist shall make a reasonable effort to obtain, record, and maintain, at the individual pharmacy, the following minimal information regarding a medical assistance recipient receiving a prescription:
- (1) Name, address, telephone number, date of birth or age, and gender;
  - (2) Individual patient history when significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist comments relevant to the individual's drug therapy, which may be recorded either manually or electronically in the patient's profile, including any failure to accept the pharmacist's offer to counsel.

(e) This section shall apply only to medical assistance recipients presenting prescriptions for covered outpatient drugs.

(f) The requirements of this section do not apply to refill prescriptions.

(g) The Mayor may adopt regulations implementing the provisions of this section to assure compliance with federal medical assistance requirements.

#### **§ 3-1210.07. Criminal penalties**

(a) Any person who violates any provision of this chapter shall, upon conviction, be subject to imprisonment not to exceed 1 year, or a fine not to exceed \$ 10,000, or both.

(b) Any person who has been previously convicted under this chapter shall, upon conviction, be subject to imprisonment not to exceed 1 year or a fine not to exceed \$ 25,000, or both.

#### **§ 3-1210.08. Prosecutions**

(a) Prosecutions for violations of this chapter shall be brought in the name of the District of Columbia by the Corporation Counsel.

(b) In any prosecution brought under this chapter, any person claiming an exemption from licensing under this chapter shall have the burden of providing entitlement to the exemption.

#### **§ 3-1210.09. Alternative sanctions**

Civil fines, penalties, and fees may be imposed as alternative sanctions for any infraction of the provisions of this chapter, or any rules or regulations issued under the authority of this chapter, pursuant to Chapter 18 of Title 2.

#### **3-1210.10. Injunctions**

(a) The Corporation Counsel may bring an action in the Superior Court of the District of Columbia in the name of the District of Columbia to enjoin the unlawful practice of any health occupation or any other action which is grounds for the imposition of a criminal penalty or disciplinary action under this chapter.

(b) The Corporation Counsel may bring an action in the Superior Court of the District of

Columbia in the name of the District of Columbia to enjoin the unlawful sale of drugs or the unlawful trade practice or unlawful operation of a pharmacy, nursing home, community residential facility, or any other establishment purporting to provide health services.

(c) Remedies under this section are in addition to criminal prosecution or any disciplinary action by a board.

(d) In any proceeding under this section, it shall not be necessary to prove that any person is individually injured by the action or actions alleged.

## **SUBCHAPTER XII. TRANSITIONAL PROVISIONS**

### **§ 3-1212.01. Transfer of personnel, records, property, and funds**

(a) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Dental Examiners are transferred to the Board of Dentistry established by this chapter.

(b) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Commission on Licensure to Practice the Healing Arts are transferred to the Board of Medicine established by this chapter.

(c) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Nurses' Examining Board are transferred to the Board of Nursing established by this chapter.

(d) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Examiners for Nursing Home Administrators are transferred to the Board of Nursing Home Administration established by this chapter.

(e) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Occupational Therapy Practice are transferred to the Board of Occupational Therapy established by this chapter.

(f) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Optometry are transferred to the Board of Optometry established by this chapter.

(g) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Physical Therapists Examining Board are transferred to the Board of Physical Therapy established by this chapter.

(h) The personnel, records, property, and unexpended balances of appropriations and other funds

which relate primarily to the functions of the Board of Pharmacy are transferred to the Board of Pharmacy established by this chapter.

(i) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Podiatry Examiners are transferred to the Board of Podiatry established by this chapter.

(j) The personnel, records, property, and unexpended balances of appropriations and other funds which relate primarily to the functions of the Board of Psychologist Examiners are transferred to the Board of Psychology established by this chapter.

### **§ 3-1212.02. Members of boards abolished**

Members of boards or commissions abolished by section 1104 shall serve as members of the successor boards to which their functions are transferred until the expiration of their terms or the appointment of their successors, whichever occurs first.

### **§ 3-1212.03. Pending actions and proceedings; existing rules and orders**

(a) No suit, action, or other judicial proceeding lawfully commenced by or against any board or commission specified in section 1104, or against any member, officer or employee of the board or commission in the official capacity of the officer or employee, shall abate by reason of the taking effect of this chapter, but the court or agency, unless it determines that survival of the suit, action, or other proceeding is not necessary for purposes of settlement of the question involved, shall allow the suit, action, or other proceeding to be maintained, with substitutions as to parties as are appropriate.

(b) No disciplinary action against a health professional or other administrative action or proceeding lawfully commenced shall abate solely by reason of the taking effect of any provision of this chapter, but the action or proceeding shall be continued with substitutions as to parties and officers or agencies as are appropriate.

(c) Except as otherwise provided in this chapter, all rules and orders promulgated by the boards abolished by this act shall continue in effect and shall apply to their successor boards until the rules or orders are repealed or superseded.

## **SUBCHAPTER XIII. APPROPRIATIONS**

### **§ 3-1213.01. Appropriations**

(a) Funds may be appropriated to carry out the purposes of this chapter.

(b) All provisions pertaining to marriage and family therapy added by the Marriage and Family

Therapy Amendment Act of 2003, effective May 10, 2004, D.C. Law 15-88, 50 DCR 10999, shall be subject to the availability of appropriations.

§ 3-1202.08. Board of Pharmacy [Formerly § 2-3302.8]

- (a) There is established a Board of Pharmacy to consist of 7 members appointed by the Mayor.
- (b) (1) The Board shall regulate the practice of pharmacy and the practice of pharmaceutical detailing.
  - (2) The Board is authorized to:
    - (A) Establish a code of ethics for the practice of pharmaceutical detailing; and
    - (B) Collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.
- (c) Of the members of the Board, 5 shall be pharmacists licensed in the District and 2 shall be consumer members.
- (d) Except as provided in subsection (e) of this section, members of the Board shall be appointed for terms of 3 years.
- (e) Of the members initially appointed under this section, 2 shall be appointed for a term of 1 year, 2 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years.

§ 3-1205.01. License required [Formerly § 2-3305.1]

A license issued pursuant to this chapter is required to practice medicine, acupuncture, chiropractic, registered nursing, practical nursing, dentistry, dental hygiene, dietetics, marriage and family therapy, massage therapy, naturopathic medicine, nutrition, nursing home administration, occupational therapy, optometry, pharmaceutical detailing, pharmacy, physical therapy, podiatry, psychology, social work, professional counseling, audiology, speech-language pathology, and respiratory care or to practice as an anesthesiologist assistant, physician assistant, physical therapy assistant, occupational therapy assistant, or surgical assistant in the District, except as provided in this chapter. A certification issued pursuant to this chapter is required to practice advanced practice registered nursing.

§ 3-1207.41. Scope of practice

- (a) An individual shall be licensed by the Board of Pharmacy before engaging in the practice of pharmaceutical detailing in the District of Columbia.
- (b) A pharmaceutical detailer shall not:
  - (1) Engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact;
  - (2) Use a title or designation that might lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation, in the District of Columbia, unless the pharmaceutical detailer currently holds such a license; or
  - (3) Attend patient examinations without the consent of the patient.

§ 3-1207.42. Qualifications for licensure

In addition to the general qualifications for licensure set forth in this chapter, an individual applying for a license to practice pharmaceutical detailing shall:

(1) Establish, to the satisfaction of the Board of Pharmacy, that he or she is a graduate of a recognized institution of higher education;

(2) Pay the required licensure fee; and

(3) Submit to the Board of Pharmacy a notarized statement that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics, as established by the Board pursuant to § 3-1202.08 and in accordance with this subchapter.

#### § 3-1207.43. Waiver of licensure requirements

The Board of Pharmacy shall waive the educational requirements for an applicant for licensure as a pharmaceutical detailer who can demonstrate, to the satisfaction of the Board, that he or she has been performing the functions of a pharmaceutical detailer, as defined in this subchapter, on a full-time, or substantially full-time, basis for at least 12 months immediately preceding March 26, 2008.

#### § 3-1207.44. Continuing education

The Mayor shall establish by rule continuing-education requirements as a condition for renewal of the license to practice pharmaceutical detailing.

#### § 3-1207.45. Penalties

In addition to the penalties set forth in this chapter, a person who practices pharmaceutical detailing without a license shall be subject to a fine of up to \$ 10,000.

**DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS  
TITLE 17. BUSINESS, OCCUPATIONS AND PROFESSIONS  
CHAPTER 40. HEALTH OCCUPATIONS: GENERAL RULES**

Secs.

4000	Applicability
4001	Application for a License, Registration, Renewal, or Reinstatement
4002	Examination
4003	Cheating on an Examination
4004	Issuance of a License, Certificate, or Registration
4005	Renewal of a License, Certificate, or Registration
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4015	Special Renewal and Continuing Education Hours Provisions for Actively Deployed Licensees
4016	Display And Use Of Name In Professional Practice
4099	Definitions

**4000      APPLICABILITY**

- 4000.1      This chapter shall apply to holders of and applicants for a license, certificate, or registration.
- 4000.2      Other chapters of this subtitle pertaining to specific health occupations shall supplement this chapter.

**4001      APPLICATION FOR A LICENSE, REGISTRATION, RENEWAL, OR REINSTATEMENT**

- 4001.1      An applicant for a license, registration, renewal, or reinstatement shall do the following:
  - (a)      Submit a completed application on the prescribed form;

- (b) Submit with the application two (2) recent passport-type photographs measuring two inches by two inches (2"x2") which clearly exposes the area from the top of the forehead to the bottom of the chin;
- (c) Pay the required fees(s);
- (d) Submit all required supporting documents, with the completed application, including transcripts, character and employment references, certified or validated test scores, and, if applicable, certified proof of licensure in other jurisdictions, except as provided in § 4001.1(e); and
- (e) Arrange for the required transcript, certificate of graduation, test results, certification or proof of licensure to be sent directly to the Board from the educational institution, testing service, professional association or government agency if the education institution, testing service, association or agency will not provide these documents to the applicant.

## **4002 EXAMINATION**

- 4002.1 An applicant desiring to take an examination shall submit an application in compliance with § 4001.1 to the board at least ninety (90) days prior to the date of the examination.
- 4002.2 An applicant who has previously taken the examination shall submit such an application at least sixty (60) days prior to the date of the examination.
- 4002.3 An applicant may not take an examination unless the materials required by § 4001.1(e) are received by the board at least forty-five (45) days prior to the date of the examination.
- 4002.4 A board may, in its discretion, permit an applicant to take an examination on a provisional basis although transcripts or other materials are not received within the period provided in § 4002.3.
- 4002.5 A board or the Director, in the discretion of the board or Director, may reduce the required periods in § 4002.1 through § 4002.3.
- 4002.6 The Director shall notify each applicant of the date, time, and place of examination and of any examination procedures at least ten (10) days (excluding Saturdays, Sundays, legal holidays, and days on which the Department is officially closed) prior to the date of the examination.
- 4002.7 The Director shall arrange for suitable space for an examination, designate persons to proctor the examination, and provide for adequate security to ensure the integrity of the examination process.

- 4002.8 The Director shall notify each applicant whether the applicant passed the examination as soon as practicable after the Director receives the examination results, unless the applicant is notified directly by a testing service.
- 4002.9 An applicant who fails an examination may not challenge the results of the examination before a board or the Director.
- 4002.10 If a testing service informs a board in writing that it erroneously determined that an applicant failed an examination and certifies to the board that the applicant passed the examination, the board shall grant a license to the applicant if the applicant has met all other qualifications for a license and has paid all required fees.
- 4002.11 If an applicant does not take an examination, the application fee shall not be refunded or credited to another examination unless a board or the Director determines that the applicant was unable to take the examination because of the following:
- (a) Illness or injury; or
  - (b) Death or serious illness of or injury to a member of the applicant's immediate family.
- 4002.12 A board or the Director, in making a determination under § 4002.11, may require a doctor's certificate or other satisfactory evidence of illness or injury.

### **4003 CHEATING ON AN EXAMINATION**

- 4003.1 No person shall cheat or assist another in cheating on an examination required under this subtitle or the Act.
- 4003.2 As used in this section, "cheating" includes, but is not limited to, the following:
- (a) Communication relating to the examination between applicants inside or outside of an examination room or copying another applicant's answers while an examination is in progress;
  - (b) Communication relating to an examination with others outside of an examination room while the examination is in progress;
  - (c) Substitution by an applicant of another person to sit in an examination room in the applicant's place; and
  - (d) Use of crib sheets, text books, or other materials not authorized by the board inside or outside an examination room while an examination is in progress.

- 4003.3 If a person designated to proctor an examination suspects that an applicant is cheating or has cheated on the examination, the person shall do the following:
- (a) If necessary, seat the applicant in a segregated location for the remainder of the examination;
  - (b) Keep a record of the applicant's seat location and identification number, and the names and identification numbers of the applicants on either side of the applicant;
  - (c) Confiscate any materials or devices that are suspected of being used by the applicant to cheat on the examination;
  - (d) Permit the applicant to complete the examination; and
  - (e) Notify the testing service, the board, and the Director that the applicant is suspected of cheating and provide the board with a copy of the examination booklet and any evidence obtained by the person proctoring the examination.

4003.4 If a board has cause to believe that an applicant has cheated or has failed to comply with an instruction of a proctor given pursuant to § 4003.3, it may propose to deny a license, imposed a civil fine, or take other actions pursuant to the procedures set forth in § 4102 of chapter 41 of this title.

4003.5 If a board determines, in accordance with the procedures set forth in chapter 41 of this title, that an applicant cheated on an examination, in addition to any other consequences under the Act or this subtitle, the applicant shall not be eligible to take another examination for a period of one (1) year from the date of the decision of the board, or other period established by the board in its order.

#### **4004 ISSUANCE OF A LICENSE, CERTIFICATE, OR REGISTRATION**

4004.1 After a determination by a board that an applicant for a license, certificate, or registration meets all the other requirements for the license, certificate, or registration under this subtitle and the Act, including the payment of all required fees, the Director shall issue the license, certificate, or registration to the applicant.

4004.2 The Director shall indicate on the face of the license, certificate, or registration any restriction on the license, certificate, or registration required by a board.

- 4004.3 An applicant for a license, certificate, or registration who is notified by the Director or a board that the application is approved shall pay the required license fee within one hundred and eighty (180) days of the date of the initial notice.
- 4004.4 The Director or a board shall send the notice by first class mail to the applicant at the applicant's address on file with the Director.
- 4004.5 If the applicant fails to pay the required fee within this period, the application shall lapse and the applicant shall be required to submit a new application and pay the required application fees to be eligible for a license, certificate, or registration.

**4005 RENEWAL OF A LICENCE, CERTIFICATE, OR REGISTRATION**

- 4005.1 The Director shall send a renewal application to a holder of a license, certificate, or registration by first class mail to the holder's address on file with the Director at least sixty (60) days prior to the expiration of the license, certificate, or registration.
- 4005.2 To be eligible for renewal, the holder of a license, certificate, or registration shall meet all of the requirements for renewal under this subtitle and the Act.
- 4005.3 A holder of a license, certificate, or registration shall notify the Department in writing of any change of home or business address within thirty (30) days of the change of address.
- 4005.4 The failure of a holder of a license, certificate, or registration to receive the notice required by § 4005.1 does not relieve the holder of the responsibility of renewing the license, certificate, or registration.
- 4005.5 A holder of a license, certificate, or registration who fails to renew prior to the expiration date may renew the license, certificate, or registration within sixty (60) days after expiration upon paying the required late fee. Upon renewal, the holder shall be deemed to have possessed a valid license, certificate, or registration during the period between the expiration of the license, certificate, or registration and the renewal thereof.
- 4005.6 If a holder of a license, certificate, or registration fails to renew the license, certificate, or registration within sixty (60) days after the expiration, the license, certificate, or registration shall be considered to have lapsed on the date of expiration and the holder shall be required to apply for reinstatement and pay the required reinstatement fee, in accordance with the applicable provisions of this subtitle and the Act.

**4006 TERM OF A LICENCE, CERTIFICATE, OR REGISTRATION**

- 4006.1 The term of a license, certificate, or registration issued or renewed pursuant to this subtitle shall be two (2) years or for the balance of the license period, whichever is shorter.
- 4006.2 The term of a license, certificate, or registration issued or renewed pursuant to this subtitle shall expire on the date established by this subtitle for the particular health occupation, unless the Director changes the renewal system pursuant to § 4006.3.
- 4006.3 The Director may change the renewal system whereby the license, certificate, or registration expires on the last day of the month of the birthdate of the applicant for or holder of the license, certificate, or registration, or by some other means for the administrative convenience of the Director.
- 4006.4 If the Director changes the renewal system under § 4006.3, in order to permit an orderly transition, the term of a license, certificate, or registration that is in effect on the date of the Director's determination may be extended up to three (3) years.

**4007 TEMPORARY LICENCES**

- 4007.1 A board may issue temporary licenses pursuant to this section if the Director determines in writing, on the request of a board or on the Director's own determination, that the issuance of temporary licenses to practice a health occupation is necessary to protect the health and welfare of the citizens of the District.
- 4007.2 Upon a determination of the Director in writing that the issuance of temporary licenses is no longer necessary to protect the health and welfare of the citizens of the District, the authority of a board to issue temporary licenses pursuant to this section shall cease, but a temporary license issued prior to the determination of the Director shall remain valid until it expires.
- 4007.3 A board may impose restrictions on practice by a holder of temporary license before or after the license is issued. The board may remove or modify any restrictions on a temporary license. The Director shall indicate any restriction on a temporary license on the face of the license or otherwise give notice of the restriction.
- 4007.4 A board may issue a temporary license pursuant to this section only to the following persons:
- (a) An applicant for a regular license who is licensed in another jurisdiction of the United States and is applying for licensure by reciprocity or endorsement; or

- (b) An applicant who meets all qualifications for a license except for the successful completion of an examination and who has applied to take the next scheduled examination pursuant to § 4002.

- 4007.5 The duration of a temporary license issued under this section shall be established by the Director, but shall not exceed ninety (90) days.
- 4007.6 An applicant for a temporary license shall submit a separate application for temporary licensure on a form approved by the Director and pay the required fee for a temporary license.
- 4007.7 A holder of a temporary license shall not represent in any manner that the holder is a regularly licensed health professional or use the terms or abbreviations restricted to regularly licensed health professionals by § 1003 of the Act, D.C. Code 3-1210.03(2001).
- 4007.8 Except as proved in this section, the holder of a temporary license is subject to the applicable provisions of the Act including, but not limited to, the following:
  - (a) Section 509, D.C. Code § 3-1205.09 (2001) (scope of license);
  - (b) Section 513, D.C. Code § 3-1205.13 (2001) (display of licenses; change of address);
  - (c) Section 514, D.C. Code § 3-1205.14 (2001) (revocation, suspension or denial or license or privilege; civil penalty; reprimand);
  - (d) Section 515, D.C. Code § 3-1205.15 (2001) (summary action);
  - (e) Section 516, D.C. Code § 3-1205.16 (2001) (cease and desist orders); and
  - (f) Section 517, D.C. Code § 3-1205.17 (2001) (voluntary surrender of license).
- 4007.9 The holder of a temporary license who violates the restrictions placed on the license shall be subject to the criminal, civil, and administrative sanctions of the Act.
- 4007.10 A board may revoke a temporary license without a hearing for any reason that the board determines to be in the interests of the health or welfare of the citizens of the District, upon a minimum of five (5) days notice given in the manner prescribed by § 4105 of chapter 41 of this title.

**4008 FALSE OR MISLEADING COMMUNICATIONS AND ADVERTISING**

- 4008.1 A health professional shall not make or cause to be made a false or misleading communication about the health professional or the health professional's services.
- 4008.2 A health professional shall not falsely represent that the health professional is certified by, a member of, or otherwise endorsed by, a professional society, association, or other organization.
- 4008.3 A health professional shall not communicate the fact that the health professional practices a particular health occupation, or specializes in a particular field of the health occupation, unless the health professional is in fact a specialist in the particular field indicated or possesses any certificate required by the health profession to be a specialist in the field.
- 4008.4 Subject to this section, a health professional may advertise professional services through media, such as a telephone directory, legal directory, newspaper or other periodical, radio or television, or through written communication not involving personal contact.
- 4008.5 As used in this section, a communication is "false" or "misleading" if it:
- (a) Contains a material misrepresentation or omits to make a representation necessary to make the statement considered as a whole not misleading; or
  - (b) Contains an assertion about the health professional or the health professional's services that cannot be substantiated.

**4009 REGULATION OF HOLDERS OF CERTIFICATE OR REGISTRATIONS**

- 4009.1 A board may take the same disciplinary actions against the holder of a certificate or registration as it may take against the holder of a license under § 514 of the Act, D.C. Code 3-1205.14 (2001) for the grounds stated in that section.
- 4009.2 The Director may take any action with respect to the holder of a registration that a board is authorized to take under the Act or this subtitle against the holder of a license or certificate.

**4010 REINSTATEMENT OF AN EXPIRED LICENSE**

- 4010.1 This section applies to the following:
- (a) An applicant for reinstatement of an expired licensed issued under the Act, in accordance with § 512 of the Act, D.C. Code § 3-1205.12

(2001); and

- (b) An applicant for reinstatement of an expired license or certificate issued under a law repealed or amended by the Act.

4010.2 An applicant for reinstatement under this section shall file an application with the board on the prescribed form and shall pay the required reinstatement fee.

4010.3 An applicant for reinstatement under this section shall demonstrate fitness to resume practice by submitting evidence satisfactory to the board that the applicant has the competency and knowledge of District and federal laws necessary to resume practice of the health occupation and that the applicant's resumption of practice will not be detrimental to the public interest or the integrity of the health profession.

4010.4 In making a determination pursuant to § 4010.3, the board shall consider the following:

- (a) The length of time that the applicant has practiced in the District or other jurisdictions;
- (b) The length of time after expiration of the applicant's license that the applicant was not practicing the health profession in the District or other jurisdictions;
- (c) Any violations by the applicant of the Act, this subchapter, or other laws, or other conduct by the applicant that would be grounds for discipline under the Act;
- (d) The applicant's present character; and
- (e) The applicant's present qualifications and competency to practice the health occupation.

4010.5 A board may require an applicant to complete certain educational or training requirements, in addition to any continuing education requirements, to be completed prior to or after reinstatement to ensure that the applicant is competent to practice the health occupation.

4010.6 A person who was licensed as a health professional under a law repealed by the Act and who was not license under the Act may apply for reinstatement pursuant to this section by March 25, 1991. After this date, such a person must apply as an applicant for a new license.

#### **4011 REINSTATEMENT AFTER REVOCATION**

- 4011.1 A health professional whose license, certificate, or registration has been revoked, or whose application for reinstatement has been denied, shall be ineligible to apply for reinstatement for a period of one (1) year from the date of the revocation or denial, unless otherwise provided in the board order of revocation or denial.
- 4011.2 An applicant for reinstatement under this section shall file an application with the board on the prescribed form and shall pay the required reinstatement fee.
- 4011.3 In addition to the requirements of § 4011.2, an applicant for reinstatement shall demonstrate fitness to resume practice by submitting evidence satisfactory to the board that the applicant has the moral qualifications, competency, and knowledge of District and federal laws necessary to resume practice of the health occupation and that the applicant's resumption of practice will not be detrimental to the public interest or the integrity of the health profession.
- 4011.4 In making a determination pursuant to § 4011.3, the board shall consider, among other factors, the following:
- (a) The nature and circumstances of the conduct, or the mental or physical condition, for which the applicant's license, certificate, or registration was revoked;
  - (b) The applicant's recognition and appreciation of the seriousness of any misconduct;
  - (c) The applicant's conduct, or mental or physical condition, since the revocation, including steps taken by the applicant to remedy prior misconduct and prevent future misconduct, or to remedy the mental or physical condition;
  - (d) The applicant's present character; and
  - (e) The applicant's present qualifications and competency to practice the health occupation.

**4012 REFERRAL FOR PROSECUTION OF PERSONS COMMITTING CERTAIN OFFENSES**

- 4012.1 A District employee or member of a board shall inform the Director and the board if the employee or board member has good cause to believe that a person has committed one (1) of the following offenses in connection with an application for a license, certificate, or registration or any proceeding before a board or the Director:

- (a) Willfully making a false statement of a material fact under oath at a hearing or other proceeding which the person does not believe is true and in fact is not true in violation of D.C. Code § 22-2402 (2005) (perjury);
- (b) Willfully procuring another to commit perjury in violation of D.C. Code § 22-2403 (2005) (subornation of perjury);
- (c) Willfully making a false statement of a material fact on an application or other official document that was sworn to before a notary public in violation of D.C. Code § 22-2404 (2005) (false swearing); or
- (d) Willfully making a false statement in writing of a material fact or which statement would reasonably be expected to be relied upon as true in violation of D.C. Code § 22-2405 (2005) (false statements).

4012.2 If the Director or the board determines that there is good cause to believe that a person committed one of the offenses listed in § 4012.1, the Director or board may refer the matter to the United States Attorney for the District of Columbia for prosecution.

4012.3 All application forms for a license, certificate, or registration under this subtitle shall contain a notice that states in substance that:

**“The making of a false statement on this application or on documents required by this application is punishable by criminal penalties.”**

#### **4013 COMPUTATION OF TIME**

4013.1 In computing any period of time specified in this chapter, the day of the act, event, or default shall not be counted, and the last day of the period shall be counted unless it is a Saturday, Sunday, legal holiday or day on which the Department is officially closed, in which event the time period shall continue until the next day that is not a Saturday, Sunday, legal holiday, or day on which the Department is officially closed.

#### **4014 LICENSE OR CERTIFICATION BY RECIPROCITY**

4014.1 An applicant for a license or certificate by reciprocity shall furnish proof satisfactory to the board regulating the health occupation of either of the following:

- (a) That the applicant is licensed or certified and in good standing as a member of the health occupation for which the applicant seeks a license or certificate in a jurisdiction on the list developed by the board pursuant to §

4014.3, by submitting from the jurisdiction a certificate of licensure or certification in good standing; or

(b) Proof of the following:

- (1) That the applicant is licensed or certified and in good standing as a member of the health occupation for which the applicant seeks a license or certificate in a jurisdiction of the United States with requirements which are substantially equivalent to the requirements of the Act, by submitting from the jurisdiction a certificate of licensure or certification in good standing; and
- (2) That the jurisdiction in which the applicant is license or certified admits members of the health occupation for which the applicant seeks a license or certificate who are licensed or certified by the District in a like manner as the District admits members of that health occupation who are licensed or certified in that jurisdiction, by arranging for the jurisdiction to provide to the Board a certificate or other written statement, signed by appropriate officials.

4014.2 A board, in its discretion, may deny an application for a license by reciprocity of a person against whom disciplinary action has been taken, or who has been convicted of a crime bearing on the applicant's fitness to practice, in another jurisdiction.

4014.3 A board may develop a list of jurisdictions whose requirements for licensure or certification are substantially equivalent to the requirements of the Act and which admit members of the health occupation regulated by the board who are licensed or certified in the District in a like manner as the District admits members of that health occupation who are licensed or certified in those jurisdictions.

4014.4 A board may interview an applicant under this section to determine whether the applicant's education, training, or character meets the requirements of the Act and this subtitle.

4014.5 A board, in its discretion, may grant a provisional license or certification not to exceed ninety (90) days to an applicant who has met the requirements of this subtitle except for the receipt by the board of required certification or other proof or licensure or certification in the other jurisdiction; Provided, that that board determines to its satisfaction, by telephone inquiry or other means, that the applicant has a license or certificate in good standing from the jurisdiction.

4014.6 The Director shall issue a provisional license granted by a board pursuant to § 4014.5.

**4015 SPECIAL RENEWAL AND CONTINUING EDUCATION HOURS PROVISIONS FOR ACTIVELY DEPLOYED LICENSEES**

4015.1 If the license of a health professional lapses while serving in the military whenever the United States is engaged in active military operations against any foreign power or hostile force, the license may be reinstated or renewed without payment of the reinstatement or late renewal fee under the following conditions:

- (a) The license was active at the time of deployment;
- (b) The application for reinstatement or renewal is made while still in the armed services or no later than six (6) months after discharge from active service or return to inactive military status;
- (c) A copy of the military activation orders or other proof of active military service accompanies the application; and
- (d) The renewal fee is paid.

4015.2 If the required continuing education contact hours were not earned for renewal during the earning period, the licensee shall be required to complete the required continuing education hours needed for renewal no later than six (6) months after discharge from active service, return to inactive military status, or return to the United States from an active war zone.

4015.3 The continuing education contact hours used for renewal shall not be used for the next licensing renewal.

4015.4 The continuing education contact hours for the next license renewal shall not be prorated.

**4016 DISPLAY AND USE OF NAME IN PROFESSIONAL PRACTICE**

4016.1 An individual holding a license, registration, or certification to practice a health occupation in the District of Columbia shall perform all professional practice in the District under the full name in which his or her license was issued. This shall mean displaying the full name in which his or her license was issued on all signage, stationary, and advertisements; and using this name in all oral and written communications with the public or his or her patients.

**4099 DEFINITIONS**

4099.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

**Act-** the District of Columbia Health Occupations Revisions Act of 1985, D.C. Law 6-99, D.C. Code §§ 3-1201 to 3-1213.01 (2001)

**Board-** the Board of Chiropractic, Board of Dentistry, Board of Dietetics and Nutrition, Board of Marriage and Family Therapy, Board of Medicine, Board of Nursing, Board of Nursing Home Administration, Board of Occupational Therapy, Board of Optometry, Board of Pharmacy, Board of Physical Therapy, Board of Psychology, Board of Podiatry, or Board of Social Work established by the Act, as the context requires.

**Certificate-** a certificate to practice a specialty of health occupation issued by a board pursuant to this subtitle or the Act.

**Day-** a calendar day.

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

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

**Legal holiday-** one of the following holidays:

- (a) New Year's Day;
- (b) Martin Luther King, Jr.'s Birthday;
- (c) Washington's Birthday;
- (d) Memorial Day;
- (e) Independence Day;
- (f) Labor Day;
- (g) Columbus Day;
- (h) Veterans Day;
- (i) Thanksgiving Day;
- (j) Christmas Day;

**DISTRICT OF COLUMBIA MUNICIPAL REGULATIONS  
TITLE 17. BUSINESS, OCCUPATIONS AND PROFESSIONS  
CHAPTER 41. HEALTH OCCUPATIONS: ADMINISTRATIVE PROCEDURES**

Secs.

- 4100      Applicability
- 4101      Complaints
- 4102      Notice of Intended Action and Opportunity for a Hearing
- 4103      Failure to Request a Hearing or Failure to Appear
- 4104      Hearing Notice Procedures
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**4100      **APPLICABILITY****

- 4100.1      This chapter shall apply to holders of and applicants for a license, certificate, or registration.
- 4100.2      The District of Columbia Administrative Procedure Act, D.C. Code §§ 2-501 to 2-511 (2001), shall supplement this chapter, except to the extent that it conflicts with the Act.

**4101      **COMPLAINTS****

- 4101.1      A board, on its own motion or on the receipt of a complaint submitted in accordance with § 4101.2, shall request the Director to investigate a health professional if the facts alleged in the complaint, if proven, would constitute sufficient grounds for disciplinary action under § 514(a) if the Act, D.C. Code § 3-1205.14(a) (2001), other provisions of the Act, or this subtitle.
- 4101.2      A person who desires to file a complaint against a health professional shall do the following:
  - (a)      Submit the complaint in writing;
  - (b)      State the facts or circumstances that form the basis of the complaint;
  - (c)      Sign the complaint and state the complainant’s name and address; and
  - (d)      Mail or deliver the complaint to the board.
- 4101.3      Nothing in § 4101.2 shall preclude a board, on its own motion, from requesting the Director to investigate a health professional based on information obtained from an individual who does not file a complaint in accordance with that subsection.
- 4101.4      Upon receiving a complaint, a board may, in its discretion, order that the health professional complained of answer the complaint within ten (10) days of receipt of the complaint. The board shall attach a copy of the complaint to an order to answer or shall describe the acts alleged in the complaint. The health professional shall respond to an order to answer either personally or through his or her attorney. An answer shall address the substantive allegations set forth in the complaint or order.
- 4101.5      If a board receives a written response from a health professional requested pursuant to § 4104.4, it may, in its discretion, send a copy of the response to the complainant and request a written reply within a time period determined by the board.

- 4101.6 Upon receipt of a health professional's answer or at any point during the course of the investigation or inquiry into the complaint, the board may determine that there is not and will not be sufficient evidence to warrant further proceedings or that the complaint fails to allege incompetence or misconduct for which a health professional may be sanctioned by the board. In such event, the board shall dismiss the complaint.
- 4101.7 For purposes of a hearing on the substance of the complaint in accordance with § 4102 should a hearing occur, a board may draw an adverse inference from a respondent's failure to respond to an order to answer the complaint and shall weigh that inference together with all other evidence in determining whether or not a matter has been proved.
- 4101.8 If a health professional violates the board's order and fails to answer within the ten (10) day period or if the board determines that there is otherwise reason to believe that the acts alleged occurred and constitute a violation pursuant to D.C. Official Code § 3-1205.14, the board may take one (1) of the following actions:
- (a) Refer the complaint to the Director for investigation;
  - (b) Set the matter for a hearing in accordance with § 4102 on the substance of the complaint or on the health professional's violation of the board's order to answer; or
  - (c) Request that the licensee or respondent attend a settlement conference in accordance with § 4108.
- 4101.9 If a board dismisses a complaint, it shall give the complainant notice in writing, sent first class mail, of the dismissal of the complaint within ten (10) days of the action.

**4102 NOTICE OF INTENDED ACTION AND OPPORTUNITY FOR A HEARING**

- 4102.1 A holder of a license (except a temporary license), certificate, or registration, or a person possessing a privilege to practice in the District under the Act, shall be given notice of, and an opportunity for, a hearing before the board regulating the health profession if the effect of the action would be one of the following:
- (a) To revoke a license, certificate, registration, or privilege;
  - (b) To suspend a license, certificate, registration, or privilege;

- (c) To reprimand the holder of a license, certificate, registration, or privilege;
- (d) To impose a civil fine;
- (e) To require a course of remediation;
- (f) To require a period of probation; or
- (g) To refuse to renew the license, certificate, or registration for any cause other than failure to pay the required renewal fee.

4102.2 If a board proposes to take an action of the type set forth in § 4102.1, it shall give written notice to the respondent in accordance with § 4105. The notice shall contain:

- (a) One of the following statements:
  - (1) A statement that the board has sufficient evidence, which, if proven to be true, establishes that the respondent has failed to answer the complaint when ordered to do so by a board pursuant to § 4101.4; or
  - (2) A statement that the board has sufficient evidence in support of the complaint, which, if proven to be true, justifies taking the proposed action, and setting forth the nature of the evidence that serves as the basis for the underlying complaint;
- (b) One of the following statements:
  - (1) That the board may take the proposed action, unless the applicant requests a hearing before the board by a letter addressed to the board, sent by certified mail or delivered in person, within twenty (20) days after service of the notice, and that the board may take the proposed action if the respondent fails to appear at a scheduled hearing; or
  - (2) That the board has scheduled a hearing on the proposed action, setting forth the date, time and place of the hearing, and that the board may take the proposed action if the respondent fails to appear at the hearing; and
- (d) A description of the rights of the respondent at a hearing as specified in § 4109.3.

- 4102.3 An applicant for a license (other than a temporary license), certificate, or registration shall be given notice of and an opportunity for a hearing before the board regulating the health profession or the Director if the effect of the action would be one of the following:
- (a) To deny permission to take an examination for any cause, except when the denial is based on the failure to meet a qualification over which the board has no discretion, including, but not limited to, the following:
    - (1) Failure to meet the minimum age requirement of eighteen (18) years; or
    - (2) Failure to meet educational or experience requirements where the acceptability of the educational program or quality of the experience is not an issue;
  - (b) To deny a license, certificate, or registration for any cause, except when the denial is based on the failure to meet a qualification over which the board has no discretion including, but not limited to, the following:
    - (1) Failure to pass an examination;
    - (2) Failure to meet the minimum age requirement of eighteen (18) years; or
    - (3) Failure to meet educational or experience requirements where the acceptability of the educational program or quality of the experience is not an issue;
  - (c) To deny a license or certificate by reciprocity or endorsement; or
  - (d) To impose a civil fine.

4102.4 If a board proposes to take an action of the type specified in § 4102.3, it shall give written notice to the applicant in accordance with § 4105. The notice shall contain the following:

- (a) A statement that the applicant has failed to satisfy the board as to the applicant's qualifications to take the examination or to be approved for licensure;
- (b) A statement that specifies in what respect the applicant has failed to satisfy the board; and
- (c) One of the following statements:

(1) That the Board may take the proposed action, unless the applicant requests a hearing before the board by a letter addressed to the board, sent by certified mail or delivered in person, within twenty (20) days after service of the notice, and that the board may take the proposed action if the respondent fails to appear at a scheduled hearing;

(2) That the board has scheduled a hearing on the proposed action, setting forth the date, time, and place of the hearing, and that the board may take the proposed action if the respondent fails to appear at the hearing; and

(d) A description of the rights of respondent at the hearing as specified in § 4109.3.

#### **4103 FAILURE TO REQUEST A HEARING OR FAILURE TO APPEAR**

4103.1 If a person who was sent a notice of a proposed action pursuant to § 4102 does not mail or deliver a request for a hearing within the time and in the manner required under that section, a board may, without a hearing, take the action contemplated in the notice.

4103.2 If a person scheduled for a hearing does not appear for the hearing, and no continuance is granted, a board may receive evidence and hear testimony and may render a decision on the basis of evidence before it. However, the board, prior to rendering a decision, may, upon written request of the respondent and payment of the required fee, send a copy of the transcript or summary of the hearing to the respondent and request proposed findings of fact and conclusions of law from the respondent.

4103.3 A board shall inform the respondent, the Corporation Counsel, and the Director of an action taken under this section.

#### **4104 HEARING NOTICE PROCEDURES**

4104.1 If a respondent requests a hearing, a board shall, within twenty (20) days following receipt of the request, notify the respondent of the date, time, and place of the hearing.

4104.2 The board shall hold the hearing not less than fifteen (15) days following the date of service of the notice, unless the board, the respondent, and the Corporation Counsel agree to the holding of the hearing at an earlier date.

#### **4105 SERVICE**

4105.1 A notice, order, decision, or pleading required by this chapter to be served upon a party shall be served upon the party or upon the representative

designated by the party or by law to receive service of papers. If a party has appeared through counsel, service may be made upon the counsel of record.

- 4105.2 Service on a respondent shall be directed to the last known address of the respondent on file with the Director and shall be completed by one of the following methods:
- (a) By personal delivery;
  - (b) By leaving it at the party's office with a person in charge or an employee or, if the office is closed or the party to be served has no office, by leaving it at the party's usual place of residence with a person of suitable discretion sixteen (16) years of age or older residing there;
  - (c) By certified mail, return receipt requested; or
  - (d) In conformity with an order of a board made in any hearing.
- 4105.3 Proof of service, stating the name and address of the person on whom service is made and the manner and date of service, may be shown by one of the following methods:
- (a) Written acknowledgement by the party or other person served in accordance with § 4105.2(b) or by the party's counsel;
  - (b) The certificate of the serving party or that party's counsel; or
  - (c) A return receipt if service is made by certified mail.
- 4105.4 If service is by personal delivery, it shall be deemed to have been served at the time when delivery is made to the party or other person served in accordance with § 4105.2(b).
- 4105.5 If service is by certified mail, it shall be deemed to have been made on the date shown on the return receipt showing delivery of the notice to the party or refusal of the party to accept delivery.
- 4005.6 If the party is no longer at the last known address as shown by the records of the Director, and no forwarding address is available, service shall be deemed to have been made on the date the return receipt bearing that notification is received by the Director.

## **4106 REPRESENTATION**

- 4106.1 A respondent appearing before a board at a hearing, or appealing a decision of an Administrative Law Judge (ALJ) before a board pursuant to § 4123, shall have the right to be represented by an attorney who is an active member of the

District of Columbia Bar. The chairperson of the board shall give notice of that appearance to the Director and the Corporation Counsel.

- 4106.2 If it appears to a board that the issues or facts in a matter before it are so complex that the interests of justice, saving time or facilitating the preparation of an adequate record would be served by the representation of a party by an attorney, the board may urge, but not require, that the party obtain the services of an attorney and may allow that party a responsible period of time within which to do so.
- 4106.3 No person may participate in a representative capacity in any hearing conducted by a board until the person delivers to the board a signed statement containing the person's name, street address, telephone number, and District of Columbia Bar Number. The written statement of counsel shall be made a part of the record.
- 4106.4 Any person authorized to appear pursuant to this section may sign any paper required or permitted either by this subtitle or the Act to be filed with a board.

#### **4107 MOTIONS AND OTHER PLEADINGS**

- 4107.1 Except by leave of a board during a hearing, a party shall make an application for an order or other relief by filing a written motion. A motion shall state with particularity the grounds on which it is based and shall clearly set forth the order or relief sought. If a motion is supported by memoranda, affidavits, or other papers, they shall be attached and served with the motion.
- 4107.2 A copy of each motion, response, opposition, reply, or other pleading filed with a board shall be served on each party separately represented, and a certificate of service shall appear at the end of the pleading showing the date and method of service.
- 4107.3 A party may file a response or opposition to a motion within ten (10) days after service of the motion, but a board, in its discretion, may shorten or extend this time, with proper notice to parties. The response or opposition shall not include a motion for other affirmative relieve against the moving party.
- 4107.4 A reply to a response or opposition may be file within three (3) days (excluding Saturdays, Sundays, legal holidays, or days on which the Department is officially closed) after service of the response or opposition, but the reply shall not reargue propositions presented in the motion nor present matters which are not strictly in reply to the response or opposition. No further pleading may be filed except by leave of a board for extraordinary cause.
- 4107.5 A motion or other pleading shall meet the following additional requirements:

- (a) It shall be typewritten on business size (8 ½ x 11) paper;
- (b) It shall contain the name of the case and number of the case, if any;
- (c) It shall be double-spaced, except footnotes and quotations, which may be single-spaced;
- (d) It shall be signed by the party on whose behalf it is filed or by that party's counsel; and
- (e) Subject to § 4107.6, it shall be accompanied with a number of copies that corresponds to the number of members of the board authorized by the Act, plus one, as follows:
  - (1) In cases before the Board of Chiropractic, six (6) copies;
  - (2) In cases before the Board of Dentistry, eight (8) copies;
  - (3) In cases before the Board of Dietetics and Nutrition, four (4) copies;
  - (4) In cases before the Board of Marriage and Family Therapy, six (6) copies;
  - (5) In cases before the Board of Medicine, twelve (12) copies;
  - (6) In cases before the Board of Nursing, twelve (12) copies;
  - (7) In cases before the Board of Nursing Home Administration, six (6) copies;
  - (8) In cases before the Board of Occupational Therapy, six (6) copies;
  - (9) In cases before the Board of Optometry, six (6) copies;
  - (10) In cases before the Board of Pharmacy, eight (8) copies;
  - (11) In cases before the Board of Physical Therapy, six (6) copies;
  - (12) In cases before the Board of Podiatry, six (6) copies;
  - (13) In cases before the Board of Psychology, six (6) copies;
  - (14) In cases before the Board of Social Work, six (6) copies;

4107.6 A board may permit respondents to file a lesser number of copies of motions or other pleadings than the number required by § 4107.5.

#### **4008 SETTLEMENT CONFERENCES**

4108.1 A board, in its discretion, may request a respondent against whom an action is proposed to attend a settlement conference.

4108.2 A board shall serve a request to attend a settlement conference in accordance with § 4105. The request shall state as follows:

- (a) That, if the respondent desires to participate in a settlement conference, the respondent is required to notify the board within ten (10) days or such other reasonable period specified in the notice;
- (b) That the respondent is entitled to be represented by an attorney;
- (c) That the respondent is not required to attend the settlement conference; and
- (d) That the respondent's failure to agree to attend a settlement conference will not be held against the respondent at a hearing based on the complaint.

4108.3 If a respondent agrees to attend a settlement conference, the board shall notify the respondent, the Director, and the Corporation Counsel, of the date, time, and place of the settlement conference.

4108.4 A board may designate a member of the Board, its counsel, or an employee of the Department to participate in a settlement conference on behalf of the board.

4108.5 The parties at a settlement conference may enter into a negotiated settlement or consent decree that is binding on all parties; Provided, that the settlement or consent decree is approved by the board.

4108.6 If the board accepts part, but not all, of the proposed negotiated settlement or consent decree, it may request the respondent to attend another settlement conference.

4108.7 A respondent who agrees to a negotiated settlement or consent decree that is approved by the board shall waive all of the respondent's rights of appeal or reconsideration under this subtitle or Act.

#### **4109 CONDUCT OF HEARINGS**

4109.1 All hearings before a board shall be opened to the public.

- 4109.2 At a hearing before a board, at least a majority of the members of the board shall be present to hear the evidence and render a decision.
- 4109.3 A respondent entitled to a hearing shall have the following rights:
- (a) The right to be represented by an attorney in accordance with § 4106;
  - (b) The right to present all relevant evidence by means of witnesses and 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 issued to compel the attendance of witnesses and the production of relevant books, papers, and other documents upon making written request for subpoenas to the board.
- 4109.4 A board may, in its discretion, deny any motion for a continuance, and shall deny a motion for a continuance unless the motion meets the following requirements:
- (a) In the opinion of the board, sets forth good cause for a continuance; and
  - (b) Is filed at least two (2) days (excluding Saturdays, Sundays, legal holidays, and days on which the Department is officially closed) before the date on which the hearing is to be held, except for extraordinary and unforeseen reasons, such as the sudden illness of a party or a party's counsel.
- 4109.5 Conflicting engagement of counsel, absence of counsel, or the employment of new counsel do not constitute good cause for a continuance of a hearing unless set forth in a motion file promptly after notice of the hearing has been given.
- 4109.6 After a hearing, and within time limits established by a board, the parties may submit proposed findings of fact, conclusions of law, and order, and may also submit memoranda of law on issues of law arising during the hearing.

#### **4110 EVIDENCE AT THE HEARING**

- 4110.1 All testimony at a hearing before a board shall be under oath or affirmation.
- 4110.2 If any part of the record in any other proceeding previously held before a board, or part of the record in any criminal or civil action (including hearings before an administrative agency) is offered in evidence, a certified true copy of that part shall be presented to the board in the form of an exhibit, unless either of the following requirements is satisfied:

- (a) The record is specified in such manner as to be readily identified, and the person offering the record agrees to supply copies later or when required by the board; or
- (b) There is a stipulation that the record may be incorporated by reference and the board directs that incorporation.

4110.3 A board shall exclude irrelevant, immaterial, and unduly repetitious evidence.

4110.4 A board may take official notice, at the request of a party or on its own motion, of the following:

- (a) The law and rules of the District of Columbia, the United States, and any state of the United States;
- (b) Material facts in the official files of a board or the Department or other District agency; or
- (c) A fact which is not subject to reasonable dispute in that it is generally known within the District of Columbia or is capable of accurate and ready determination by resort to sources the accuracy of which cannot reasonably be questioned.

4110.5 If a board takes official notice of a material fact not appearing in the evidence in the record, a party shall be given an opportunity to show the contrary at the hearing or on motion made within five (5) days after the hearing.

4110.6 The parties may, by stipulation in writing filed with a board, agree on the facts or any portion thereof involved in a hearing. The parties may also stipulate the testimony that would be given by a witness if the witness were present. A board, in its discretion, may require additional evidence regarding any matter covered by a stipulation.

#### **4111 CONDUCT OF PARTIES AND COUNSEL AT THE HEARING**

4111.1 All parties at a hearing shall maintain decorum and good order at all times, and a board may exclude or have removed from the hearing room any person violating any reasonable order of the chairperson of the board.

4111.2 A board may bar counsel from further participation in a hearing for disruptive conduct.

4111.3 If counsel has been barred from participating in a hearing, a board may proceed with the hearing if consistent with the due process rights of the parties. Otherwise, the board shall adjourn the hearing to give the party

whose counsel has been barred an opportunity to secure new representation expeditiously.

- 4111.4 Counsel who has been barred from participating in a hearing may seek, and a board may grant, reinstatement to participate in the hearing on such terms as the board prescribes. The board shall not permit a reinstatement application to delay the proceedings.

#### **4112 SUBPOENAS**

- 4112.1 A board shall issue subpoenas to compel witnesses to appear and testify or to produce books, records, papers, or documents on its own motion or upon the request of a party.
- 4112.2 A board shall issue subpoenas in the name of the Mayor of the District of Columbia. A subpoenaed witness, other than one employed by the District of Columbia Government, shall be entitled to a reasonable fee established by the Director, but the fee shall not be required to be paid in advance.
- 4112.3 Subpoenas issued by a board shall be enforceable in the manner prescribed in § 519(f) of the Act, D.C. Code § 3-1205.19(f)(3) (2001).

#### **4113 HEARINGS BY PANELS OF A BOARD**

- 4113.1 A board may authorize a panel of no less than three (3) members of the board to conduct a hearing in any matter that the board is authorized to conduct a hearing under this chapter.
- 4113.2 The panel of the board shall have the powers and duties given to the board by this chapter and the Act, except the power to render a final decision.
- 4113.3 After hearing the evidence, the panel shall submit a recommended decision to the board. At the same time, the board shall serve the respondent with a copy of the decision and send a copy of the decision to the Corporation Counsel.
- 4113.4 A recommended decision of a panel shall contain the following:
- (a) Findings of fact;
  - (b) Conclusions of law based on the findings of fact and application of the laws; and
  - (c) A recommended order.
- 4113.5 A board may accept or reject the recommended decision of the panel in whole or in part.

- 4113.6 Except as provided in § 4113.7, a board, within sixty (60) days of the hearing, shall render a decision and notify the Director, the respondent and the Corporation Counsel of the action.
- 4113.7 If the decision of the board is adverse to the respondent and the panel that heard the case did not constitute a majority of the members of the board, the board, prior to issuing a final decision, shall serve the respondent with a copy of the decision and give the respondent an opportunity to file exceptions, and written argument in support thereof, with the board within ten (10) days of the date of service.
- 4113.8 A board shall consider any exceptions and argument filed by a respondent pursuant to § 4113.7 in issuing a final decision. If the respondent does not file exceptions within the required period, the proposed decision of the board shall become the final decision of the board.
- 4113.9 A board may, with the agreement of all parties, extend the sixty (60) day period in which it is required to render a decision pursuant to § 519(h) of Act, D.C. Code § 3-1205.19(h) (2001).

#### **4114 HEARINGS BY ADMINISTRATIVE LAW JUDGES**

- 4114.1 A board may delegate its authority to conduct a hearing to an ALJ pursuant to § 103(c) of the Department of Consumer and Regulatory Affairs Civil Infractions Act of 985, D.C. Code § 2-1801.03(c) (2001), by notifying the Director in writing of the name of the case and the decision of the board to delegate its authority to conduct the hearing.
- 4114.2 The ALJ conducting a hearing has the powers and duties given to the board by this chapter and the Act, except the power to render a final decision.
- 4114.3 After hearing the evidence, an ALJ shall, within thirty (30) days of the hearing, submit a recommended decision to the board. At the same time, the ALJ shall serve the respondent with a copy of the decision and send a copy of the decision to the Corporation Counsel.
- 4114.4 A recommended decision of an ALJ shall contain the following:
- (a) Findings of fact;
  - (b) Conclusions of law based on the findings of fact and application of the laws; and
  - (c) A recommended order.
- 4114.5 A board may accept or reject the recommended decision of an ALJ in whole or in part.

- 4114.6 Except as provided in § 4114.7, a board, within thirty (30) days of the recommended decision of the ALJ, shall render a decision and notify the Director, the respondent, the ALJ, and the Corporation Counsel of the action.
- 4114.7 If the decision of the board is adverse to the respondent, the board, prior to issuing a final decision, shall serve the respondent with a copy of the decision and give the respondent an opportunity to file exceptions, and written argument in support thereof, with the board within ten (10) days of the date of service.
- 4117.8 A board shall consider any exceptions and argument filed by a respondent pursuant to § 4114.7 in issuing a final decision. If the respondent does not file exceptions within the required period, the proposed decision of the board shall become the final decision of the board.
- 4117.9 A board may, with the agreement of all parties, extend the sixty (60) day period in which it is required to render a decision pursuant to § 519(h) of Act, D.C. Code § 3-1205.19(h) (2001).

#### **4115 BURDEN OF PROOF**

- 4115.1 In a hearing resulting from a proposed disciplinary action under § 4102.1, the District shall have the burden of proving by a preponderance of the evidence that the action should be taken.
- 4115.2 In a hearing resulting from a proposed action to deny a license, certificate, or registration under § 4102.3, the applicant shall have the burden of satisfying the board of the applicant's qualifications by a preponderance of the evidence.

#### **4116 RECORD OF A HEARING**

- 4116.1 In all hearings conducted under this chapter, a board shall make a complete record of all evidence presented during the course of a hearing.
- 4116.2 A board shall make a transcript of a hearing on a proposed action specified in § 4102.1, unless the parties and the board agree not to have a transcript made.
- 4116.3 A board may make a transcript of a hearing on a proposed action specified in § 4102.3, and shall make a transcript upon written request of a party or made at least five (5) days prior to the hearing.
- 4116.4 If a board does not make a transcript of the hearing, it shall make an electronic recording of the hearing.
- 4116.5 A board shall provide a copy of an approved transcript or recording of a hearing to any person requesting it, upon payment of the required fee.

4116.6 A party may move to correct a transcript by filing a motion with a board within ten (10) days of receipt of the transcript. If no opposition to the motion is filed, the transcript may, upon approval by the board, be changed to reflect the corrections.

4116.7 In the event of disputes with respect to the record, a board shall settle the record and rule on all contested motions to correct the record.

#### **4117 DECISIONS OF A BOARD**

4117.1 A board shall render a decision, in writing, no later than sixty (60) days after the day the hearing is completed.

4117.2 A decision of a board shall contain the following:

- (a) Findings of fact;
- (b) Conclusions of law based upon the findings of fact and application of the laws;
- (c) An order; and
- (d) A statement informing the respondent of the right to have the decision reviewed by the District of Columbia Court of Appeals, and the time within which judicial review must be sought according to the rules of that Court.

4117.3 A board, in addition to taking other disciplinary action, may revoke the license of a health professional whose license has expired if the decision was based on conduct that occurred while the health professional was licensed.

4117.4 The chairperson of the board may sign an order, decision, or other document of the board on behalf of the board.

4117.5 Within five (5) days after the decision is rendered, a board shall serve a copy of the written decision upon the respondent, or the respondent's counsel of record, in accordance with § 4105.

4117.6 A board shall issue its findings of fact, conclusions of law, and order in writing except when it determines that the interests of the health, safety, or welfare of the public require that the findings of fact, conclusions of law, or order of the board be issued orally without delay.

4117.7 Oral findings of fact, conclusions of law, and an order issued in accordance with § 4117.6 shall be final and shall be recorded as final at the time they are communicated to the parties. Promptly thereafter, a board shall state its oral

findings of fact, conclusions of law, and order in writing, and the chairperson shall sign the written decision and serve a copy on all parties or their attorneys of record.

4117.8 A board, on motion by a respondent, may, in its discretion, stay the imposition of an order pending appeal or reconsideration.

**4118 SUMMARY ACTION**

4118.1 The Director shall serve a written notice of a summary suspension or restriction of a license of a health professional under § 515 of the Act, D.C. Code § 3-1205.15 (2001), in accordance with § 4105.

4118.2 A notice issued under this section shall state the following:

- (a) The action taken;
- (b) The reasons for which the action was taken;
- (c) That the action is effective upon service of the notice or at a time and date specified in the notice;
- (d) That the respondent has a right to make a written request for a hearing before the Director within seventy-two (72) hours of the service of the notice, or such longer period stated in the notice;
- (e) That the respondent's request for a hearing will not stay the action;
- (f) That the respondent has a right to a hearing within seventy-two (72) hours of the Director's receipt of the respondent's request for a hearing;
- (g) A description of a respondent's rights at a hearing as specified in § 4109.3; and
- (h) The address to which the respondent's request for a hearing must be delivered or mailed.

4118.3 An action under this section shall take effect immediately upon service, unless the notice states that it takes effect at a later time, and remains in effect until superseded by a decision of the Director.

4118.4 A respondent who requests a hearing within seventy-two (72) hours of service of a notice of summary action, or such longer period stated in the notice, shall have a right to a hearing under this section.

- 4118.5 The Director shall hold a hearing on a summary action within seventy-two (72) hours of the Director's receipt of the respondent's request, unless the respondent agrees to a later hearing time.
- 4118.6 In conduction a hearing under this section, the Director shall have all of the powers and duties of a board under this chapter.
- 4118.7 In a hearing under this section, the District has the burden of proving by substantial evidence that the action was necessary to prevent imminent danger to the health or safety of the citizens of the District.
- 4118.8 The Director shall issue a decision within seventy-two (72) hours of a hearing under this section and shall serve the respondent or the respondent's counsel with the decision as soon thereafter as practicable.
- 4118.9 A decision of the Director under this section shall contain the following:
- (a) Findings of fact;
  - (b) Conclusions of law based upon the findings of fact and application of the laws;
  - (c) An order; and
  - (d) A statement informing the respondent of the right to have the decision reviewed by the District of Columbia Court of Appeals, and the time within which judicial review must be sought according to the rules of that Court.
- 4118.10 The Director shall notify the board that regulates the health profession of the respondent of the Director's decision at the same time that it notifies the respondent.
- 4118.11 An order of the Director under this section shall remain in effect until one (1) of the following occurs:
- (a) The order expires under its own terms;
  - (b) The order is superseded by an order of a board under this section; or
  - (c) The order is reversed by the District of Columbia Court of Appeals.
- 4118.12 Within sixty (60) days after the Director notifies the board of a summary action, the board shall determine whether there is sufficient cause to propose a disciplinary action under § 4102.

- 4118.13 If a board determines that there is sufficient cause to propose a disciplinary action, the board shall take one (1) of the following actions:
- (a) Set the matter for a hearing in accordance with § 4102; or
  - (b) Request that the respondent attend a settlement conference in accordance with § 4108.
- 4118.14 If a board determines that there is not sufficient cause to propose a disciplinary action, the board shall take one (1) of the following actions:
- (a) Enter an order restoring the respondent's license or removing the restriction from the respondent's license which was imposed by the summary action; or
  - (b) Request that the Director undertake further investigation of the matter.
- 4118.15 An order of a board entered after its determination pursuant to §§ 4418.13 or 4118.14 supersedes an order of the Director to the extent that the order of the Director is inconsistent with the order of the board.
- 4118.16 If a board requests the Director to undertake further investigation pursuant to § 4118.14(b), the Director shall complete the investigation and report to the Board within sixty (60) days of the date of the request.

#### **4119 CEASE AND DESIST ORDERS**

- 4119.1 A board or the Director shall serve a cease and desist order on a health professional issued under §516 of the Act, D.C. Code § 3-1205.16 (2001), in accordance with § 4105. The order shall take effect immediately upon service, unless the order states that it takes effect at a later time.
- 4119.2 An order issued under this section shall state the following:
- (a) The action taken;
  - (b) The reasons for which the action was taken;
  - (c) That the action is effective upon service of the order or at a time and date specified in the order;
  - (d) That the respondent has a right to a hearing if the respondent requests a hearing in writing within fifteen (15) days of the service of the order;
  - (e) That the respondent has a right to an expedited hearing if the respondent requests an expedited hearing within ten (10) days of the service, and

that such a request constitutes a waiver by the respondent of the right to fifteen (15) days notice under the Act;

- (f) That the respondent's request for a hearing shall not stay the action;
- (g) A description of a respondent's rights at a hearing as specified in § 4109.3; and
- (h) The address to which the respondent's request must be delivered or mailed.

4119.3 If a respondent requests a hearing pursuant to §516(b) of the Act, D.C. Code § 3-1205.16(b)(1) (2001), the board or, in the case of an order issued by the Director, an ALJ, shall hold a hearing no earlier than fifteen (15) days and not later than forty-five (45) days after the board or Director receives the request.

4119.4 If a respondent requests an expedited hearing pursuant to §516(c)(1) of the Act, D.C. Code § 3-1205.16(c)(1) (2001), the board or, in case of an order issued by the Director, an ALJ, shall hold a hearing no earlier than five (5) days and no later than ten (10) days after the board or Director receives the request. In this case the notice of the hearing shall be served on the respondent in accordance with § 4105 at least five (5) days prior to the hearing.

4119.5 A respondent may waive the respondent's right to a hearing within the time periods required by §§ 4119.3 and 4119.4.

4119.6 If a board renders a decision under this section, the decision shall contain the following:

- (a) Findings of fact;
- (b) Conclusions of law based upon the findings of fact and application of the laws;
- (c) An order; and
- (d) A statement informing the respondent of the right to have the decision reviewed by the District of Columbia Court of Appeals, and the time within which judicial review must be sought according to the rules of that Court.

4119.7 If an ALJ conducts a hearing under this section, the ALJ shall have all the powers and duties of a board under this chapter.

4119.8 If an ALJ renders a decision under this section, the decision shall contain the following:

- (a) Findings of fact;
- (b) Conclusions of law based upon the findings of fact and application of the laws;
- (c) An order; and
- (d) A statement informing the respondent of the right to have the decision reviewed by the board regulating the health occupation and the time within which this review must be sought as specified in § 4123.

4119.9 A board or an ALJ rendering a decision under this section shall serve the respondent or the respondent's counsel with a copy of the decision as soon as practicable. If an ALJ renders a decision, the ALJ shall notify the board regulating the health occupation of the decision at the same time the ALJ notifies the respondent.

4119.10 A respondent who is aggrieved by a decision of an ALJ under this section may appeal the decision to the board regulating the health occupation in accordance with § 4123.

## **4120 PETITIONS FOR RECONSIDERATION**

4120.1 A respondent or the Corporation Counsel may file a petition for reconsideration, rehearing, or reargument within ten (10) days after the date of the service of the decision on that party. The party filing a petition shall serve a copy of the petition on each party separately represented.

4120.2 Neither the filing nor the granting of a petition shall operate as a stay of a decision unless specifically ordered by a board. A stay shall be granted only upon good cause, which shall involve a consideration of the likelihood of board error, irreparable harm to the petitioning party, the harm to other parties, and the public interest.

4120.3 A petition shall state briefly and specifically the following:

- (a) The matters of record or points of law alleged to have been erroneously decided or overlooked;
- (b) The grounds relied upon; and
- (c) The relief sought.

- 4120.4 If a petition is based in whole or in part on new matter, the matter shall be set forth in an affidavit, containing a statement that the petitioner could not with due diligence have known or have discovered the new matter prior to the hearing before the board.
- 4120.5 A board, in its discretion, may permit or require oral argument upon a petition before the board.
- 4120.6 A board shall grant or deny a petition within forty-five (45) days after the filing of the petition, but the failure by the board to act within that period shall be deemed a denial of the petition.
- 4120.7 A decision shall be in writing, and shall be signed by the chairperson. The chairperson shall serve copies of the decision on all parties or their counsels of record.

#### **4121 REOPENING A HEARING**

- 4121.1 If, because of accident, sickness, or other good cause, a respondent fails to receive a notice of a hearing or fails to appear for a hearing, the respondent may, within fifteen (15) days from the date of service of the decision, apply to the board to reopen the hearing.
- 4121.2 If a board finds good cause to reopen a hearing, the board shall, as soon as practicable, fix a time and place for a hearing and give the respondent and the Corporation Counsel notice of the hearing.
- 4121.3 A board may also reopen a hearing for any other cause sufficient to it; Provided, that no appeal is pending before a court or has been decided by a court.
- 4121.4 A decision of a board to reopen a hearing shall be entirely within the discretion of the board and shall not be subject to review.

#### **4122 JUDICIAL REVIEW: RECORD ON APPEAL**

- 4122.1 A party aggrieved by a decision of a board issued after a hearing may seek review of the decision by the District of Columbia Court of Appeals in accordance with the District of Columbia Administrative Procedure Act, D.C. Code §§ 2-501 to 2-511 (2001).
- 4122.2 Upon receipt by a board of a notice of appeal, the chairperson shall promptly acknowledge receipt, advise the Director of that receipt, and request the Director to compile, index, and transmit to the board the originals or copies of all documents pertinent to the appeal, including the following:
- (a) A copy of the decision or order from which an appeal is taken, together

with any findings of fact and conclusions of law on which the decision or order is based;

- (b) All documents relied on by the board, including any relevant documents timely submitted to the board by the respondent or by other parties to the hearing; and
- (c) A transcript or summary of all testimony given or statements made during the course of any hearings, conferences, or investigations concerning the matter in dispute, conducted by the board prior to the filing of the notice of appeal.

4122.3 The Director shall provide to all parties to the appeal a copy of the Director's index of the record on appeal.

4122.4 The record may be shortened if, with permission of the court, all parties to the review proceedings so stipulate.

4122.5 The documents transmitted pursuant to this section, and any supplements to the documents, shall be available for inspection by the parties at a location designed by the Director.

### **4123 ADMINISTRATIVE APPEALS TO A BOARD OF A DECISION OF AN ADMINISTRATIVE LAW JUDGE**

4123.1 This section shall apply to appeals from decisions of ALJ's under this chapter by the following persons:

- (a) Persons found by an ALJ to have committed an infraction involving a violation of this subtitle, the Act, or any other act regulating health professionals pursuant to the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, D.C. Law 6-42, D.C. Code § 2-1801.01 (2001); and
- (b) Persons against whom a cease and desist order has been entered pursuant to § 516 of the Act, D.C. Code § 3-1213.01 (2001); and
- (c) Any party aggrieved by an order of an ALJ issued pursuant to D.C. official Code § 2-1831.16(b).

4123.2 A notice of appeal from a decision issued by an ALJ shall be sent to the address stated in the decision and shall be delivered or postmarked within fifteen (15) days from the date of service of the final decision.

4123.3 A notice of appeal of a decision shall include the following information:

- (a) That an appeal is taken;

- (b) A copy or identification of the final decision from which the appeal is taken;
- (c) A concise statement indicating why the respondent believes the final decision is in error;
- (d) The full name, street address, and telephone number of the respondent and the respondent's counsel, if any; and
- (e) The signature of the respondent or the respondent's counsel.

4123.4 Upon receipt of a notice of appeal, the Director shall promptly acknowledge receipt and complete and index documents pertinent to the appeal, including the following:

- (a) A copy of the decision or order from which the appeal is taken, together with any findings of fact and conclusions or law on which the decision or order is based;
- (b) All documents relied on by an ALJ, including any relevant documents timely submitted to the ALJ by a respondent or by other parties to the proceedings; and
- (c) A transcript or summary of all testimony given or statements made during the course of any proceedings, conferences, or investigations concerning the matter in dispute, conducted by the ALJ prior to the filing of the notice of appeal.

4123.5 The Director shall transmit the notice of appeal and the documents described in §§ 4123.4(a) and (b) to the board within ten (10) days of the Director's receipt of the notice of appeal. The Director shall transmit the transcript of summary described in § 4123.4(c) as soon as practicable after the transcript or summary is completed.

4123.6 The Director shall send the respondent and the Corporation Counsel a copy of the Director's index of the record on appeal.

4123.7 The documents transmitted pursuant to this section, and any supplements to the documents, shall be available for inspection by the parties at a location designated by the Director.

4123.8 The record may be shortened if, with permission of the board, all parties to the review proceedings so stipulate.

- 4123.9 The Director, on motion of party, or on the Director's own motion, may require or permit a party to supplement the documents transmitted pursuant to this section.
- 4123.10 A board, in its discretion, may permit the parties to appear before it and present oral argument before the board in accordance with such limitations as to time of argument or other restrictions as the board may prescribe.
- 4123.11 The board acting pursuant to this section may affirm, modify, vacate, set aside, or reverse any order or decision of an ALJ.
- 4123.12 A board may hold unlawful and set aside any order or decision or findings and conclusions of law of an ALJ that it finds to be as follows:
- (a) Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
  - (b) In excess of statutory authority or authority under this chapter;
  - (c) Without observance of procedures provided by statute or this chapter; or
  - (d) Unsupported by a preponderance of the evidence in the record of the hearing.
- 4123.13 A party may petition a board to reconsider its decision in accordance with § 4120.
- 4123.14 A party aggrieved by a final decision of a board may seek review of the decision by the District of Columbia Court of Appeals in accordance with the District of Columbia Administrative Procedure Act, D.C. Code §§2-501 to D.C. Official Code of § 2-511 (2001).

#### **4124 COMPUTATION OF TIME**

- 4124.1 In computing any period of time specified in this chapter, the day of the act, event, or default shall not be counted, and the last day of the period shall be counted unless it is a Saturday, Sunday, legal holiday, or day on which the Department is officially closed, in which event the time period shall continue until the next day that is not a Saturday, Sunday, legal holiday, or day on which the Department is officially closed.

#### **4199 DEFINITIONS**

- 4199.1 As used in this chapter, the following terms and phrases shall have the meanings ascribed:

**Act-** the District of Columbia Health Occupations Revisions Act of 1985, D.C. Law 6-99, D.C. Code §§ 3-1201.01 to 3-1213.01 (2001).

**Administrative Law Judge (ALJ)-** a hearing examiner authorized to hear cases pursuant to the Department of Consumer and Regulatory Affairs Civil Infractions Act of 1985, D.C. Code § 2-1801.01, et seq.

**Board-** the Board of Chiropractic, Board of Dentistry, Board of Dietetics and Nutrition, Board of Marriage and Family Therapy, Board of Medicine, Board of Nursing, Board of Nursing Home Administration, Board of Occupational Therapy, Board of Optometry, Board of Pharmacy, Board of Physical Therapy, Board of Psychology, Board of Podiatry, or Board of Social Work established by the Act, as the context requires.

**Certificate-** a certificate to practice a specialty of health occupation issued by a board pursuant to this subtitle or the Act.

**Chairperson-** the chairperson of a health occupation board designated by the Mayor pursuant to §405(c) of the Act, D.C. Code § 3-1204.05, or a person designated by the board to preside at a hearing or act in place of the chairperson.

**Day-** a calendar day.

**Department-** the Department of Health.

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

**Health Professional-** a person who holds a license, certificate, or registration issued under the authority of this subtitle or the Act.

**Legal holiday-** one of the following holidays:

- (a) New Year's Day;
- (b) Martin Luther King, Jr.'s Birthday;
- (c) Washington's Birthday;
- (d) Memorial Day;
- (e) Independence Day;
- (f) Labor Day;
- (g) Columbus Day;

- (h) Veterans Day;
- (i) Thanksgiving Day;
- (j) Christmas Day;
- (k) Any other day designated as a legal holiday by the President, the Congress, the Mayor of the Council of the District of Columbia, on the actual day the legal holiday is celebrated by the government of the District of Columbia.

**License-** a license to practice a health occupation issued by a board pursuant to this subtitle or the Act.

**Registration-** a registration required to practice a health occupation issued pursuant to this subtitle or the Act.

**Respondent-** a person against whom an adverse action is contemplated, proposed, or taken.

**DISTRICT  
OF COLUMBIA  
MUNICIPAL  
REGULATIONS  
for  
PHARMACISTS**

## CHAPTER 65 PHARMACISTS

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### **6500 GENERAL PROVISIONS**

- 6500.1 This chapter shall apply to applicants for and holders of a license to practice pharmacy and to pharmacy interns.
- 6500.2 Chapters 40 (Health Occupations: General Rules), and 41 (Health Occupations: Administrative Procedures) of this title shall supplement this chapter.

### **6501 TERM OF LICENSE**

- 6501.1 Subject to § 6501.2, a license issued pursuant to this chapter shall expire at 12:00 midnight the last day of February of each odd-numbered year.
- 6501.2 If the Director changes the renewal system pursuant to § 4006.3 of Chapter 40 of this title, a license issued pursuant to this chapter expires at 12:00 midnight of the last day of the month of the birthdate of the holder of the license, or other date established by the Director.

### **6502 EDUCATION AND TRAINING REQUIREMENTS**

- 6502.1 Except as otherwise provided in this subtitle, an applicant shall furnish proof satisfactory to the Board, in accordance with § 504(i) of the Act, D.C. Official Code § 3-1205.04(i) (2001), of the following:
- (a) That the applicant has successfully completed an educational program in the practice of pharmacy and holds a Bachelor of Science or Doctor of Pharmacy

degree from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE) at the time the applicant graduates; and

- (b) That the applicant has successfully completed a pharmacy internship consisting of one of the following:
  - (1) One thousand (1,000) hours of pre-licensure professional practice in a program administered by a college of pharmacy accredited by ACPE at the time the applicant does the internship; or
  - (2) One thousand five hundred (1,500) hours of independent pre-licensure professional practice under the supervision of a licensed pharmacist who uses the standards for pre-licensure professional practice described in § 6502.2; or
  - (3) Two (2) rotations totaling six hundred and sixty (660) hours of pre-licensure professional practice administered by a college of pharmacy accredited by ACPE at the time the applicant does the internship and five hundred and ten (510) hours of independent pre-licensure professional practice under the supervision of a licensed pharmacist who uses the standards for pre-licensure professional described in § 6502.2.

6502.2 The Board shall give credit for independent pre-licensure professional practice required by §§ 6502.1(b)(2) and (3) if it meets the following requirements:

- (a) Seventy percent (70%) of the work was spent performing the following pharmacy tasks:
  - (1) Filling prescriptions;
  - (2) Compounding drugs;
  - (3) Evaluating prescriptions
  - (4) Handling controlled substances;
  - (5) Handling toxic drugs and substances;
  - (6) Substituting generic drugs for brand name drugs;
  - (7) Storing and packing drugs;
  - (8) Instructing patients;
  - (9) Maintaining prescription records; and
  - (10) Handling veterinarian products;

- (b) A student who is enrolled in a school of pharmacy may be given credit only for hours of work performed during school breaks or vacations;
- (c) Work performed in the following areas is subject to a maximum of five hundred (500) hours of credit:
  - (1) Work-study in industry or government;
  - (2) Research; and
  - (3) Community service projects;
- (d) Credit shall not be given for more than forty (40) hours of pre-licensure professional practice hours per week; and
- (e) Credit for pre-licensure professional practice performed in the District of Columbia shall:
  - (1) Not begin to accrue until the Board has registered the intern in accordance with the procedures set forth in § 6509 of this chapter; and
  - (2) Only be given for pre-licensure professional practice hours performed as part of a formalized internship program and under the supervision of the individual's assigned preceptor.

- 6502.3 For independent pre-licensure practice hours completed in the District of Columbia, the Board shall only give credit for the independent pre-licensure professional practice required by §§ 6502.1(b)(2) and (3) if it meets the requirements set forth in § 6502.2 of this chapter.
- 6502.4 For independent pre-licensure practice hours completed outside of the District of Columbia, the Board shall recognize the hours and apply the hours to the applicant's required total for licensure only if:
  - (a) The hours have been certified in writing by the Board of Pharmacy of the state in which they were obtained; and
  - (b) The hours were performed within two years from the date of the application for registration in the District of Columbia.
- 6502.5 Beginning with the academic period ending May 2009, in addition to the requirements of §§ 6502.1(b) of this chapter, each applicant for a pharmacist license shall submit proof of having completed an additional five hundred (500) hours of independent pre-licensure practice in a pharmacy setting with the emphasis being on the distribution of medicines and prescriptions.

**6503            APPLICANTS EDUCATED IN FOREIGN COUNTRIES**

- 6503.1            The Board may grant a license to practice pharmacy to an applicant who completed an educational program in a foreign country, which program was not recognized by the ACPE, if the applicant meets the following:
- (a) Meets all requirements of this chapter except for § 6502.1(a) and
  - (b) Demonstrates to the satisfaction of the Board that the applicant's education and training are substantially equivalent to the requirements of this chapter and the Act by submitting the documentation required by this section.
- 6503.2            An applicant under this section shall furnish proof satisfactory to the Board that the applicant holds a degree from a school of pharmacy with at least a five (5) year curriculum at the time of graduation, unless the applicant graduated prior to January 1, 2003 in which case a four (4) year curriculum will be accepted.
- 6503.3            An applicant under this section shall possess a Foreign Pharmacy Graduate Examination Committee Certification (FPGEC).
- 6503.4            An applicant under this section shall receive passing scores on the North American Pharmacist Licensure Examination (NAPLEX) or its successor, and the Multistate Pharmacy Jurisprudence Examination for the District of Columbia (MPJE) or its successor. The passing score of the NAPLEX and MPJE are the passing scores established by the National Association of Boards of Pharmacy on each test that forms a part of the examinations.
- 6503.5            An applicant under this section shall submit with a completed application certified transcripts of the applicant's pharmacy educational record(s).
- 6503.6            If a document required by this chapter is in a language other than English, an applicant shall arrange for its translation into English by a translation service acceptable to the Board and shall submit to the Board a translation signed by the translator attesting to its accuracy.
- 6503.7            The Board may waive the transcript requirement of § 6503.5 on a showing of extraordinary hardship if the applicant is able to establish by substitute documentation that the applicant possesses the requisite education and degrees.
- 6503.8            The Board may interview an applicant under this section to determine whether the applicant's education or training meets the requirements of the Act and this chapter.

**6504 LICENSE BY EXAMINATION**

6504.1 To qualify for a license by examination, an applicant shall:

- (a) Meet the education requirements set forth under § 6502.1(a), or if the applicant was educated in a foreign country meet the requirements set forth under § 6503;
- (b) Meet the training requirements set forth under § 6502.1(b);
- (c) Receive a passing score on each test that forms a part of the NAPLEX, or its successor, which shall be the passing score as determined by the NABP;
- (d) Receive a passing score on each test that forms a part of the MPJE for the District of Columbia, or its successor, which shall be the passing score as determined by the NABP;
- (e) Be at least 18 years of age; and
- (f) Have not been convicted of a crime involving moral turpitude or bearing directly on the fitness of the applicant to be licensed.

6504.2 An applicant for licensure by examination, who has previously successfully completed the NAPLEX and/or MPJE examinations, but has not actively engaged in the practice of pharmacy in the United States or was not actively licensed as a pharmacist in the United States for more than five (5) years prior to the date of the application, in addition to the other requirements of this section, shall be required to do the following in order to qualify for licensure under this section:

- (a) Retake the NAPLEX and MPJE examinations; and
- (b) Register as a Pharmacy Intern and complete an additional pharmacy internship consisting of seven hundred and fifty (750) hours of independent pre-licensure professional practice under the supervision of a licensed pharmacist who uses the standards for pre-licensure professional practice described in § 6502 of this chapter.

6504.3 To apply for a license by examination, an applicant shall:

- (a) Submit a completed application to the Board on the required forms and include:
  - (1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:
    - (i) Submit with the application a sworn affidavit, under penalty of

perjury, stating that he or she does not have a social security number; and

(ii) Submit proof acceptable to the Board that he or she is legally authorized to be in the United States, such as a Certificate of Citizenship or Naturalization, Resident Alien Card, a valid foreign passport with a visa; or a work permit card from the Department of Homeland Security (I-766 or I-688B).

- (2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and
- (3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.

(b) Submit official transcripts mailed directly to the Board of Pharmacy from each educational institution in a sealed envelope, which shall verify that the applicant has successfully completed an educational program in the practice of pharmacy meeting the requirements set forth in § 6502.1(a) of this chapter;

(c) Applicants educated in foreign countries must submit a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification in lieu of an official transcript;

(d) Submit proof acceptable to the Board that the applicant has successfully completed a pharmacy internship meeting the training requirements set forth in § 6502.1(b) of this chapter;

(e) Pay all required fees; and

(f) Successfully complete the NAPLEX and MPJE examinations after receiving Board approval to take the examinations and arrange to have the score results sent directly to the Board.

6504.4 An applicant under this section shall successfully complete the NAPLEX and MPJE examinations within one (1) year from the date the Board approves the applicant to take the examinations.

6504.5 If an applicant under this section fails to successfully complete the NAPLEX and MPJE examinations within one (1) year from the date of approval to take the exam, his or her application shall be considered abandoned and closed by the Board. The applicant shall thereafter be required to reapply, comply with the current requirements for licensure, and pay the required fees.

6504.6 If an applicant under this section fails to successfully complete the NAPLEX and

MPJE examinations within one (1) year from the date of approval to take the exam, then upon expiration of his or her supervised practice letter, the applicant shall immediately cease from practicing. Thereafter the applicant may perform only the duties of a pharmacy technician until the applicant receives a pharmacist license.

6504.7 A supervised practice letter issued under this section is not renewable and shall expire one (1) year from the date of issuance.

## **6505 LICENSE BY SCORE TRANSFER**

6505.1 To qualify for a license by score transfer, an applicant shall:

- (a) Meet the education requirements set forth under § 6502.1(a), or if the applicant was educated in a foreign country meet the requirements set forth under § 6503;
- (b) Meet the training requirements set forth under § 6502.1(b);
- (c) Have received a passing score on each test that forms a part of the NAPLEX, or its successor, which shall be the passing score as determined by the NABP;
- (d) Receive a passing score on each test that forms a part of the MPJE for the District of Columbia, or its successor, which shall be the passing score as determined by the NABP;
- (e) Be at least 18 years of age;
- (f) Have not been convicted of a crime involving moral turpitude or bearing directly on the fitness of the applicant to be licensed; and
- (g) Have requested a score transfer to the District of Columbia at the time the applicant applied to take his or her initial NAPLEX examination.

6505.2 To apply for a license by score transfer, an applicant shall:

- (a) Submit a completed application to the Board on the required forms and include:
  - (1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:
    - (i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and

(ii) Submit proof acceptable to the Board that he or she is legally authorized to be in the United States, such as a Certificate of Citizenship or Naturalization, Resident Alien Card, a valid foreign passport with a visa, or a work permit card from the Department of Homeland Security (I-766 or I-688B).  
or a valid foreign passport with a visa.

- (2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and
- (3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.

- (b) Submit the NABP score transfer form with the application for licensure;
- (c) Submit proof acceptable to the Board that the applicant has successfully completed a pharmacy internship meeting the training requirements set forth in § 6502.1(b) of this chapter;
- (d) Pay all required fees; and
- (e) Successfully complete the MPJE examination after receiving Board approval to take the examination and arrange to have the score result sent directly to the Board.

6505.3 An applicant under this section shall successfully complete the MPJE examination within one (1) year from the date the Board approves the applicant to take the examination.

6505.4 If an applicant under this section fails to successfully complete the MPJE examination within one (1) year from the date of approval to take the exam, his or her application shall be considered abandoned and closed by the Board. The applicant shall thereafter be required to reapply, comply with the current requirements for licensure, and pay the required fees.

6505.5 If an applicant under this section fails to successfully complete the MPJE examination within one (1) year from the date of approval to take the exam, then upon expiration of his or her supervised practice letter, the applicant shall immediately cease from practicing. Thereafter the applicant may become registered as a registered pharmacy technician, if he or she meets the requirements for registration, and perform only the duties of a registered pharmacy technician until the applicant receives a pharmacist license.

6505.6 A supervised practice letter issued under this section is not renewable and shall expire one (1) year from the date of issuance.

**6506 LICENSE BY RECIPROCITY WITH LICENSURE TRANSFER**

6506.1 To qualify for a license by reciprocity with license transfer, an applicant shall:

- (a) Meet the education requirements set forth under § 6502.1(a), or if the applicant was educated in a foreign country meet the requirements set forth under § 6503;
- (b) Have met the training requirements in the state in which his or her initial license was obtained;
- (c) Have received a passing score on each test that forms a part of the NAPLEX, or its successor, which shall be the passing score as determined by the NABP;
- (d) Receive a passing score on each test that forms a part of the MPJE for the District of Columbia, or its successor, which shall be the passing score as determined by the NABP;
- (e) Be at least 18 years of age;
- (f) Have not been convicted of a crime involving moral turpitude or bearing directly on the fitness of the applicant to be licensed; and
- (g) Obtain a NABP licensure transfer to the District of Columbia.

6506.2 To apply for a license by reciprocity with licensure transfer, an applicant shall:

- (a) Submit a completed application to the Board on the required forms and include:
  - (1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:
    - (i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and
    - (ii) Submit proof acceptable to the Board that he or she is legally authorized to be in the United States, such as a Certificate of Citizenship or Naturalization, Resident Alien Card, a valid foreign passport with a visa; or a work permit card from the Department of Homeland Security (I-766 or I-688B).
  - (2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the

area from the top of the forehead to the bottom of the chin; and

(3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.

(b) Submit the NABP licensure transfer form to the District of Columbia with the application for licensure;

(c) Pay all required fees; and

(d) Successfully complete the MPJE examination after receiving Board approval to take the examination and arrange to have the score result sent directly to the Board.

6506.3 An applicant under this section shall successfully complete the MPJE examination within six (6) months from the date the Board approves the applicant to take the examination.

6506.4 If an applicant under this section fails to successfully complete the MPJE examination within six (6) months from the date of approval to take the exam, his or her application shall be considered abandoned and closed by the Board. The applicant shall thereafter be required to reapply, comply with the current requirements for licensure, and pay the required fees.

6506.5 If an applicant under this section fails to successfully complete the MPJE examination within six (6) months from the date of approval to take the exam, then upon expiration of his or her supervised practice letter, the applicant shall immediately cease from practicing. Thereafter the applicant may become registered as a registered pharmacy technician, if he or she meets the requirements for registration, and perform only the duties of a registered pharmacy technician until the applicant receives a pharmacist license.

6506.6 A supervised practice letter issued under this section is not renewable and shall expire six (6) months from the date of issuance.

## **6507 LICENSE BY RECIPROCITY WITH WAIVER OF LICENSURE TRANSFER FORM**

6507.1 Only applicants who were previously licensed in the District of Columbia to practice pharmacy may apply for licensure by reciprocity with waiver of licensure transfer.

6507.2 To apply for a license by reciprocity with waiver of licensure transfer form, an applicant shall:

(a) Submit a completed application to the Board on the required forms and

include:

(1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:

(i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and

(ii) Submit proof acceptable to the Board that he or she is legally authorized to be in the United States, such as a Certificate of Citizenship or Naturalization, Resident Alien Card, a valid foreign passport with a visa; or a work permit card from the Department of Homeland Security (I-766 or I-688B).

(2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and

(3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.

(b) Submit proof acceptable to the Board of previous licensure in the District of Columbia to practice pharmacy;

(c) Submit verification of current licensure in good standing in another state to practice pharmacy; and

(d) Pay all required fees.

## **6508**

### **SUPERVISED PRACTICE OF PHARMACY**

#### **6508.1**

Only the following persons may practice pharmacy under supervision:

(a) An applicant for a pharmacist license whose initial application for licensure is pending before the Board and who has received a supervised practice letter from the Board, but shall be limited to the same scope of duties as a registered pharmacy intern;

(b) A licensee who is working under supervised practice pursuant to an Order of the Board;

(c) A pharmacy intern who is registered with the Board, subject to the limitations set forth under District of Columbia law and regulations; or

(d) An applicant who is required pursuant to this chapter to complete professional practice hours in order to obtain licensure, reinstatement of licensure, or reactivation of licensure.

6508.2 A supervisor shall be responsible for ensuring that the individual(s) under his or her supervision is authorized to practice under supervision and may be subject to disciplinary action for supervising unlicensed or unauthorized personnel.

6508.3 For purposes of this section, supervision shall mean that the supervisor is physically present in the pharmacy area and shall include personal observation where appropriate, evaluation, oversight, review, and correction of services provided by the supervisee.

6508.4 A supervisor shall be fully responsible for supervised practice by a supervisee during the period of supervision, and is subject to disciplinary action for any violation of the Act or this chapter by the person being supervised.

6508.5 A supervisee shall be subject to all applicable provisions of the Act and this chapter.

6508.6 If the Board finds that a person practicing under supervision has violated the Act or this title, the Board may, in addition to any other disciplinary actions permitted by the Act, deny, revoke, suspend, or restrict the privilege of the supervisee to practice.

## **6509 REGISTRATION OF PHARMACY INTERNS**

6509.1 Except as provided in 6509.2 of this chapter, this section shall apply to pharmacy interns who are performing independent, pre-licensure professional practice in satisfaction of the internship required by § 6502.1(b)(2) and (3) under the supervision of a pharmacist licensed in the District of Columbia.

6509.2 Beginning with the academic period ending May 2009, all individuals engaging in pre-licensure professional practice or working as a pharmacy intern in the District shall register with the Board after entering the first professional year of college of pharmacy whether or not the hours will be counted toward the total requirement for licensure as a pharmacist.

6509.3 A pharmacy intern is required to be registered with the Board as an intern before being employed as an intern in a pharmacy in the District or beginning an internship.

- 6509.4 Credit for internship hours performed in the District of Columbia shall not begin to accrue until the Board has registered the intern and shall only be given for pre-licensure professional practice hours performed as part of a formalized internship program and under the supervision of the individual's assigned preceptor.
- 6509.5 To qualify to register to perform a pharmacy internship, an applicant shall:
- (a) Meet the education requirements set forth under § 6502.1(a), or if the applicant was educated in a foreign country meet the requirements set forth under § 6503, or be currently enrolled in an educational program in the practice of pharmacy at an ACPE accredited school or school pending initial ACPE accreditation;
  - (b) Be at least 18 years of age; and
  - (c) Have not been convicted of a crime involving moral turpitude or bearing directly on the fitness of the applicant to be registered.
- 6509.6 To register as a pharmacy intern, an applicant shall:
- (a) Submit a completed application to the Board on the required forms and include:
    - (1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:
      - (i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and
      - (ii) Submit proof acceptable to the Board that he or she is legally authorized to be in the United States, such as a Certificate of Citizenship or Naturalization, Resident Alien Card, a valid foreign passport with a visa; or a work permit card from the Department of Homeland Security (I-766 or I-688B).
    - (2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and
    - (3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.
  - (b) Submit official transcripts mailed directly to the Board of Pharmacy from each educational institution in a sealed envelope, which shall verify that the applicant has successfully completed an educational program in the practice

of pharmacy meeting the requirements set forth in § 6502.1(a) or § 6503.1(a) of this chapter or is currently enrolled in an educational program in the practice of pharmacy at an ACPE accredited school ;

- (c) Applicants educated in foreign countries must submit a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification in lieu of an official transcript;
- (d) Pay all required fees; and
- (e) Submit a completed preceptor form signed by his or her preceptor which shall include:
  - (1) The name and District of Columbia pharmacist license number of the preceptor;
  - (2) The location where the internship will be performed;
  - (3) A description of the duties the intern will perform;
  - (4) The expected start date of the internship; and
  - (5) The Oath of the Preceptor set forth in § 6511.3 of this chapter.

6509.7 For applicants who have graduated from a college of pharmacy prior to registering as an intern, a registration as a pharmacy intern shall expire one (1) year from the date of its issuance. The Board may, in its discretion, renew a registration for successive periods of one (1) year if the pharmacy intern demonstrates due diligence in working toward completing the clinical internship requirement of § 6502.1(b)(2) or (3).

6509.8 For applicants enrolled in a college of pharmacy at the time of registering as an intern, a registration as a pharmacy intern shall be valid until whichever of the following occurs first:

- (a) While he or she is enrolled in a pharmacy program and for not more than one year after his or her graduation from the pharmacy program;
- (b) Until such intern is expelled, suspended, dismissed or withdraws from an approved pharmacy program; or
- (c) Until such intern becomes licensed as a pharmacist.

**6510 PRE-LICENSURE PROFESSIONAL PRACTICE OF PHARMACY INTERNS**

- 6510.1 This section shall apply to pharmacy interns who are performing independent, pre-licensure professional practice in satisfaction of the internship required by §§ 6502.1(b)(2) and (3) under the direct supervision of a pharmacist in the District, or who are otherwise registered with the Board to practice as a pharmacy intern.
- 6510.2 No person not properly registered with the Board as a pharmacy intern shall take, use, or exhibit the title of pharmacy intern, intern, extern, graduate pharmacist or any other similar title.
- 6510.3 A pharmacy intern may practice as an intern under the supervision of any pharmacist licensed in good standing in the District of Columbia. However, the Board shall only grant pre-licensure professional practice hours for those pharmacy tasks:
- (a) Performed under the supervision of the intern's Board approved assigned preceptor; and
  - (b) Where the preceptor was physically present on the pharmacy premises and in the pharmacy area at the time.
- 6510.4 A pharmacy intern shall not change preceptors or worksites without first submitting a new preceptor form to the Board.
- 6510.5 A pharmacy intern shall not compound or dispense any drug by prescription except under the direct supervision of a pharmacist licensed under the Act who is physically present and guiding the action.
- 6510.6 A pharmacy intern shall not accept an oral prescription for a Schedule II controlled substance.
- 6510.7 A pharmacy intern may not perform a final review or exercise final decision-making with respect to any of the following without the prior review and approval of the licensed pharmacist: drug utilization review; clinical conflict resolution, prescriber contact concerning prescription drug order clarification or therapy modification; or dispensing process validation.
- 6510.8 A pharmacy intern shall be identified by badge as an intern while performing pharmacy tasks.
- 6510.9 A pharmacy intern shall not in any manner falsely represent or imply to the public that he or she is a pharmacist.

- 6510.10 A pharmacy intern shall not supervise another pharmacy intern, a pharmacy student, or a pharmacy technician.
- 6510.11 The Board shall only give credit for independent pre-licensure professional practice hours required by §§ 6502.1(b)(2) and (3) if the work meets the following requirements set forth in § 6502.2 of this chapter.

**6511 DUTIES OF A PRECEPTOR**

6511.1 This section shall apply only to preceptors who are supervising pharmacy interns in the performance of independent, pre-licensure professional practice in satisfaction of the internship required by § 6502.1(b)(2) and (3) of this chapter.

6511.2 To qualify to serve as a preceptor, a pharmacist shall:

- (a) Be licensed in good standing to practice pharmacy in the District of Columbia;
- (b) Have been engaged in the practice of pharmacy for at least two (2) years on a full-time basis immediately prior to serving as a preceptor; and
- (c) Not currently be the subject of a disciplinary sanction or investigation in any jurisdiction.

6511.3 Prior to supervising a pharmacy intern, a preceptor shall sign the “Oath of Preceptor,” which states as follows:

“I submit that I shall answer all questions concerning the training of the pharmacy intern under my supervision truthfully to the best of my knowledge and belief and that the training I provide will in accordance to the requirements set forth in 17 DCMR §§ Chapter 65 and the practice of pharmacy as required by law.”

6511.4 Before allowing any person to work as a pharmacy intern, the preceptor shall verify that the person is currently registered with the Board.

6511.5 A preceptor shall ensure that at least seventy percent (70%) of a pharmacy intern’s training consists of learning to perform the following tasks:

- (a) Filling prescriptions;
- (b) Compounding drugs;
- (c) Evaluating prescriptions;
- (d) Handling controlled substances;

- (e) Handling toxic drugs and substances;
- (f) Substituting generic drugs for brand name drugs;
- (g) Storing and packaging drugs;
- (h) Instructing patients;
- (i) Maintaining prescription records; and
- (j) Handling veterinary products.

- 6511.6 A preceptor shall be responsible for the tasks performed by a pharmacy intern. A preceptor may be disciplined for any violation of the Act or this chapter in the performance of pharmacy tasks by the intern and under the preceptor's supervision.
- 6511.7 A preceptor shall not supervise more than one pharmacy intern at one time while the intern is on duty and performing internship tasks without prior approval by the Board. This provision shall not apply to students who are enrolled in ACPE accredited programs while performing clerkship hours toward fulfillment of graduation requirements.
- 6511.8 If the preceptor has evidence of, or strongly suspects, that the pharmacy intern may have violated any law or regulation regarding the practice of pharmacy, prescription drugs or controlled substances, the preceptor shall notify the Board in writing, within ten (10) days or immediately, if any danger to the public health or safety may exist.

**6512 REPEALED**

**6513 CONTINUING EDUCATION REQUIREMENTS**

- 6513.1 Except as provided in § 6513.2, this section shall apply to applicants for the renewal, reactivation, or reinstatement of a license for a term expiring February 28, 2011, and for subsequent terms.
- 6513.2 This section shall not apply to applicants for an initial license by examination or reciprocity, nor does it apply to applicants for the first renewal of a license.
- 6513.3 A continuing education credit shall be valid only if it is part of a program approved by the Board in accordance with § 6514 of this chapter.
- 6513.4 An applicant for renewal of a license shall:

- (a) Have completed a minimum of forty (40) contact hours of continuing education credit in approved programs, which shall include at least two (2) hours in Human Immunodeficiency Virus (HIV) training and at least two (2) hours in medication/dispensing errors training during the two (2) year period preceding the date the license expires;
- (b) Attest to completion of the required continuing education credits on the renewal application form; and
- (c) Be subject to a random audit.

6513.5 Not more than thirty (30) contact hours of continuing education credit may be accepted in any renewal period, or for reinstatement or reactivation of a license for approved home study or other mediated instruction continuing education courses.

6513.6 A minimum of ten (10) contact hours of the required forty (40) continuing education credits shall be obtained by attendance at live continuing education programs.

6513.7 To qualify for a license, a person in inactive status within the meaning of § 511 of the Act, D.C. Official Code § 3-1205.11 for five (5) years or less who submits an application to reactivate a license shall submit proof pursuant to § 6513.10 of having completed twenty (20) contact hours of approved continuing education credit in the year immediately preceding the date of the application, which shall include at least two (2) hours in Human Immunodeficiency Virus (HIV) training and at least two (2) hours in medication/dispensing errors training.

6513.8 To qualify for a license, a person in inactive status within the meaning of § 511 of the Act, D.C. Official Code § 3-1205.11 for more than five (5) years who submits an application to reactivate a license shall submit proof pursuant to § 6513.10 of having completed approved continuing education credit in the year immediately preceding the date of the application as follows:

- (a) Forty (40) contact hours of approved continuing education credit which shall include at least two (2) hours in Human Immunodeficiency Virus (HIV) training and at least two (2) hours in medication/dispensing errors training; and
- (b) One hundred sixty (160) hours within a sixty (60) day period of professional practice under the supervision of a pharmacist performing tasks listed in § 6502.2(a).

6513.9 To qualify for a license, an applicant for reinstatement of a license shall

submit proof pursuant to § 6513.10 of having completed approved continuing education credit in the year immediately preceding the date of the application as follows:

- (a) Forty (40) contact hours of approved continuing education credit which shall include at least two (2) hours in Human Immunodeficiency Virus (HIV) training and at least two (2) hours in medication/dispensing errors training; and
- (b) One hundred sixty (160) hours within a sixty (60) day period of professional practice under the supervision of a pharmacist performing tasks listed in § 6502.2(a).

6513.10 Except as provided in § 6513.12, an applicant under this section shall prove completion of required continuing education credits by submitting with the application the following information with respect to each program:

- (a) The name and address of the sponsor of the program;
- (b) The name of the program, its location, a description of the subject matter covered, and the names of the instructors;
- (c) The dates on which the applicant attended the program;
- (d) The hours of credit claimed; and
- (e) Verification by the sponsor of completion, by signature or stamp.

6513.11 Beginning with the 2005 renewal period, the Board shall conduct a random audit of continuing education credits at the completion of each renewal period.

6513.12 Applicants for renewal of a license shall only be required to prove completion of the required continuing education credits by submitting proof pursuant to § 6513.10 if requested to do so as part of the random audit, or if otherwise requested to do so by the Board.

6513.13 An applicant for renewal of a license who fails to renew the license by the date the license expires may renew the license for up to sixty (60) days after the date of expiration by completing the application, submitting the required supporting documents, and paying the required late fee. Upon renewal, the applicant shall be deemed to have possessed a valid license during the period between the expiration of the license and the renewal thereof.

6513.14 If an applicant for renewal of a license fails to renew the license and pay the late fee within sixty (60) days after the expiration of applicant's license, the license shall be considered to have lapsed on the date of expiration. The

applicant shall thereafter be required to apply for reinstatement of an expired license and meet all requirements and fees for reinstatement.

6513.15 The Board may, in its discretion, grant an extension of the sixty (60) day period, up to a maximum of one (1) year, to renew after expiration if the applicant's failure to renew was for good cause. As used in this section, "good cause" includes the following:

- (a) Serious and protracted illness of the applicant; and
- (b) The death or serious and protracted illness of a member of the applicant's immediate family.

6513.16 An extension granted under this section shall not exempt the pharmacist from complying with the continuing education requirements for any other renewal period.

#### **6514 APPROVED CONTINUING EDUCATION PROGRAMS**

6514.1 The Board may, in its discretion, approve continuing education programs that contribute to the growth of an applicant in professional competence in the practice of pharmacy and which meet the other requirements of this section.

6514.2 The Board may approve continuing education programs that meet the requirements of § 6514.3 and provide instruction in one of the following subjects:

- (a) Properties and actions of drugs and drug dosage forms;
- (b) Etiology, characteristics, and therapeutics of the disease state;
- (c) Pharmaceutical practice;
- (d) Legal, psychological, and socio-economic aspects of health care delivery; or
- (e) Principles, techniques, and theories of pharmacy management and administration.

6514.3 To qualify for approval by the Board, a continuing education program shall be a lecture, conference, seminar, course of instruction, or workshop and be prepared, offered, or administered by one of the following:

- (a) Providers approved by the ACPE;
- (b) The Accreditation Council for Continuing Medical Education (sponsored or co-sponsored) and designated as an American Medical Association

Physician's Recognition Award Category 1 program by the sponsoring organization;

- (c) A governmental unit;
- (d) A health care facility; or
- (e) An institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education.

6514.4 The Board may issue a list of approved continuing education programs.

6514.5 An applicant shall have the burden of verifying whether a program is approved by the Board pursuant to this section prior to attending the program.

6514.6 The Board may approve the following continuing education activities by an applicant:

- (a) Serving as an instructor or speaker at a lecture, conference, seminar, workshop, course of instruction, or in-service training; and
- (b) Publication of an article or book review in a professional journal or bulletin or publication of a book or chapter in a book.

## **6515 CONTINUING EDUCATION CREDITS**

6515.1 A contact hour shall consist of at least fifty (50) minutes of instruction in an approved continuing education program and shall equal one-tenth (0.1) of a continuing education credit ("CEU").

6515.2 For approved undergraduate or graduate courses, each semester hour of credit constitutes fifteen (15) contact hours of continuing education credit, and each quarter hour constitutes ten (10) contact hours of continuing education credit.

6515.3 The Board may grant a maximum of ten (10) contact hours of continuing education credits per year to an applicant who attends in-service education programs.

6515.4 The Board may grant credit for both preparation and presentation time to an applicant who serves as an instructor or speaker at an acceptable program, subject to the following restrictions:

- (a) The maximum amount of credit which may be granted for preparation time is twice the amount of the associated presentation time; and

- (b) The maximum amount of credit which may be granted pursuant to this subsection is fifty percent (50%) of an applicant's continuing education requirement; and
- (c) The presentation must have been completed during the period for which credit is claimed.

6515.5 The Board may grant an applicant who is an author or editor of a published book in the field of pharmacy thirty (30) contact hours of continuing education credits, if the book has been published or accepted for publication during the period for which credit is claimed, and the applicant submits proof of this fact with the application.

6515.6 The Board may grant an applicant who is an author of a published original paper in the field of Pharmacy eight (8) contact hours of continuing education credits, subject to the same restrictions set forth for books in § 6515.5.

6515.7 The Board may grant an applicant who is the sole author of a published book review, review paper, or abstract, in the field of Pharmacy, two (2) contact hours of continuing education credits, subject to the same restrictions set forth for books in § 6515.5.

**[6516-6517] RESERVED**

**6518 BOARD OF PHARMACY**

6518.1 The Board shall elect from its members a secretary and such other officers as it deems appropriate and necessary to conduct its business.

6518.2 The secretary, in the chairperson's absence, shall have all of the powers and may perform all of the duties of the chairperson.

6518.3 The Board shall meet at least twice each calendar year and shall hold additional meetings as deemed necessary by the Board upon proper notice in the District of Columbia Register.

6518.4 The chairperson or a majority of the Board may call special meetings upon reasonable notice to all Board members.

**6599 DEFINITIONS**

6599.1 As used in this chapter, the following terms have the meanings ascribed:

**ACPE**— The Accreditation Council for Pharmaceutical Education.

**Act-** The District of Columbia Health Occupation Revision Act of 1985 (“Act”), effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 et seq.)

**Adulterated drug or device** – an adulterated drug or device as defined in § 501 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 351.

**Applicant** – a person applying for a license to practice pharmacy under this chapter.

**Board** – the Board of Pharmacy, established by § 208 of the Act, D.C. Official Code § 3-1202.08 (2001).

**Coded prescription** – a prescription employing words and symbols chosen by the prescriber and a cooperating pharmacist for secrecy from other pharmacists.

**Contact hour** – a period of at least fifty (50) minutes of instruction in a continuing education program. One (1) contact hour equals one-tenth (0.1) of a continuing education credit.

**Department**—The District of Columbia Department of Health.

**Director**— The Director of the District of Columbia Department of Health.

**Distribution**--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.

**Enrolled in a pharmacy program**—In order to be considered enrolled in a school of pharmacy, a person shall not be absent from school for more than two (2) consecutive semesters or three (3) consecutive quarters.

**FPGEC-** Foreign Pharmacy Graduate Examination Committee.

**Home-Study and other Mediated Instruction** - Covers all continuing education activities, including Internet courses, which do not provide for direct interaction between faculty and participants and may include audio tapes, video tapes, cable television, computer assisted instruction, journal articles, monographs, etc.

**MPJE-** Multistate Pharmacy Jurisprudence Examination for the District of Columbia

**NABP-** National Association of Boards of Pharmacy

**NAPLEX-** North American Pharmacist Licensure Examination

**Pharmacist** – a person licensed to practice pharmacy under the Act.

**Pharmacy intern** – a person registered in the District to practice pharmacy under the direct supervision of a pharmacist and who is fulfilling internship (sometimes called externship) requirements in accordance with the chapter.

**Preceptor** – means a pharmacist licensed in good standing in the District, who has been approved by the Board to supervise the pre-licensure professional practice of a pharmacy intern.

**Prescriber** – a health professional licensed in the United States and authorized by law to prescribe the particular drug or device.

**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.

**Registration** – a document issued by the Board authorizing a pharmacy intern to do pre-licensure professional practice in the District with a designated preceptor.

**Supervised practice letter**— document issued by the Board authorizing the individual to practice the same scope of duties as a pharmacy intern under the supervision of a pharmacist licensed under the Act, while his or her application for licensure in the District of Columbia is pending or as otherwise authorized by the Board.

6599.2 The definitions in § 4099 of chapter 40 of this title are incorporated by reference and made applicable to this chapter.

**DISTRICT OF  
COLUMBIA  
MUNICIPAL  
REGULATIONS  
for  
PHARMACEUTICAL  
DETAILERS**

## CHAPTER 83

## PHARMACEUTICAL DETAILERS

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### **8300 GENERAL PROVISIONS**

- 8300.1 Effective, October 1, 2008, this chapter shall apply to applicants for and holders of a license to practice pharmaceutical detailing.
- 8300.2 Effective April 1, 2009, a person shall be licensed under the Act before the individual may practice pharmaceutical detailing in the District of Columbia.
- 8300.3 A person who practices pharmaceutical detailing in the District of Columbia without a license shall be subject to a fine of up to ten thousand dollars (\$10,000.00) in addition to the other penalties and sanctions set forth in the Act and the HORA.
- 8300.4 Chapters 40 (Health Occupations: General Rules), and 41 (Health Occupations: Administrative Procedures) of this title shall supplement this chapter.
- 8300.5 For purposes of this chapter, an individual shall be deemed as engaging in the practice of pharmaceutical detailing if:
- (a) He or she is acting as a representative of a pharmaceutical manufacturer or labeler; and
  - (b) Communicating in person with a licensed health professional or an employee or representative of a licensed health professional located in the District of Columbia;
  - (c) In a non-conference setting, as defined in this chapter;

(d) For the purpose of selling, marketing, or promoting a prescription or over-the-counter pharmaceutical product for use in humans, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such product.

8300.6 The scope of this chapter shall not apply to representatives who only sell, market, or promote veterinary drugs.

8300.7 The scope of this chapter shall not apply to the act of providing information about a pharmaceutical product solely for the purpose of conducting or pertaining to clinical trials, investigational drugs, or a Risk Evaluation and Mitigation Strategy pursuant to the Federal Food, Drug and Cosmetic Act.

8300.8 The scope of this chapter shall not apply to activities taking place at a conference, as defined in this chapter.

8300.9 The scope of this chapter shall not apply to health professionals participating in a conference, as defined in this chapter, including conferences targeting a local audience, solely as a speaker or presenter with respect to his or her area of expertise.

## **8301 TERM OF LICENSE**

8301.1 Subject to § 8301.2, a license issued pursuant to this chapter shall expire at 12:00 midnight the last day of February of each even-numbered year.

8301.2 If the Director changes the renewal system pursuant to § 4006.3 of Chapter 40 of this title, a license issued pursuant to this chapter shall expire at 12:00 midnight of the last day of the month of the birth date of the holder of the license, or other date established by the Director.

## **8302 EDUCATIONAL REQUIREMENTS**

8302.1 Except as otherwise provided in this chapter, an applicant shall furnish proof satisfactory to the Board that the applicant is a graduate of an institution of higher education recognized by the Board in accordance with § 742 of the Act, D. C. Official Code § 3-1207.42 (2001).

8302.2 An applicant shall submit an official certificate of graduation in a sealed envelope from the educational institution to the Board with the completed application.

8302.3 The Board may grant a license to practice pharmaceutical detailing to an applicant who is a graduate of an institution of higher education from a foreign country, if

the institution or education program was accredited by an accrediting body recognized by the Secretary of the United States Department of Education or the Council on Postsecondary Accreditation at the time the applicant graduated.

8302.4 If a document required by this chapter is in a language other than English, an applicant shall arrange for its translation into English by a translation service acceptable to the Board and shall submit a translation signed by the translator attesting to its accuracy.

### **8303 WAIVER OF EDUCATIONAL REQUIREMENTS**

8303.1 Except as provided in § 8303.2, the Board shall waive the educational requirements set forth under § 8302.1 of this chapter for an applicant for licensure who can demonstrate to the satisfaction of the Board that he or she has been performing the functions of a pharmaceutical detailer as defined in § 8399 of this chapter on a full-time, or substantially full-time, basis for at least 12 months immediately preceding March 26, 2008.

8303.2 The Board may extend the waiver set forth in § 8303.1 up to an additional 12 months for an applicant who was on approved leave under the Family and Medical Leave Act or the District of Columbia Family Medical Leave Act for any portion of the 12 months immediately preceding March 26, 2008. The waiver may only be extended by the actual amount of leave taken by the applicant under the Acts up to an additional 12 months.

8303.3 To apply for a waiver of the educational requirements set forth under § 8302.1 of this chapter, an applicant shall:

(a) Submit a sworn statement attesting to the fact that the applicant has been performing the functions of a pharmaceutical detailer as defined in § 8399 of this chapter, for at least thirty-two (32) hours per week for at least twelve (12) months immediately preceding March 26, 2008, which shall include:

(1) The applicant's employers and contact information;

(2) The time period of practice;

(3) The name(s) and contact information of supervisor(s) or professional colleagues, as applicable; and

(4) A description of the applicant's duties; and

(b) Submit two (2) letters of attestation from current or previous supervisors who supervised the applicant's work in pharmaceutical detailing and who can attest to the fact that the applicant has been practicing as a pharmaceutical detailer for at least twelve (12) months. If the applicant does not have at least two (2)

supervisors who can provide letters, applicant may submit one letter from a professional colleague who has first-hand knowledge that the applicant has been practicing as a pharmaceutical detailer for at least twelve (12) months.

## **8304 APPLICATION FOR LICENSURE**

8304.1 To apply for a license, an applicant shall:

- (a) Meet the education requirements set forth under § 8302 of this chapter or the requirements for waiver under § 8303 of this chapter;
- (b) Submit a completed application to the Board on the required forms and include:
  - (1) The applicant's social security number on the application. If the applicant does not have a social security number, the applicant shall:
    - (i) Submit with the application a sworn affidavit, under penalty of perjury, stating that he or she does not have a social security number; and
    - (ii) Provide the Board with his or her social security information once a social security number has been obtained;
  - (2) Two (2) recent passport-type photographs of the applicant's face measuring two inches by two inches (2" x 2"), which clearly expose the area from the top of the forehead to the bottom of the chin; and
  - (3) One (1) clear photocopy of a U.S. government-issued photo ID, such as a driver's license, as proof of identity.
- (c) Submit an official certificate of graduation or transcript in a sealed envelope from the educational institution(s) to the Board, which shall verify that the applicant meets the educational requirements set forth under § 8302 of this chapter;
- (d) Submit a notarized statement to the Board that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics as set forth in § 8305;
- (e) If applying by waiver, submit two (2) letters of recommendation meeting the requirements under § 8303 of this chapter; and
- (f) Pay all required fees.

8304.2 The Board shall make a decision whether to approve or to initiate the process to deny an application for licensure within sixty (60) days after receipt of a completed application package containing all required materials, information, and supporting documents.

8304.3 If the Board initiates the process to deny an application, the Board shall send a written notice to the Applicant of the Board's decision to initiate the process within sixty (60) days. However, the formal denial process under the Administrative Procedures Act shall not be included within the sixty (60) day requirement.

### **8305 CODE OF ETHICS**

8305.1 A pharmaceutical detailer shall not engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact. Practices and conduct in compliance with the Food and Drug Administration's laws, regulations, policies and guidelines shall not be deemed a violation of this subsection.

8305.2 A pharmaceutical detailer shall not use a title or designation that might lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or any other similar health occupation, in the District of Columbia, unless the pharmaceutical detailer holds an active license to practice that health occupation.

8305.3 A pharmaceutical detailer shall not attend patient examinations without the express, written consent of the patient.

8305.4 A pharmaceutical detailer shall not willfully harass, intimidate, or coerce a licensed health professional, or an employee or representative of a licensed health professional through any form of communication, including through the sending of messages of disappointment for the failure to prescribe certain medications.

8305.5 For purposes of § 8305.4, the Board shall use a reasonable person standard to determine whether the conduct constitutes willful harassment, intimidation, or coercion.

8305.6 A pharmaceutical detailer shall not continue to make sales calls upon a health professional, or an employee or representative of a health professional after the health professional prescriber has requested in writing to the pharmaceutical detailer or the detailer's employer not to receive any further sales calls.

- 8305.7 For purposes of § 8305.6, unless the person continuing to make the sales calls has actual knowledge of the request, a pharmaceutical manufacturer or labeler’s employees and representatives will not be deemed to have knowledge of a health care provider’s request until thirty (30) days after the health care provider submits the written request to the pharmaceutical detailer or his or her employer.
- 8305.8 A pharmaceutical detailer shall not offer a gift or remuneration of any kind to a member of a medication advisory committee; except that a pharmaceutical detailer may give medication samples to a member of a medication advisory committee that is also a licensed physician engaged in the practice of medicine.
- 8305.9 A pharmaceutical detailer shall not employ any inducement or misleading statements to gain access to a healthcare professional.
- 8305.10 A pharmaceutical detailer shall provide information to healthcare professionals That is accurate and fairly balanced in compliance with FDA policy and practices on the provision of information to health care professionals. However, nothing in this section shall be construed to require a pharmaceutical detailer to promote a competitor’s product.
- 8305.11 In addition to the regulations set forth under this section, any holder of a license under this chapter or any person authorized to practice pharmaceutical detailing functions under this chapter shall comply with the standards of ethical and professional conduct established by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its publication entitled “PhRMA Code on Interactions With Healthcare Professionals” as it may be amended or republished from time to time. Where there is a conflict between this publication and the regulations set forth in this Chapter or the provisions of the Act, the regulations and/or Act shall control.

## **8306 CONTINUING EDUCATION REQUIREMENTS**

- 8306.1 This section shall apply to applicants for the renewal, reactivation, or reinstatement of a license.
- 8306.2 A continuing education credit shall be valid only if it is part of a program or activity approved by the Board in accordance with § 8307 of this chapter.
- 8306.3 An applicant for renewal of a license shall:
- (a) Have completed a minimum of fifteen (15) contact hours of approved continuing education credit during the two (2) year period preceding the date the license expires;

(b) Attest to completion of the required continuing education credits on the renewal application form; and

(c) Be subject to a random audit.

8306.4 To qualify for a license, a person in inactive status within the meaning of § 511 of the Act, D.C. Official Code § 3-1205.11 (2001) who submits an application to reactivate a license shall submit proof pursuant to § 8306.6 of having completed fifteen (15) hours of approved continuing education credit within the two (2) year period preceding the date of the application for reactivation of that applicant's license and an additional eight (8) hours of approved continuing education credit for each additional year that the applicant was in inactive status beginning with the third year.

8306.5 To qualify for a license, an applicant for reinstatement of a license shall submit proof pursuant to § 8306.6 of having completed fifteen (15) hours of approved continuing education credit obtained within the two (2) year period preceding the date of the application for reinstatement of the applicant's license and an additional eight (8) hours of approved continuing education credit for each additional year that the license was expired beginning with the third year.

8306.6 Except as provided in § 8306.8, an applicant under this section shall prove completion of required continuing education credits by submitting with the application the following information with respect to each program:

(a) The name and address of the sponsor of the program;

(b) The name of the program, its location, a description of the subject matter covered, and the names of the instructors;

(c) The dates on which the applicant attended the program;

(d) The hours of credit claimed; and

(e) Verification by the sponsor of completion, by signature or stamp.

8306.7 Beginning with the 2010 renewal period, the Board shall conduct a random audit of continuing education credits at the completion of each renewal period.

8306.8 Applicants for renewal of a license shall only be required to prove completion of the required continuing education credits by submitting proof pursuant to § 8603.6 if requested to do so as part of the random audit, or if otherwise requested to do so by the Board.

8306.9 An applicant for renewal of a license who fails to renew the license by the date

the license expires may renew the license for up to sixty (60) days after the date of expiration by completing the application, submitting the required supporting documents, and paying the required additional late fee. Upon renewal, the applicant shall be deemed to have possessed a valid license during the period between the expiration of the license and the renewal thereof.

8306.10 If an applicant for renewal of a license fails to renew the license and pay the late fee within sixty (60) days after the expiration of applicant's license, the license shall be considered to have lapsed on the date of expiration. The applicant shall thereafter be required to apply for reinstatement of an expired license and meet all requirements and fees for reinstatement.

8306.11 The Board may, in its discretion, grant an extension of the sixty (60) day period to renew after expiration if the applicant's failure to renew was for good cause. As used in this section, "good cause" includes the following:

- (a) Serious and protracted illness of the applicant; and
- (b) The death or serious and protracted illness of a member of the applicant's immediate family.

8306.12 An extension granted under this section shall not exempt the licensee from complying with the continuing education requirements for any other renewal period.

## **8307 APPROVED CONTINUING EDUCATION PROGRAMS**

8307.1 The Board may, in its discretion, approve continuing education programs that contribute to the growth of an applicant in professional competence in the practice of pharmaceutical detailing and which meet the other requirements of this section.

8307.2 The Board may approve continuing education programs that meet the requirements of § 8307.3 and provide instruction in one of the following subjects:

- (a) General medical and pharmaceutical terminology and abbreviations;
- (b) Food and Drug Administration laws and regulations pertaining to drug marketing, labeling, and clinical trials;
- (c) The cost-effectiveness of pharmacological treatments;
- (d) Therapeutic drug classes and categories;
- (e) Professional ethics;

- (f) Properties and actions of drugs and drug delivery mechanisms;
- (g) Etiologies, characteristics, and therapeutics of disease states;
- (h) Pharmacology; and
- (i) The anatomical and physiological effect of pharmaceuticals.

8307.3 To qualify for approval by the Board, a continuing education program shall be an educational program given at a conference, a lecture, seminar, course of instruction, workshop, or on the Internet, and be prepared, offered, or administered by one of the following:

- (a) A nationally or locally accredited program provider;
- (b) A governmental unit;
- (c) A health care facility;
- (d) A pharmaceutical company; or
- (e) An institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education.

8307.4 The Board may issue a list of approved continuing education programs.

8307.5 An applicant shall have the burden of verifying whether a program is approved by the Board pursuant to this section prior to attending the program.

8307.6 The Board may approve the following continuing education activities by an applicant:

- (a) Serving as an instructor or speaker at a lecture, conference, seminar, workshop, course of instruction, or in-service training; and
- (b) Publication of an article or book review in a professional journal or bulletin or publication of a book or chapter in a book.

**8308 CONTINUING EDUCATION CREDITS**

8308.1 A minimum of fifty (50) minutes shall constitute one (1) contact hour.

8308.2 For approved undergraduate courses, each semester hour of credit shall constitute fifteen (15) contact hours of continuing education credit.

- 8308.3 The Board may grant credit to an applicant who serves as an instructor or speaker at an acceptable program for both preparation and presentation time, subject to the following restrictions:
- (a) The maximum amount of credit which may be granted for preparation time shall be twice the amount of the associated presentation time; and
  - (b) The maximum amount of credit which may be granted pursuant to this subsection shall be fifty percent (50%) of an applicant's continuing education requirement; and
  - (c) The presentation shall have been completed during the period for which credit is claimed.
- 8308.4 The Board may grant an applicant who is an author or editor of a published book fifteen (15) continuing education credits, if the book has been published or accepted for publication during the period for which credit is claimed, and the applicant submits proof of this fact in the application.
- 8308.5 The Board may grant an applicant who is an author of a published original paper five (5) continuing education credits, subject to the same restrictions set forth for books in § 8308.4.
- 8308.6 The Board may grant an applicant who is the sole author of a published book review, review paper, or abstract, two (2) continuing education credits, subject to the same restrictions set forth for books in § 8308.4.

**8309 AUTHORITY TO COLLECT INFORMATION AND RECORD RETENTION**

- 8309.1 In carrying out its functions under the Act, the Board of Pharmacy and an agent acting on its behalf is authorized to collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.
- 8309.2 Upon receipt of a verbal or written request by the Board or its agent for information pursuant to § 8309.1 of this chapter, a pharmaceutical detailer shall provide the requested information within ten (10) business days of the request.
- 8309.3 Refusal by a pharmaceutical detailer to provide the requested information with the time allotted shall constitute a basis for disciplinary action under the Health Occupations Revision Act of 1985, effective march 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*)
- 8309.4 A pharmaceutical detailer shall retain documents and information relating to

his or her communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District for a period of five years from the date of the communication or contact.

8309.5 Within ten (10) days of leaving the employ of a pharmaceutical company, a pharmaceutical detailer shall provide written notification to the Board of his or her departure and the name, address, email, and telephone number of the person within the company who may be contacted for retrieving the records required to be maintained under this chapter.

8309.6 For purposes of complying with this section, a pharmaceutical detailer shall maintain documents and information relating to his or her communications with licensed health professionals or with employees or representatives of licensed health professionals that include but are not limited to:

- (a) The name, business address, and telephone number of the healthcare professional the detailer visited;
- (b) The date, time and location of the visit;
- (c) The products discussed;
- (d) Whether samples were provided; and
- (e) The type of materials provided to the health care professional, if applicable.

**8310 LICENSURE AND RENEWAL FEES**

8310.1 The fees related to pharmaceutical detailers are as follows:

- |                           |          |
|---------------------------|----------|
| (a) Initial license fee   | \$175.00 |
| (b) Biennial renewal fee  | \$165.00 |
| (c) Late fee              | \$85.00  |
| (d) Duplicate certificate | \$34.00  |
| (e) License verification  | \$34.00  |

## **8311 SUPERVISED PRACTICE**

- 8311.1 An applicant for a pharmaceutical detailer license may engage in the supervised practice of pharmaceutical detailing under the supervision of a licensed pharmaceutical detailer for a period not to exceed sixty (60) days under the following conditions:
- (a) The applicant has an initial application for licensure pending before the Board;
  - (b) Has received a supervised practice letter from the Board; and
  - (c) Has not previously received a supervised practice letter from the Board.
- 8311.2 The supervising pharmaceutical detailer shall be fully responsible for the supervised practice of the supervisee during the period of supervision, and is subject to disciplinary action for any violation of the Act or this chapter by the person being supervised.
- 8311.3 A supervisee shall be subject to all applicable provisions of the Act and this chapter.
- 8311.4 If the Board finds that a person practicing under supervision has violated the Act or this title, the Board may, in addition to any other disciplinary actions permitted by the Act, deny, revoke, suspend, or restrict the privilege of the supervisee to practice.

## **8399 DEFINITIONS**

- 8399.1 As used in this Chapter the following terms shall have the meanings ascribed:

**Act-** SafeRx Amendment Act of 2008, effective March 26, 2008 (D.C. Law 17-0131; 55 DCR 4462, published on April 25, 2008 (the Act), and Mayor's Order Mayor's Order 2008-94, dated July 3, 2008.

**Applicant** – a person applying for a license to practice pharmacy under this chapter.

**Board** – the Board of Pharmacy, established by § 208 of the Act, D.C. Official Code § 3-1202.08.

**Conference-** A meeting, symposium, expo, exhibit, convention, assembly, or like gathering for the discussion of health-related issues consisting of multi-pharmaceutical company or labeler representation and targeting a regional, national or international audience.

**Department-** Department of Health

**Director-** Director of the Department

**District of Columbia Family Medical Leave Act-** District of Columbia Family Medical Leave Act of 1990, effective October 3, 1990 (D.C. Law 8-181; D.C. Official Code § 32-501 *et seq.*)

**Family Medical Leave Act-** Family Medical Leave Act of 1993, approved February 5, 1993 (107 Stat. 7; 29 U.S.C. § 2601 *et seq.* )

**FDA-** the federal Food and Drug Administration

**HORA-** Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*)

**Institution of Higher Education-** as defined in § 101 of the Higher Education Act of 1965, as amended, approved October 7, 1998 (112 Stat. 1581; 20 U.S.C. § 1001).

**Labeler-** An entity or person that receives pharmaceutical products from a manufacturer or wholesaler and repackages those pharmaceuticals for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.

**Manufacturer-** a manufacturer of pharmaceutical products and includes subsidiary or affiliate of a manufacturer.

**Medication Advisory Committee-** any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by the government of the District of Columbia.

**Multi-pharmaceutical or labeler representation-** at least three or more pharmaceutical companies or labelers which shall not be subsidiaries, or affiliations of the same company or parent company.

**Pharmaceutical Company-** any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biologic product, including any person acting as its agent or representative.

**Pharmaceutical Detailer:** a person licensed under the Act to engage in the practice of pharmaceutical detailing.

**Pharmaceutical Product-** a drug or biologic regulated by the federal Food and Drug Administration.

**Practice of Pharmaceutical detailing-** the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product.

**Sales Call-** any in person communication with a health care professional or his or her employees or representatives for the direct purpose of selling marketing, or promoting a pharmaceutical product, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such pharmaceutical product on behalf of a pharmaceutical manufacturer or labeler.

# SECTION III.



## DRUG MANUFACTURERS AND DISTRIBUTORS

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE II. PRESCRIPTION DRUGS**  
**CHAPTER 7. DRUG MANUFACTURE AND DISTRIBUTION**

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- § 48-701. DEFINITIONS
  - § 48-702. PROHIBITIONS
  - § 48-703. LICENSE REQUIREMENTS
  - § 48-704. LICENSURE OF A DRUG MANUFACTURER, DISTRIBUTOR, OR WHOLESALER
  - § 48-705. RENEWAL OF LICENSE
  - § 48-706. CONDITIONAL LICENSE
  - § 48-707. REGISTRATION OF AN OUT-OF-STATE DRUG MANUFACTURER, DISTRIBUTOR, REPACKAGER, OR WHOLESALER
  - § 48-708. INSPECTIONS
  - § 48-709. SUMMARY ACTION
  - § 48-710. SUSPENSION, DENIAL, OR REVOCATION
  - § 48-711. CRIMINAL ACTION
  - § 48-712. CIVIL INFRACTIONS
  - § 48-713. CEASE AND DESIST ORDER; EMBARGO
  - § 48-714. RULES
  - § 48-715. EXCEPTIONS
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**§ 48-701. Definitions**

For the purposes of this chapter, the term:

- (1) "Distribute" means:
  - (A) To sell any drug for resale;
  - (B) To act as a broker, agent, distributor, jobber, or wholesaler of any drug; or
  - (C) To otherwise negotiate a sale for the resale of any drug.
- (2) "Drug" means any substance as defined under § 47-2885.02.
- (3) "Manufacture" means:
  - (A) (i) 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;
  - (ii) Any packaging or repackaging of the substance or drug; or

(iii) 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.

(B) "Manufacture" 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.

(4) "Wholesaler" means 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.

(5) "Conditional license" means a license issued pursuant to specific conditions.

## § 48-702. Prohibitions

No person shall:

- (1) Manufacture, distribute, or wholesale any drug in the District of Columbia ("District") unless the person holds a license or registration as required by this chapter issued by the Mayor to manufacture, distribute, or wholesale drugs;
- (2) Manufacture, distribute, or wholesale in the District, any drug that is adulterated, misbranded, or otherwise unfit for use;
- (3) Engage in manufacturing activities under a license issued pursuant to this chapter unless performed under the personal and immediate supervision of a pharmacist licensed by the District of Columbia or by an individual certified by the Mayor 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;
- (4) Display, cause, permit to be displayed, or possess a cancelled, revoked, suspended, fictitious, or fraudulently altered license to manufacture, distribute, or wholesale drugs;

- (5) Lend or transfer a license to manufacture, distribute, or wholesale drugs;
- (6) Fail or refuse to surrender to the Mayor a license to manufacture, distribute, or wholesale a drug, if the license has been suspended, revoked, or cancelled, or if the manufacture, distribution, or wholesale activity has terminated;
- (7) Permit an unlawful use of a license;
- (8) Misrepresent or fail to state a material fact to the Mayor with respect to a license application or a licensee's activities;
- (9) Falsely represent to any person that he or she is licensed;
- (10) Obtain a drug unless the drug is obtained legally from a legally authorized manufacturer, distributor, or wholesaler; or
- (11) Violate any provision of this chapter, rules issued pursuant to this chapter, or any applicable federal or District law.

### **§ 48-703. License requirements**

- (a) To obtain a license to manufacture, distribute, or wholesale any drug, any person who has a principal place of business in the District shall submit a completed application form with the required application fee to the Mayor and comply with the requirements of this chapter and the rules issued pursuant to this chapter.
- (b) If a person manufactures, distributes, or wholesales any drug at more than one place of business in the District, the person shall apply for a separate license for each place of business.
- (c) If a licensee manufactures, distributes, or wholesales a drug not listed on the application, the licensee shall notify the Mayor prior to the commencement of the activity.
- (d) If a licensee ceases to manufacture, distribute, or wholesale any drug listed in the application, the licensee shall notify the Mayor of the change no later than 7 days after ceasing the activity.
- (e) Each licensee shall maintain records as required by the Mayor, including but not limited to the quantities of each drug manufactured, distributed, or wholesaled daily and the name, address, purchaser, place of delivery, and quantity of any drug sold, transferred, or distributed by a licensee.

(f) Any license issued pursuant to this section shall be issued as a Public Health: Pharmacy and Pharmaceuticals endorsement to a basic business license under the basic business license system as set forth in subchapter I-A of Chapter 28 of Title 47.

**§ 48-704. Licensure of a drug manufacturer, distributor, or wholesaler**

The Mayor shall make available a license application form that requests:

- (1) The name of the applicant and the address of the place of business for which the applicant seeks a license;
- (2) 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 one class of stock in the corporation or who owns 10% or more of the total stock of the corporation;
- (3) 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 (2) and (9) of this section shall be provided by the partner or joint venturer;
- (4) A description of the activity for which the applicant seeks a license;
- (5) A list of any drugs that the applicant proposes to manufacture, distribute, or wholesale in the District;
- (6) Proof of current approval by the United States Food and Drug Administration for registration of producers of drugs and medical devices pursuant to § 510 of the Federal Food, Drug and Cosmetic Act ("Food, Drug and Cosmetic Act"), approved June 25, 1938 (52 Stat. 1040; 21 U.S.C. 360);
- (7) If the applicant proposes to manufacture, distribute, or wholesale a controlled substance as defined in § 102 of the Drug Abuse Prevention and Control Act, approved October 27, 1970 (84 Stat. 1242; 21 U.S.C. 802), proof of current registration with the Mayor and the United States Drug Enforcement Administration;
- (8) A valid certificate of occupancy; and
- (9) A certificate of good standing from the Mayor if the applicant is a corporation.

**§ 48-705. Renewal of license**

Prior to the expiration of a license, the Mayor shall mail a renewal notice to the licensee that includes:

- (1) The expiration date of the current license;
- (2) The date by which the renewal application must be received by the Mayor in order for the renewal license to be issued and mailed to the licensee before the licensee's current license expires;
- (3) The amount of the renewal fee; and
- (4) Any other information the Mayor deems appropriate or necessary to renew the license.

**§ 48-706. Conditional license**

The Mayor may issue a conditional license to a person if the person does not meet all of the requirements of this chapter, the rules issued pursuant to this chapter, or any applicable federal law, provided the failure to meet the requirements does not endanger the health, safety, or welfare of the community, and the Mayor mandates that the requirements be met by a specific date.

**§ 48-707. Registration of an out-of-state drug manufacturer, distributor, repackager, or wholesaler**

- (a) An out-of-state drug manufacturer, distributor, or wholesaler who conducts distribution activities within the District shall register with the Mayor on a form prescribed by the Mayor, renew the registration as required by rule, and pay the required registration fee.
- (b) A person registered to conduct distribution activities within the District shall be licensed or registered and in good standing under federal law and the laws of the state in which the person is incorporated or has a principal place of business.
- (c) The Mayor may withdraw a registration for failure to maintain a license or registration in good standing under state or federal law.

**§ 48-708. Inspections**

(a) The Mayor shall conduct an on-site inspection of an applicant's facility before a license is granted.

(b) The Mayor, at any reasonable hour and consistent with constitutional guidelines, may enter a facility to conduct an announced or unannounced inspection of the facility to determine if the facility is in compliance with this chapter, the rules issued pursuant to this chapter, or any other District or locally enforceable federal law applicable to the manufacture, distribution, or wholesale of drugs.

**§ 48-709. Summary action**

(a) If the Mayor determines that the conduct of a licensee presents an imminent danger to the health and safety of the residents of the District, the Mayor may suspend or revoke the license, or convert the license to a conditional license of the drug manufacturer, distributor, or wholesaler prior to a hearing.

(b) At the time of the suspension, revocation, or restriction of a license, the Mayor shall provide the licensee with written notice that states the action being taken, the basis for the action, and the right of the licensee to request a hearing.

(c) A licensee shall have the right to request a hearing within 3 days of service of notice of the suspension, revocation, or restriction of the license. The Mayor shall hold a hearing within 3 days of receipt of a timely request and shall issue a decision within 3 days of the hearing.

(d) The Mayor shall inform the licensee of the decision in writing and provide findings of fact and conclusions of law. The findings shall be supported by reliable, probative, and substantial evidence. The Mayor shall provide a copy of the decision to each party to a case or to his or her attorney of record.

(e) Any person aggrieved by a decision pursuant to this section may file an appeal with the Mayor within 10 days of the decision.

**§ 48-710. Suspension, denial, or revocation**

(a) The Mayor may deny, suspend, or revoke a license, or convert the license to a conditional license, if the Mayor determines that:

- (1) The person has violated a provision of this chapter, the rules issued pursuant to this chapter, or any other applicable federal or District law; or
- (2) The person fraudulently or deceptively obtained or attempted to obtain a license in violation of this chapter, the rules issued pursuant to this chapter, or any other applicable federal or District law.

(b) The Mayor shall revoke any license issued pursuant to this chapter upon conviction of the licensee for a criminal violation of this chapter, the rules issued pursuant to this chapter, or any applicable federal law.

#### **§ 48-711. Criminal action**

A person who willfully violates § 48-702(1) is guilty of a misdemeanor, and, upon conviction, shall be fined not more than \$ 5,000 for the first offense or \$ 10,000 for the second or subsequent offense, imprisoned for not more than one year, or both. Each day that a violation continues is a separate violation under this chapter.

#### **§ 48-712. Civil infractions**

Civil fines, penalties, and fees may be imposed as sanctions for any violation of this chapter or the rules issued pursuant to this chapter, pursuant to Chapter 18 of Title 2.

#### **§ 48-713. Cease and desist order; embargo**

(a) If the Mayor determines that a hazardous condition exists that may endanger the health, safety, or welfare of the community, the Mayor may issue a cease and desist order to require a violator to cease operation immediately. Any person subject to a cease and desist order may appeal the cease and desist order within 7 days, excluding Saturdays, Sundays, and legal holidays, but shall be required to comply with the order pending appeal. The Mayor shall hold a hearing within 7 days of the receipt of a timely request and issue a decision within 7 days after the hearing.

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

**§ 48-714. Rules**

(a) The Mayor shall issue rules pursuant to this chapter in accordance with the provisions of subchapter I of Chapter 5 of Title 2.

(b) The proposed rules shall include, but not be limited to:

- (1) A schedule of license fees;
- (2) Standards for the exemption of certain employees employed by a licensed manufacturer, distributor, or wholesaler;
- (3) Procedures to govern the issuance, denial, renewal, suspension, conversion, or revocation of a license; and
- (4) Standards pertaining to labeling, handling, recordkeeping, and storage.

**§ 48-715. Exceptions**

This chapter shall not apply to any cosmetic unless the cosmetic is a drug as defined by § 201 of the Food, Drug and Cosmetic Act.

**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
  - § 22-401. APPLICATION FOR IN STATE LICENSURE
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DISTRIBUTORS, REPACKAGERS, AND WHOLESALERS
  - § 22-406. EXEMPTIONS
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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 or 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.<sup>1</sup>
- 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

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

<sup>2</sup> 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.,<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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<sup>3</sup> 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 § 33-1009<sup>4</sup> shall be notified in writing of the action being taken and that the licensee is entitled to a hearing, upon written request

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

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

<sup>6</sup> 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

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

defined under D.C. Code § 33-501 et seq.<sup>8</sup>

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

<sup>9</sup> 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. CONTROLLED SUBSTANCE REGISTRATION FOR**  
**MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS**

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- § 22-1000. COVERAGE
  - § 22-1001. SCHEDULES OF CONTROLLED SUBSTANCES
  - § 22-1002. PERSONS REQUIRED TO REGISTER
  - § 22-1003. APPLICATIONS FOR REGISTRATION
  - § 22-1004. [REPEALED]
  - § 22-1005. PERSONS EXEMPT FROM REGISTRATION FEE
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  - § 22-1013. SUSPENSION OF REGISTRATION PENDING FINAL ORDER
  - § 22-1014. EXTENSION OF REGISTRATION
  - § 22-1015. ADDRESS FOR NOTICES
  - § 22-1016. VIOLATIONS
  - § 22-1017. FAILURE TO COMPLY WITH RULES
  - § 1018-1029 [RESERVED]
  - § 22-1030. CONTROLLED SUBSTANCES FEES
  - § 22-1099. DEFINITIONS
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**§ 22-1000. 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, §§ 48-901.02 et seq.)(2001), hereinafter referred to as the “Act.”
  
- 1000.2        To the extent consistent with the Act, regulations promulgated by the Federal Government pursuant to Title 21, Chapter II, of the Code of Federal Regulations (21CFR Part 1300 to End), and in effect as of the effective date of this chapter, shall be used as a guide in administering the Act.

**§ 22-1001. 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.

## **§ 22-1002. 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 biennially and maintain current a registration issued by the Director in accordance with this chapter, unless exempted by federal law, 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 biennially 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 biennially 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.

### **§ 22-1003. APPLICATIONS FOR REGISTRATION**

- 1003.1 Unless otherwise exempted by federal law or this chapter, a person shall register with the Department and obtain and maintain a registration certificate before the person:
- (a) Manufactures, distributes, or dispenses controlled substances in the District;
  - (b) Conducts research or instructional activities with controlled substances listed in Schedules II through V in the District;
  - (c) Conducts research or instructional activities with a controlled substance listed in Schedule I in the District;
  - (d) Conducts a chemical analysis with controlled substances listed in any schedule in the District; or
  - (e) Engages in any other activity for which registration is required.
- 1003.2 For practitioners, a District of Columbia controlled substances registration issued pursuant to this chapter shall expire simultaneously with the expiration of the practitioner's District of Columbia health professional license, certification, or occupation registration.
- 1003.3 For non-practitioners, a District of Columbia controlled substance registration issued pursuant to this chapter shall expire at 12:00 midnight of December 31 of each even-numbered year.
- 1003.4 Applications to renew a registration must be filed in a timely manner, not less than sixty (60) days prior to the expiration of the registration.
- 1003.5 A registration certificate expires on the date shown on the certificate.
- 1003.6 The Director shall mail a renewal application or a notice to renew to a registrant not less than thirty (30) days before the expiration date shown on the certificate.
- 1003.7 If a person fails to apply for renewal of a registration before the expiration date of his or her registration, he or she shall thereafter apply for a new registration and the prior registration shall be deemed to have expired on the date specified on the

registration.

- 1003.8 Any person who is required to be registered and who is not so registered may apply for registration at any time and may obtain an application form by writing to the Department of Health's Pharmaceutical Control Division, 717 14<sup>th</sup> Street, NW., 6<sup>th</sup> Floor, Washington, D.C. 20005.
- 1003.9 To apply for a controlled substances registration, an applicant shall:
- (a) Submit a completed application to the Department on the required forms which shall be signed by the:
- (1) Applicant, if an individual;
  - (2) General partner, if the applicant is a partnership; or
  - (3) Officer responsible for the applicant, if the applicant is a corporation or other entity; and
- (b) Pay all applicable fees.
- 1003.10 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.
- 1003.11 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.
- 1003.12 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.
- 1003.13 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.
- 1003.14 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.
- 1003.15 If the information requested on the application is not applicable to the applicant, the applicant shall indicate such on the form.
- 1003.16 The Director may require an applicant to submit additional documentation

pertinent to the registration or written statements in support of an application to:

- (a) Clarify application information; or
- (b) Determine if the applicant meets the requirements of this chapter.

1003.17 The Director may deny an application if the applicant fails to provide information within fifteen (15) days of receipt of the Director's request.

1003.18 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.

**§ 22-1004. [REPEALED]**

**§ 22-1005. 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.

**§ 22-1006. 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.

#### **§ 22-1007. 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.

#### **§ 22-1008. 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.

## **§ 22-1009. 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.<sup>1</sup>
- 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, 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;

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<sup>1</sup> As of April 2007, the Pharmaceutical Control Division is now located at 717 14<sup>th</sup> Street, N.W., 6<sup>th</sup> Floor, Washington, D.C. 20005, 202-724-4900.

(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.

## **§ 22-1010. 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.

## **§ 22-1011. 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.

## **§ 22-1012. 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.

### **§ 22-1013. 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.

#### **§ 22-1014. 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.

#### **§ 22-1015. ADDRESS FOR NOTICES**

1015.1 Unless the Act or this chapter otherwise provide, all notice required under this chapter to be sent to the Department or Director shall be sent to the Department of Health, Pharmaceutical Control Division, 717 14<sup>th</sup> Street, NW, 6<sup>th</sup> Floor, Washington, DC 20005, or to its successor agency by certified mail, return receipt requested.

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.

#### **§ 22-1016. 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.

## § 22-1017. 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.

## § 1018-1029. [RESERVED]

## § 22-1030. CONTROLLED SUBSTANCES FEES

1030.1 The fees for a controlled substances registration shall be as follows:

- (a) Initial registration-- \$130.00
- (b) Biennial renewal -- \$130.00
- (c) Late filing-- \$35.00
- (d) Duplicate certificate-- \$25.00
- (e) Reinspection-- \$130.00

## § 22-1099. DEFINITIONS

1099.1 When used in this chapter, the following words or phrases shall have the meaning 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) (2001).

**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-** Department of Health

**Director-** Director of the Department

**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.

**Federal Act-** means the Controlled Substance Act (84 Stat. 1242; 21 U.S.C. 801) or the Controlled Substance Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

**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.

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

**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.

**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.

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE II. PRESCRIPTION DRUGS**  
**CHAPTER 8A. AFFORDABILITY OF PRESCRIPTION DRUGS- ACCESSRX**  
**PROGRAM**

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SUBCHAPTER I. ACCESSRX PROGRAM

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**SUBCHAPTER I. ACCESSRX PROGRAM**  
**PART A. GENERAL**

**§ 48-831.01. Findings and declaration of intent.**

The Council finds that:

- (1) Affordability is critical in providing access to prescription drugs for District of Columbia residents.
- (2) AccessRx enables the District to take steps to make prescription drugs more affordable for qualified District residents, thereby increasing the overall health of District residents, promoting healthy communities, and protecting the public health and welfare.
- (3) AccessRx can be integrated with any District-wide program for the uninsured.
- (4) The intent of AccessRx is not to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified District residents under AccessRx.

**§ 48-831.02. Definitions.**

For the purposes of this chapter, the term:

- (1) "AccessRx" means the District of Columbia AccessRx program established by 48-831.03.
- (2) "Average wholesale price" means the wholesale price charged for a specific commodity that is assigned by the drug wholesaler and is listed in a nationally recognized drug pricing registry that is updated daily and charged to the retail pharmacy.
- (3) "Basic component of AccessRx" includes the provision of drugs and medications for cardiac conditions and high blood pressure, diabetes, arthritis, anticoagulation, hyperlipidemia, osteoporosis, chronic obstructive pulmonary disease and asthma,

incontinence, thyroid diseases, glaucoma, Parkinson's disease, multiple sclerosis, amyotrophic lateral sclerosis, and other conditions approved by the Department. The term "basic component of AccessRx" shall also include the provision of over-the-counter medications that are prescribed by a health care provider and approved as cost-effective by the Department.

(4) (A) "Covered entity" means:

(i) Any hospital or medical service organization, insurer, health coverage plan, or health maintenance organization licensed in the District that contracts with another entity to provide prescription drug benefits for its customers or clients;

(ii) Any health program administered by the Department or the District in its capacity as provider of health coverage; or

(iii) Any employer, labor union, or other group of persons organized in the District that contracts with another entity to provide prescription drug benefits for its employees or members.

(B) The term "covered entity" does not include a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, long-term care, or other limited benefit health insurance policies and contracts.

(5) "Covered individual" means a member, participant, enrollee, contract holder, policy holder, or beneficiary of a covered entity who is provided a prescription drug benefit by the covered entity. The term "covered individual" includes a dependent or other person provided a prescription drug benefit through a policy, contract, or plan for a covered individual.

(6) "Department" means the Department of Health.

(7) "Director" means the Director of the Department of Health.

(8) "District" means the District of Columbia.

(9) "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

(10) "Initial discounted price" for a drug means the price the Department pays D.C. Medicaid participating retail pharmacies for that drug for District of Columbia Medicaid recipients.

(11) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.

(12) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or

affiliate of a manufacturer.

(13) "Marketing" means advertising and promotional activities, including, but not limited to, the activities described in 48-831.03.

(14) "National Drug Code registration number" means the number registered for a drug pursuant to the listing system established by the United States Food and Drug Administration under section 510 of the Federal Food, Drug, and Cosmetic Act, approved October 10, 1962 (76 Stat. 794; 21 U.S.C. § 360).

(15) "Participating retail pharmacy" or "retail pharmacy" means a retail pharmacy located in the District, or another business licensed to dispense prescription drugs in the District, that participates in the program.

(16) "Pharmacy benefits management" means a service provided to covered entities to facilitate the provision of prescription drug benefits to covered individuals, including negotiating pricing and other terms with drug manufacturers and retail pharmacies. "Pharmacy benefits management" may include any or all of the following:

(A) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(B) Clinical formulary development and management services;

(C) Rebate contracting and administration;

(D) Certain patient compliance, therapeutic intervention, and generic substitution programs; and

(E) Disease management programs.

(17) "Pharmacy benefits manager" means an entity that performs pharmacy benefits management. The term "pharmacy benefits manager" includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity.

(18) "Qualified resident" means a resident of the District who is eligible for the AccessRx program pursuant to this subchapter.

(19) "Secondary discounted price" means the initial discounted price minus any further discounts paid for out of the AccessRx Fund.

(20) "Supplemental component of AccessRx" includes all prescription drugs and medications provided under the D.C. Medicaid program excluding those provided pursuant to the basic component of AccessRx.

**§ 48-831.03. Establishment of AccessRx.**

(a) AccessRx is hereby established. AccessRx shall be administered by the Department, which shall utilize, among other things, manufacturer rebates, pharmacy discounts, and aggregate purchasing to reduce prescription drug prices. In addition, the Department shall investigate the purchase of prescription drugs from outside of the United States.

(b) The Department shall administer AccessRx and other medical and pharmaceutical assistance programs in a manner that is advantageous to the programs and to the enrollees in those programs. In implementing this subchapter, the Department may coordinate the other programs and AccessRx and may take actions to enhance efficiency, reduce the cost of prescription drugs, and maximize the benefits to the programs and enrollees, including providing the benefits of AccessRx to enrollees in other programs.

**§ 48-831.04. Cost containment and savings with respect to existing publicly funded pharmaceutical programs.**

The Department shall make every effort to reduce and contain the cost of prescription drugs purchased for publicly funded pharmaceutical assistance programs, including D.C. Medicaid, the D.C. Health Care Alliance, and the Department of Mental Health. These efforts shall include manufacturer rebates, pharmacy discounts, and reductions through aggregate purchases, and may include importation of pharmaceuticals from outside of the United States. These savings shall be deposited in the AccessRx Fund established in 48-831.10.

**§ 48-831.05. Rebate agreement.**

A drug manufacturer or labeler that sells prescription drugs in the District through any publicly funded pharmaceutical assistance program shall enter into a rebate agreement with the Department under AccessRx. The rebate agreement shall require the manufacturer or labeler to make rebate payments to the District for deposit in the AccessRx Fund each calendar quarter or according to a schedule established by the Department.

**§ 48-831.06. Rebate amount.**

(a) The Director of the Department shall negotiate the amount of the rebate required from a manufacturer or labeler in accordance with this subchapter.

(b) The Director shall take into consideration the rebate calculated under the Medicaid Rebate Program pursuant to section 1927 of the Social Security Act, approved November 5, 1990 (104 Stat. 1388-143; 42 U.S.C. § 1396r-8), the average wholesale price of prescription drugs, and any other information on prescription drug prices and price discounts.

(c) The Director shall use the Director's best efforts to obtain an initial rebate amount equal to

or greater than the rebate calculated under the Medicaid program pursuant to 42 U.S.C. § 1396r-8.

(d) With respect to the rebate that takes effect on October 1, 2005 pursuant to 48-831.33(d), the Director shall use the Director's best efforts to obtain an amount equal to or greater than the amount of any discount, rebate, or price reduction for prescription drugs provided to the federal government. If the Department is not able to achieve the rebate amount described by this subsection, the Department shall report that fact to the standing committee of the Council having jurisdiction over the Department.

**§ 48-831.07. Operation of program.**

(a) Participating retail pharmacies shall submit claims to the Department to verify the amount charged to qualified residents and to receive reimbursement.

(b) The Department shall not impose transaction charges on participating retail pharmacies that submit claims or receive payments under AccessRx.

(c) On a periodic basis, to be established by the Department, the Department shall reimburse a participating retail pharmacy for:

(1) The discounted price provided to uninsured qualified residents pursuant to § 48-831.33; and

(2) Prescription drugs dispensed to low-income elderly pursuant to § 48-831.23.

(d) The Department shall conduct ongoing quality assurance activities similar to those used in the D.C. Medicaid program.

(e) The Department shall collect utilization data from participating retail pharmacies submitting claims necessary to calculate the amount of the rebate from the manufacturer or labeler. The Department shall protect the confidentiality of all information subject to confidentiality protection under District or federal law, rule or regulation.

**§ 48-831.08. Discrepancies in rebate amounts.**

(a) (1) Upon receipt of the data from the Department, the manufacturer or labeler shall calculate the quarterly payment. If a discrepancy is discovered, the Department may, at its expense, hire a mutually agreed-upon independent auditor to verify the manufacturer's calculation. If a discrepancy is still found, the manufacturer or labeler shall justify its calculation or make payments to the Department for any additional amount due. The manufacturer or labeler may, at its expense, hire a mutually agreed-upon independent auditor to verify the accuracy of the utilization data provided by the Department. If a discrepancy is discovered, the Department shall justify its data or refund any excess payment to the manufacturer or labeler.

(2) If the dispute over the rebate amount is not resolved, a request for a hearing with supporting documentation shall be submitted to the Office of Administrative Hearings. Failure to resolve the dispute may be cause for terminating the drug rebate agreement and denying payment to the manufacturer or labeler for any drugs.

(b) All prescription drugs of a manufacturer or labeler that enters into a rebate agreement that appear on the list of approved drugs shall be immediately available and the cost of the drugs shall be reimbursed, except as provided in this section.

**§ 48-831.09. Action with regard to nonparticipating manufacturers and labelers.**

(a) The names of manufacturers and labelers who do and do not enter into rebate agreements pursuant to this subchapter are public information. The Department shall release this information to health care providers and the public on a regular basis. The Department also shall publicize participation by manufacturers and labelers that is of particular benefit to the public.

(b) The Department shall impose prior authorization requirements, as permitted by law, in all publicly funded pharmaceutical assistance programs to the extent the Department determines it is appropriate to do so in order to encourage manufacturer and labeler participation in AccessRx, as long as the additional prior authorization requirements remain consistent with the goals of the D.C. Medicaid program and Title 19 of the Social Security Act, approved July 30, 1965 (79 Stat. 343; 42 U.S.C. § 1396 et seq.).

**§ 48-831.10. AccessRx Fund.**

(a) The AccessRx Fund is established as a nonlapsing, dedicated fund, into which shall be deposited revenue from manufacturers and labelers that pay rebates pursuant to this subchapter and any appropriations or allocations designated for the AccessRx Fund, along with accruing interest, to be used for the purposes specified in subsection (b) of this section.

(b) All funds in the AccessRx Fund, including any surplus or interest, shall be used to:

(1) Reimburse retail pharmacies for discounted prices provided to uninsured qualified residents pursuant to § 48-831.33;

(2) Pay benefits described in § 48-831.23; and

(3) Reimburse the Department for contracted services, including pharmacy claims processing fees, administrative and associated computer costs, and other reasonable program costs.

(c) The funds deposited in the AccessRx Fund shall not revert to the General Fund but shall continually be available for the uses designated in subsection (b) of this section, subject to

authorization by Congress in an appropriations act.

**§ 48-831.11. Eligibility procedures.**

The Department shall:

- (1) Establish simplified procedures for determining eligibility and issuing AccessRx enrollment cards to qualified residents;
- (2) Undertake outreach efforts to build public awareness of AccessRx and maximize enrollment of qualified residents; and
- (3) Adjust the requirements and terms of AccessRx to accommodate any new federally funded prescription drug program.

**§ 48-831.12. Method of prescribing or ordering drugs.**

The method of prescribing or ordering drugs may include, but is not limited to, the use of standard or larger prescription refill sizes in order to minimize operational costs and maximize economy. Unless the prescribing physician indicates otherwise, the use of the lowest cost generic or chemically equivalent drugs is required; provided, that these drugs are of the same quality and have the same mode of delivery as is provided to the general public, consistent with good pharmaceutical practice.

**§ 48-831.13. Third-party administration.**

The Department may contract with one or more third parties to administer any or all components of AccessRx, including outreach, eligibility, claims, administration, and rebate recovery and redistribution.

**§ 48-831.14. Waivers.**

The Department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this chapter.

**§ 48-831.15. Annual summary report.**

The Department shall submit a written report on the enrollment and financial status of AccessRx to the Council by the 2nd week of January each year.

**§ 48-831.16. Agreements with governments of other jurisdictions and other entities.**

The District may negotiate and enter into purchasing alliances and regional strategies with the governments of other jurisdictions, and with other public and private entities, for the purpose of reducing prescription drug prices for residents of the District.

**§ 48-831.17. Rulemaking.**

The Mayor is authorized to issue any rules necessary to implement the provisions of this subchapter.

**SUBCHAPTER I. ACCESSRX PROGRAM  
PART. B ACCESSRX FOR THE ELDERLY**

**§ 48-831.21. Establishment of AccessRx for the low-income elderly.**

(a) The Department shall conduct a program to provide low-cost prescription and nonprescription drugs, medications, and medical supplies to low-income elderly individuals ("AccessRx for low-income elderly").

(b) The Director shall provide sufficient personnel to ensure efficient administration of the program. The extent and magnitude of the program shall be determined by the Director on the basis of the calculated need of the recipient population and the available funds.

(c) The Department may not spend more on this program than is available through appropriations from the General Fund, dedicated revenue, federal or other grants, and other established and committed funding sources. The Director may accept, for the purpose of carrying out this program:

(1) Federal funds appropriated under any federal law relating to the furnishing of free or low-cost drugs to elderly individuals, and may take such action as is necessary for the purposes of carrying out that federal law; and

(2) Funds that may be available from any other agency of government, individual, group, or corporation.

**§ 48-831.22. Eligibility for low-income elderly.**

To be eligible, an individual shall:

(1) Be a resident of the District;

(2) Be at least 62 years of age; and

- (3) Have a household income that is not more than 200% of the federal poverty level.

**§ 48-831.23. Payment for drugs by low-income elderly.**

(a) The Director shall establish the amount of payment to be made by eligible low-income elderly individuals toward the cost of prescription or nonprescription drugs, medications, and medical supplies furnished under AccessRx for low-income elderly; provided, that:

- (1) The total cost paid by the low-income elderly individual for any covered purchase of a prescription or nonprescription drug or medication provided under the basic component of AccessRx does not exceed 20% of the price allowed for that prescription under AccessRx rules, or \$ 2, whichever is greater; and

- (2) For the supplemental component of AccessRx, except as otherwise provided in this section, the total cost paid by the low-income elderly individual for any covered purchase of a prescription drug or medication shall not exceed 50% of the price allowed for that prescription under AccessRx.

(b) Prior to January 1, 2006, the Director shall establish annual limits on the costs incurred by eligible household members for prescription or nonprescription drugs or medications covered under AccessRx for low-income elderly. After the annual limits have been established, beginning on January 1, 2007, AccessRx for low-income elderly shall pay 80% of the cost of all prescription or nonprescription drugs or medications covered by the supplemental component of AccessRx. The limits shall be set by the Director by regulation as necessary to operate the program within the AccessRx for low-income elderly budget.

**SUBCHAPTER I. ACCESSRX PROGRAM**  
**PART. C ACCESS FOR UNINSURED RESIDENTS OF THE DISTRICT OF**  
**COLUMBIA**

**§ 48-831.31. Establishment of AccessRx for uninsured District residents.**

The Department shall conduct a program to negotiate low-cost prescription and nonprescription drugs, medications, and medical supplies for uninsured District residents ("AccessRx for uninsured"). The Director shall provide sufficient personnel to ensure efficient administration of the program. The extent and magnitude of the program shall be determined by the Director on the basis of the calculated need of the recipient population and available funds.

**§ 48-831.32. Eligibility of the uninsured.**

To be eligible, an individual shall:

- (1) Be a resident of the District;
- (2) Have a household income that is not more than 350% of the federal poverty level;  
and
- (3) Not be enrolled in any public or private medical insurance program.

**§ 48-831.33. Discounted prices for uninsured qualified residents.**

- (a) Any participating retail pharmacy that sells prescription drugs covered by a rebate agreement pursuant to § 48-831.05 shall discount the retail price of those drugs sold to uninsured qualified residents.
- (b) The Department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.
- (c) Beginning January 1, 2005, a participating retail pharmacy shall offer the initial discounted price.
- (d) Beginning no later than October 1, 2005, a participating retail pharmacy shall offer the secondary discounted price, if available.

**SUBCHAPTER I. ACCESSRX PROGRAM  
PART. D. ACCESSRX PHARMACEUTICAL RESOURCE CENTER**

**§ 48-831.41. Establishment of AccessRx Pharmaceutical Resource Center.**

The Department shall conduct a program to provide life saving prescription and nonprescription medications and medical supplies by enrolling eligible individuals into pharmaceutical assistance programs. Of the funds appropriated for the Department of Health for fiscal year 2006, the Director shall enter into a contract with the Archdiocesan Health Care Network, Catholic Charities in the amount of \$1.956 million to operate and administer the program and provide sufficient personnel to ensure appropriate oversight of the program.

**§ 48-831.42. Eligibility.**

(a) To be eligible, an individual shall:

- (1) Be a resident of the District;
- (2) Have a household income not exceeding 300% of the federal poverty level; and
- (3) Lack prescription coverage.

(b) Eligibility shall be determined by the contract organization administering the program.

(c) Eligibility for District Medicaid, DC Healthcare Alliance, and other public programs shall be screened at the time an individual seeks to enroll in the program, and appropriate referrals shall be made to the Income Maintenance Administration in the Department of Human Services.

**SUBCHAPTER II. TRANSPARENT BUSINESS PRACTICES****§ 48-832.01. Fiduciary duty.**

(a) A pharmacy benefits manager owes a fiduciary duty to a covered entity and shall discharge that duty in accordance with all applicable laws. In performance of that duty, a pharmacy benefits manager shall adhere to the practices set forth in this section.

(b) (1) A pharmacy benefits manager shall:

- (A) Perform its duties with care, skill, prudence, and diligence and in accordance with the standards of conduct applicable to a fiduciary in an enterprise of a like character and with like aims;
- (B) Discharge its duties with respect to the covered entity for the primary purpose of providing benefits to covered individuals and defraying reasonable expenses incurred; and
- (C) Notify the covered entity in writing of any activity, policy or practice of the pharmacy benefits manager that directly or indirectly presents any conflict of interest with the duties imposed by this subchapter; and

(2) A pharmacy benefits manager that receives from any drug manufacturer or labeler any payment or benefit of any kind in connection with the utilization of prescription drugs by covered individuals, including payments or benefits based on volume of sales or market share, shall pass that payment or benefit on in full to the covered entity. This provision does not prohibit the covered entity from agreeing by contract

to compensate the pharmacy benefits manager by returning a portion of the benefit or payment to the pharmacy benefits manager.

(c) (1) Upon request by a covered entity, a pharmacy benefits manager retained by that covered entity shall:

(A) Provide information showing the quantity of drugs purchased by the covered entity and the net cost to the covered entity for the drugs. This information shall include all rebates, discounts, and other similar payments. If requested by the covered entity, the pharmacy benefits manager shall provide such quantity and net cost information on a drug-by-drug basis by National Drug Code registration number rather than on an aggregated basis; and

(B) Disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefits manager and any prescription drug manufacturer or labeler, including, without limitation, formulary management and drug-substitution programs, educational support, claims processing, and data sales fees.

(2) A pharmacy benefits manager providing information to a covered entity under this section may designate that information as confidential. Information designated as confidential may not be disclosed by the covered entity to any other person or entity without the consent of the pharmacy benefits manager, unless ordered by a court of the District for good cause shown.

(d) The following provisions apply to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual:

(1) The pharmacy benefits manager may substitute a lower-priced therapeutically equivalent drug for a higher-priced prescribed drug.

(2) If the substitute drug costs more than the prescribed drug, the substitution shall be made for medical reasons that benefit the covered individual. If a substitution is being made under this paragraph, the pharmacy benefits manager shall obtain the approval of the prescribing health professional or that person's authorized representative after disclosing to the covered individual and the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefits manager as a result of the substitution.

(3) The pharmacy benefits manager shall transfer in full to the covered entity any benefit or payment received in any form by the pharmacy benefits manager as a result of a prescription drug substitution under paragraphs (1) or (2) of this subsection.

#### **§ 48-832.02. Compliance.**

Compliance with the requirements of this subchapter is required in all contracts between a

pharmacy benefits manager and a covered entity executed after May 18, 2004.

**§ 48-832.03. Enforcement.**

A violation of this subchapter is a violation of Chapter 39 of Title 28, for which a fine of not more than \$ 10,000 may be adjudged.

**SUBCHAPTER III. FULL DISCLOSURE OF PRESCRIPTION DRUG  
MARKETING COSTS**

**§ 48-833.01. Requirement to disclose prescription drug marketing costs.**

A manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District shall report marketing costs for prescription drugs in the District. These marketing costs shall be reported to the Department for the purposes of assisting the District in its role as a purchaser of prescription drugs and as an administrator of prescription drug programs, enabling the District to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services, and furthering the role of the District as guardian of the public interest.

**§ 48-833.02. Manner of reporting.**

By July 1st of each year, a manufacturer or labeler of prescription drugs that directly or indirectly distributes prescription drugs for dispensation to residents of the District shall file a report with the Department in the form and manner provided by the Department. The report shall be accompanied by payment of a fee, as set by the Department in rule, to support the work of the Department under this subchapter.

**§ 48-833.03. Content of annual report by manufacturer or labeler.**

(a) Except as provided in subsection (b) of this section, the annual report filed pursuant to § 48-853.02 shall include the following information as it pertains to marketing activities conducted within the District in a form that provides the value, nature, purpose, and recipient of the expense:

(1) All expenses associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone communications as they pertain to District residents;

(2) With regard to all persons and entities licensed to provide health care in the District, including health care professionals and persons employed by them in the

District, carriers licensed under Title 31, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:

(A) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;

(B) All expenses associated with food, entertainment, gifts valued at more than \$ 25, and anything provided to a health care professional for less than market value;

(C) All expenses associated with trips and travel; and

(D) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and

(3) The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (1) and (2) of this subsection, including all forms of payment to those employees. The cost reported under this paragraph shall reflect only that portion of payment to employees or contractors that pertains to activities within the District or to recipients of the advertising or promotional activities who are residents of or are employed in the District.

(b) The following marketing expenses are not subject to the requirements of this subchapter:

(1) Expenses of \$ 25 or less;

(2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; and

(3) Scholarships and reimbursement of expenses for attending a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

#### **§ 48-833.04. Department reports.**

By November 30th of each year, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Council and the Corporation Counsel. By January 1, 2005, and every 2 years thereafter, the Department shall provide a report to the Council and the Corporation Counsel, providing information in aggregate form, containing an analysis of the data submitted to the Department, including the scope of prescription drug marketing activities and expenses and their effect on the cost,

utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

**§ 48-833.05. Confidentiality; public information.**

Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this subchapter is confidential and is not a public record. Data compiled in aggregate form by the Department for the purposes of reporting required by this subchapter is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

**§ 48-833.06. Penalty.**

This subchapter may be enforced in a civil action brought by the Corporation Counsel. A manufacturer or labeler that fails to provide a report as required by this subchapter commits a civil violation for which a fine of \$ 1,000 plus costs and attorney's fees may be adjudged.

**§ 48-833.07. Rulemaking.**

The Mayor is authorized to issue any rules necessary to implement the provisions of this subchapter.

**§ 48-833.08. Report.**

The Department shall report to the committee of the Council having jurisdiction over health and human services matters on or before January 1, 2005 and on or before July 1, 2005 on the assessment of fees on manufacturers and labelers of prescription drugs.

**§ 48-833.09. Applicability date.**

This subchapter shall apply as of July 1, 2004.

## Chapter 8B. Off-label Informed Consent.

### § 48-841.01. Short title

This chapter may be cited as the "Off-Label Informed Consent Act of 2008."

### § 48-841.02. Definitions

For the purposes of this chapter, the term:

- (1) "FDA" means the federal Food and Drug Administration.
- (2) "Off-label use" means the use of a prescription drug to treat a condition that is not included in the labeling for that medication, as approved by the federal Food and Drug Administration.
- (3) "Prescriber" means a person who is licensed, registered, or otherwise authorized by the District to prescribe and administer prescription drugs in the course of a professional practice.

### § 48-841.03. Off-label use of medication

Before prescribing, administering, or furnishing a prescription medication for an off-label use, a prescriber shall make every reasonable effort to:

- (1) Explain to the patient, in easily understood terms, that the medication is not within the uses approved for that medication by the FDA; and
- (2) Provide the patient with information regarding the potential risks and side effects associated with using the medication for the off-label use.

### § 48-841.04. Penalties

Failure to comply with this chapter may be used by a health-occupation board as a factor when determining licensure status for a prescriber; provided, that a prescriber shall not be subject to an adverse licensure action if the Board of Medicine determines that the prescribing, administering, or furnishing of the prescription medication for the off-label use was clearly evidence-based and the common practice within the medical community.

## Chapter 8C. Medication Advisory Committees.

### § 48-842.01. Short title

This chapter may be cited as the "Medication Advisory Committee Receiving Gifts or Remuneration Prohibition Act of 2008."

### § 48-842.02. Definitions

For the purposes of this chapter, the term:

- (1) "Medication advisory committee" means any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by the government of the District of Columbia.

(2) "Pharmaceutical company" means any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biological product, including any person acting as its agent or representative.

#### § 48-842.03. Prohibition on gifts and remuneration

(a) A pharmaceutical company shall not offer a gift or remuneration of any kind to a member of a medication advisory committee.

(b) A member of a medication advisory committee shall not accept a gift or remuneration of any kind from a pharmaceutical company.

(c) Nothing in this section shall prohibit the offering or acceptance of medication samples to members of a medication advisory committee who are licensed physicians engaged in the practice of medicine.

#### § 48-842.04. Penalties

### Chapter 8D. Pharmaceutical Education Program.

A violation of this chapter shall be punishable by a fine of \$ 1,000 per violation.

#### § 48-843.01. Short title

This chapter may be cited as the "Pharmaceutical Education Program Establishment Act of 2008."

#### § 48-843.02. Definitions

For the purposes of this chapter, the term "pharmaceutical product" shall have the same meaning as provided in § 3-1201.02(10A)(B)(iii).

#### § 48-843.03. Establishment of the Pharmaceutical Education Program

(a) There is established an evidence-based Pharmaceutical Education Program ("Program") within the Department of Health. The Program shall:

(1) Educate prescribers who participate in the District of Columbia Medicaid program, and other publicly funded, contracted, or subsidized health-care programs, on the therapeutic and cost-effective utilization of pharmaceutical products;

(2) Inform prescribers about pharmaceutical product marketing practices that are intended to circumvent competition from generic, other therapeutically-equivalent alternatives, or other evidence-based treatment options; and

(3) Utilize, or incorporate into the Program, other independent educational resources or models proven effective in promoting high-quality, evidenced-based, cost-effective information regarding the effectiveness and safety of pharmaceutical products.

(b) The Program shall be made available to prescribers who do not participate in the District of Columbia Medicaid program or other publicly funded, contracted, or subsidized health-care programs on a subscription basis.

(c) If approved by the Board of Medicine, the PE program may be used to satisfy continuing education requirements for the practice of medicine.

#### § 48-843.04. Applicability

This chapter shall apply upon inclusion of its fiscal effect in an approved budget and financial plan.

### Chapter 8E. Evaluation Of Pharmaceutical Regulation.

#### § 48-844.01. Short title

This chapter may be cited as the "SafeRX Evaluation Act of 2008."

#### § 48-844.02. Definitions

For the purposes of this chapter, the term:

- (1) "Pharmaceutical product" shall have the same meaning as provided in § 3-1201.02(10A)(B)(iii).
- (2) "Practice of pharmaceutical detailing" shall have the same meaning as provided in § 3-1201.02(10A).

#### § 48-844.03. Evaluation

(a) Within 60 days of September 30, 2010, the Department of Health shall submit to the Council a comprehensive evaluation on the effectiveness of D.C. Law 17-131, which shall include:

- (1) The number of individuals licensed to engage in the practice of pharmaceutical detailing since March 26, 2008;
- (2) The number of applicants for licensure to engage in the practice of pharmaceutical detailing not approved by the Board of Pharmacy;
- (3) The number of applicants for licensure to engage in the practice of pharmaceutical detailing for whom the educational requirements were waived;
- (4) An assessment of the appropriateness and efficacy of the continuing education requirements established pursuant to D.C Law 17-131;
- (5) The number of individuals identified as engaging in the practice of pharmaceutical detailing without a license;
- (6) The amount of fines levied against persons charged with engaging in the practice of pharmaceutical detailing without a license;
- (7) The total amount and origin of revenue deposited into the Board of Pharmacy Fund;
- (8) The total amount of funds deposited into the Board of Pharmacy Fund that were used for the administration of the duties of the Board of Pharmacy;
- (9) The number and types of penalties levied for failure to comply with the requirements of off-label use of medication as set forth in § 48-841.03;
- (10) The number and amount of fines levied for violations as a result of pharmaceutical companies offering gifts or remuneration in violation of § 48-842.03;

(11) The number of persons who participated in the Pharmaceutical Education Program established by § 48-843.03;

(12) An assessment of the quality and effectiveness of the Pharmaceutical Education Program based on an assessment of data gathered from those who participated in the program. The data may be gathered by surveying those who participated in the program, using an evaluative instrument developed for that purpose;

(13) An assessment of the extent to which regulation of the practice of pharmaceutical detailing has improved the practice of selling, providing information about, or promoting a pharmaceutical product.

(b) The evaluation may be used to determine if D.C. Law 17-131 should be repealed or amended.

D.C. Code Title 3. District of Columbia Boards and Commissions.  
Subtitle I. General  
Chapter 12. Health Occupations Boards  
Unit. A. General

Licensure and Regulation of Pharmaceutical Detailers

§ 3-1202.08. Board of Pharmacy [Formerly § 2-3302.8]

- (a) There is established a Board of Pharmacy to consist of 7 members appointed by the Mayor.
- (b) (1) The Board shall regulate the practice of pharmacy and the practice of pharmaceutical detailing.  
(2) The Board is authorized to:
  - (A) Establish a code of ethics for the practice of pharmaceutical detailing; and
  - (B) Collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.
- (c) Of the members of the Board, 5 shall be pharmacists licensed in the District and 2 shall be consumer members.
- (d) Except as provided in subsection (e) of this section, members of the Board shall be appointed for terms of 3 years.
- (e) Of the members initially appointed under this section, 2 shall be appointed for a term of 1 year, 2 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years.

§ 3-1205.01. License required [Formerly § 2-3305.1]

A license issued pursuant to this chapter is required to practice medicine, acupuncture, chiropractic, registered nursing, practical nursing, dentistry, dental hygiene, dietetics, marriage and family therapy, massage therapy, naturopathic medicine, nutrition, nursing home administration, occupational therapy, optometry, pharmaceutical detailing, pharmacy, physical therapy, podiatry, psychology, social work, professional counseling, audiology, speech-language pathology, and respiratory care or to practice as an anesthesiologist assistant, physician assistant, physical therapy assistant, occupational therapy assistant, or surgical assistant in the District, except as provided in this chapter. A certification issued pursuant to this chapter is required to practice advanced practice registered nursing.

§ 3-1207.41. Scope of practice

- (a) An individual shall be licensed by the Board of Pharmacy before engaging in the practice of pharmaceutical detailing in the District of Columbia.
- (b) A pharmaceutical detailer shall not:
  - (1) Engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact;
  - (2) Use a title or designation that might lead a licensed health professional, or an employee or representative of a licensed health professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation, in the District of Columbia, unless the pharmaceutical detailer currently holds such a license; or
  - (3) Attend patient examinations without the consent of the patient.

§ 3-1207.42. Qualifications for licensure

In addition to the general qualifications for licensure set forth in this chapter, an individual applying for a license to practice pharmaceutical detailing shall:

(1) Establish, to the satisfaction of the Board of Pharmacy, that he or she is a graduate of a recognized institution of higher education;

(2) Pay the required licensure fee; and

(3) Submit to the Board of Pharmacy a notarized statement that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics, as established by the Board pursuant to § 3-1202.08 and in accordance with this subchapter.

§ 3-1207.43. Waiver of licensure requirements

The Board of Pharmacy shall waive the educational requirements for an applicant for licensure as a pharmaceutical detailer who can demonstrate, to the satisfaction of the Board, that he or she has been performing the functions of a pharmaceutical detailer, as defined in this subchapter, on a full-time, or substantially full-time, basis for at least 12 months immediately preceding March 26, 2008.

§ 3-1207.44. Continuing education

The Mayor shall establish by rule continuing-education requirements as a condition for renewal of the license to practice pharmaceutical detailing.

§ 3-1207.45. Penalties

In addition to the penalties set forth in this chapter, a person who practices pharmaceutical detailing without a license shall be subject to a fine of up to \$ 10,000.

**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE III. ILLEGAL DRUGS**  
**CHAPTER 9. CONTROLLED SUBSTANCES**  
**UNIT A. CONTROLLED SUBSTANCES ACT**

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SUBCHAPTER IV. OFFENSES AND PENALTIES

- § 48-904.01. Prohibited acts A; penalties
- § 48-904.02. Prohibited acts B; penalties
- § 48-904.03. Prohibited acts C; penalties
- § 48-904.03a. Prohibited acts D; penalties
- § 48-904.04. Penalties under other laws
- § 48-904.05. Effect of acquittal or conviction under federal law
- § 48-904.06. Distribution to minors
- § 48-904.07. Enlistment of minors to distribute
- § 48-904.07a. Drug free zones
- § 48-904.08. Second or subsequent offenses
- § 48-904.09. Attempt; conspiracy
- § 48-904.10. Possession of drug paraphernalia

SUBCHAPTER V. ENFORCEMENT AND ADMINISTRATIVE PROVISIONS

- § 48-905.01. Cooperative arrangements; confidentiality
- § 48-905.02. Forfeitures
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SUBCHAPTER VI. MISCELLANEOUS

- § 48-906.01. Pending proceedings
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- § 48-906.03. Severability

SUBCHAPTER VII. DRUG INTERDICTION AND DEMAND REDUCTION FUND

- § 48-907.01. Establishment of Fund
  - § 48-907.02. Funding and disbursements
  - § 48-907.03. Grant Award Committee
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**SUBCHAPTER IV. OFFENSES AND PENALTIES**

**§ 48-904.01. Prohibited acts A; penalties**

(a) (1) Except as authorized by this chapter, it is unlawful for any person knowingly or intentionally to manufacture, distribute, or possess, with intent to manufacture or distribute, a

controlled substance.

(2) Any person who violates this subsection with respect to:

(A) A controlled substance classified in Schedule I or II that is a narcotic or abusive drug shall be imprisoned for not more than 30 years or fined not more than \$ 500,000, or both;

(B) Any other controlled substance classified in Schedule I, II, or III, except for a narcotic or abusive drug, is guilty of a crime and upon conviction may be imprisoned for not more than 5 years, fined not more than \$ 50,000, or both; except that upon conviction of manufacturing, distributing or possessing with intent to distribute 1/2 pound or less of marijuana, a person who has not previously been convicted of manufacturing, distributing or possessing with intent to distribute a controlled substance or attempting to manufacture, distribute, or possess with intent to distribute a controlled substance may be imprisoned for not more than 180 days or fined not more than \$ 1000 or both;

(C) A substance classified in Schedule IV, is guilty of a crime and upon conviction may be imprisoned for not more than 3 years, fined not more than \$ 25,000, or both; or

(D) A substance classified in Schedule V, is guilty of a crime and upon conviction may be imprisoned for not more than one year, fined not more than \$ 10,000, or both.

(b) (1) Except as authorized by this chapter, it is unlawful for any person to create, distribute, or possess with intent to distribute a counterfeit substance.

(2) Any person who violates this subsection with respect to:

(A) A counterfeit substance classified in Schedule I or II that is a narcotic or abusive drug shall be imprisoned for not more than 30 years or fined not more than \$ 500,000, or both;

(B) Any other counterfeit substance classified in Schedule I, II, or III, except for a narcotic or abusive drug, is guilty of a crime and upon conviction may be imprisoned for not more than 5 years, fined not more than \$ 50,000, or both;

(C) A counterfeit substance classified in Schedule IV, is guilty of a crime and upon conviction may be imprisoned for not more than 3 years, fined not more than \$ 25,000, or both; or

(D) A counterfeit substance classified in Schedule V, is guilty of a crime and upon conviction may be imprisoned for not more than 1 year, fined not more

than \$10,000, or both.

(c) Repealed.

(d) It is unlawful for any person knowingly or intentionally to possess a controlled substance unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his or her professional practice, or except as otherwise authorized by this chapter. Any person who violates this subsection is guilty of a misdemeanor and upon conviction may be imprisoned for not more than 180 days, fined not more than \$ 1,000, or both.

(e) (1) If any person who has not previously been convicted of violating any provision of this chapter, or any other law of the United States or any state relating to narcotic or abusive drugs or depressant or stimulant substances is found guilty of a violation of subsection (d) of this section and has not previously been discharged and had the proceedings dismissed pursuant to this subsection, the court may, without entering a judgment of guilty and with the consent of such person, defer further proceedings and place him or her on probation upon such reasonable conditions as it may require and for such period, not to exceed one year, as the court may prescribe. Upon violation of a condition of the probation, the court may enter an adjudication of guilt and proceed as otherwise provided. The court may, in its discretion, dismiss the proceedings against such person and discharge him or her from probation before the expiration of the maximum period prescribed for such person's probation. If during the period of probation such person does not violate any of the conditions of the probation, then upon expiration of such period the court shall discharge such person and dismiss the proceedings against him or her. Discharge and dismissal under this subsection shall be without court adjudication of guilt, but a nonpublic record thereof shall be retained solely for the purpose of use by the courts in determining whether or not, in subsequent proceedings, such person qualifies under this subsection. Such discharge or dismissal shall not be deemed a conviction for purposes of disqualifications or disabilities imposed by law upon conviction of a crime (including the penalties prescribed under § 48-904.08 for second or subsequent convictions) or for any other purpose.

(2) Upon the dismissal of such person and discharge of the proceedings against him under paragraph (1) of this subsection, such person may apply to the court for an order to expunge from all official records (other than the nonpublic records to be retained under paragraph (1) of this subsection) all recordation relating to his or her arrest, indictment or information, trial, finding of guilty, and dismissal and discharge pursuant to this subsection. If the court determines, after hearing, that such person was dismissed and the proceedings against him or her discharged, it shall enter such order. The effect of such order shall be to restore such person, in the contemplation of this law, to the status he or she occupied before such arrest or indictment or information. No person as to whom such order has been entered shall be held thereafter under any provision of any law to be guilty of perjury or otherwise giving a false statement by reason of failure to recite or acknowledge such arrest, or indictment, or trial in response to any inquiry made of him or her for any purpose.

(f) The prosecutor may charge any person who violates the provisions of subsection (a) or (b) of this section relating to the distribution of or possession with intent to distribute a controlled or counterfeit substance with a violation of subsection (d) of this section if the interests of justice so dictate.

(g) For the purposes of this section, "offense" means a prior conviction for a violation of this section or a felony that relates to narcotic or abusive drugs, marijuana, or depressant or stimulant drugs, that is rendered by a court of competent jurisdiction in the United States.

#### **§ 48-904.02. Prohibited acts B; penalties**

(a) It is unlawful for any person:

- (1) Who is subject to subchapter III of this chapter to distribute or dispense a controlled substance in violation of § 48-903.08;
- (2) Who is a registrant, to manufacture a controlled substance not authorized by registration, or to distribute or dispense a controlled substance not authorized by registration to another registrant or other authorized person;
- (3) To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice, or information required under this chapter;
- (4) To refuse an entry into any premises for any inspection authorized by this chapter;
- (5) Knowingly to keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or other structure or place, which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances or which is used for keeping or selling them in violation of this chapter;
- (6) Who is a law-enforcement official, as designated by the Mayor, or a designated civilian employee of the Metropolitan Police Department, to divulge any knowledge relating to the records, order forms, or prescriptions of registrants which he or she received by virtue of his or her office, except in connection with officially authorized duties or in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the registrant to whom such records, order forms, or prescriptions relate is a party; or
- (7) To use to his or her own advantage or to reveal, other than to duly authorized officers or employees of the District of Columbia or the United States, or to the courts when relevant in any judicial proceeding under this subchapter or subchapter III of this chapter, any information acquired in the course of an authorized inspection concerning any method or process which as a trade secret is entitled to protection.

(b) Except as provided for in subsection (c) of this section, any person who violates this section shall, with respect to any violation, be subject to a civil penalty of not more than \$ 50,000.

(c) If a violation of this section is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was so committed, such person shall be guilty of a crime and upon conviction may be imprisoned for not more than one year, fined not more than \$ 50,000, or both.

#### **§ 48-904.03. Prohibited acts C; penalties**

(a) It is unlawful for any person knowingly or intentionally:

(1) To distribute as a registrant a controlled substance classified in Schedule I or II, except pursuant to an order form as required by § 48-903.07;

(2) To use in the course of the manufacture or distribution of a controlled substance a registration number which is fictitious, revoked, suspended, or issued to another person;

(3) To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge;

(4) To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter; or

(5) To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render the drug a counterfeit substance.

(b) Any person who violates this section is guilty of a crime and upon conviction may be imprisoned for not more than 4 years, fined not more than \$ 50,000, or both.

#### **§ 48-904.03a. Prohibited acts D; penalties**

(a) It shall be unlawful for any person to knowingly open or maintain any place to manufacture, distribute, or store for the purpose of manufacture or distribution a narcotic or abusive drug.

(b) Any person who violates this section shall be imprisoned for not less than 5 years nor more than 25 years, fined not more than \$ 500,000, or both.

**§ 48-904.04. Penalties under other laws**

Any penalty imposed for violation of this chapter is in addition to, and not in lieu of, any civil or administrative penalty or sanction otherwise authorized by law.

**§ 48-904.05. Effect of acquittal or conviction under federal law**

No person shall be prosecuted for a violation of any provision of this chapter if such person has been acquitted or convicted under any United States statute governing the sale or distribution of controlled substances of the same act or omission which is alleged to constitute a violation of this chapter.

**§ 48-904.06. Distribution to minors**

(a) Any person who is 21 years of age or over and who violates § 48-904.01(a) by distributing a controlled substance which is listed in Schedule I or II and which is a narcotic drug, phencyclidine, or a phencyclidine immediate precursor to a person who is under 18 years of age may be punished by the fine authorized by § 48-904.01(a)(2)(A), by a term of imprisonment of up to twice that authorized by § 48-904.01(a)(2)(A), or by both.

(b) Any person who is 21 years of age or over and who violates § 48-904.01(a) by distributing for remuneration any other controlled substance which is listed in Schedule I, II, III, IV, or V, except for phencyclidine or a phencyclidine immediate precursor, to a person who is under 18 years of age may be punished by the fine authorized by § 48-904.01(a)(2)(B), (C), or (D), respectively, by a term of imprisonment up to twice that authorized by § 48-904.01(a)(2)(B), (C), or (D), respectively, or both.

**§ 48-904.07. Enlistment of minors to distribute**

(a) Any person who is 21 years of age or over and who enlists, hires, contracts, or encourages any person under 18 years of age to sell or distribute any controlled substance, in violation of § 48-904.01(a), for the profit or benefit of such person who enlists, hires, contracts, or encourages this criminal activity shall be punished for sale or distribution in the same manner as if that person directly sold or distributed the controlled substance.

(b) Anyone found guilty of subsection (a) of this section shall be subject to the following additional penalties:

(1) Upon a first conviction the party may be imprisoned for not more than 10 years,

fined not more than \$ 10,000, or both;

(2) Upon a second or subsequent conviction, the party may be imprisoned for not more than 20 years, fined not more than \$ 20,000, or both.

#### **§ 48-904.07a. Drug free zones**

(a) All areas within 1000 feet of a public or private day care center, elementary school, vocational school, secondary school, public charter school, junior college, college, or university, or any public swimming pool, playground, video arcade, youth center, public library, or in and around public housing, as defined in section 3(1) of the United States Housing Act of 1937, approved August 22, 1974 (88 Stat. 654; 42 U.S.C. § 1437a(b)), the development or administration of which is assisted by the United States Department of Housing and Urban Development, or an event sponsored by any of the above entities shall be declared a drug free zone.

(b) Any person who violates § 48-904.01(a) by distributing or possessing with the intent to distribute a controlled substance which is listed in Schedule I, II, III, IV, or V within a drug free zone shall be punished by a fine up to twice that otherwise authorized by this chapter to be imposed, by a term of imprisonment up to twice that otherwise imposed, or both.

#### **§ 48-904.08. Second or subsequent offenses**

(a) Any person convicted of a second or subsequent offense under this chapter may be imprisoned for a term up to twice the term otherwise authorized, fined an amount up to twice that otherwise authorized, or both.

(b) For purposes of this section, an offense is considered a second or subsequent offense if, prior to commission of the offense, the offender has at any time been convicted under this chapter or under any statute of the United States or of any state relating to narcotic drugs, depressants, stimulants, or hallucinogenic drugs.

(c) A person who is convicted of violating § 48-904.06 may be sentenced according to the provisions of § 48-904.06 or according to the provisions of this section, but not both.

#### **§ 48-904.09. Attempt; conspiracy**

Any person who attempts or conspires to commit any offense defined in this subchapter is punishable by imprisonment or fine or both which may not exceed the maximum punishment prescribed for the offense, the commission of which was the object of the attempt or conspiracy.

**§ 48-904.10. Possession of drug paraphernalia**

Whoever, except for a physician, dentist, chiropodist, or veterinarian licensed in the District of Columbia or a state, registered nurse, registered embalmer, manufacturer or dealer in embalming supplies, wholesale druggist, industrial user, official of any government having possession of the proscribed articles by reason of his or her official duties, nurse or medical laboratory technician acting under the direction of a physician or dentist, employees of a hospital or medical facility acting under the direction of its superintendent or officer in immediate charge, person engaged in chemical, clinical, pharmaceutical or other scientific research, acting in the course of their professional duties, has in his or her possession a hypodermic needle, hypodermic syringe, or other instrument that has on or in it any quantity (including a trace) of a controlled substance with intent to use it for administration of a controlled substance by subcutaneous injection in a human being shall be fined not more than \$ 1000 or imprisoned for not more than 180 days, or both.

**SUBCHAPTER V. ENFORCEMENT AND ADMINISTRATIVE PROVISIONS****§ 48-905.01. Cooperative arrangements; confidentiality**

(a) The Mayor shall cooperate with the Board of Education, federal agencies, and other state agencies in discharging the Mayor's responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, the Mayor may:

- (1) Arrange for the exchange of general information among governmental officials concerning the general use and abuse of controlled substances; and
- (2) Coordinate and cooperate in training programs concerning controlled substance law enforcement within the District of Columbia.

(b) Results, information, and evidence received from the D.E.A. relating to the regulatory functions of this chapter, including results of inspections conducted by it, may be relied and acted upon by the Mayor in the exercise of the Mayor's regulatory functions under this chapter.

(c) (1) A practitioner engaged in medical practice or research shall not nor shall be compelled to:

- (A) Furnish to the Mayor the name or identity of a patient or research subject without the prior consent of the patient or research subject; or
- (B) Furnish the name or identity of an individual that the practitioner is obligated to keep confidential in any civil, criminal, administrative, legislative, or other proceedings in the District of Columbia without prior

consent of such individual.

(2) This section per se shall not limit, in a criminal investigation or prosecution or in an administrative proceeding by the Commission on Licensure to Practice the Healing Art in the District of Columbia, the authority to subpoena dispensing logs or other records of a practitioner containing information concerning the sale, prescription, or distribution of controlled substances under this chapter. The court may order sealed any information furnished without consent, pursuant to the provisions of this subsection.

### **§ 48-905.02. Forfeitures**

(a) The following are subject to forfeiture:

(1) All controlled substances which have been manufactured, distributed, dispensed, or acquired in violation of this chapter;

(2) All raw materials, products, and equipment of any kind which are used, or intended for use, in manufacturing, compounding, processing, or delivering any controlled substance in violation of this chapter;

(3) All property which is used, or intended for use, as a container for property described in paragraph (1) or (2) of this subsection;

(4) All conveyances, including aircraft, vehicles or vessels, which are used, or intended for use, to transport, or in any manner to facilitate the transportation, for the purpose of sale or receipt of property described in paragraph (1) or (2) of this subsection; provided, that:

(A) No conveyance used by any person as a common carrier in the transaction of business as a common carrier is subject to forfeiture under this section unless it appears that the owner or other person in charge of the conveyance is a consenting party or privy to a violation of this chapter;

(B) No conveyance is subject to forfeiture under this section by reason of any act or omission established by the owner thereof to have been committed or omitted without his or her knowledge or consent;

(C) Repealed; or

(D) A forfeiture of a conveyance encumbered by a bona fide security interest is subject to the interest of the secured party if he or she neither had knowledge of nor consented to the act or omission;

(5) All books, records, and research products and materials, including formulas, microfilm, tapes, and data, which are used, or intended for use, in violation of this

chapter;

(6) All cash or currency which has been used, or intended for use, in violation of this chapter;

(7) Everything of value furnished or intended to be furnished in exchange for a controlled substance in violation of this chapter, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, or securities used or intended to be used to facilitate any violation of this chapter.

(A) No property shall be forfeited under this paragraph, to the extent of the interest of an owner, by reason of any act or omission established by the owner to have been committed or omitted without the owner's knowledge or consent; and

(B) All moneys, coins and currency found in close proximity to forfeitable controlled substances, forfeitable drug manufacturing or distributing paraphernalia or records of the importation, manufacture, or distribution of controlled substances, are presumed to be forfeitable under this paragraph. The burden of proof is upon any claimant of the property to rebut this presumption; and

(8) Any real property that is used or intended to be used in any manner to commit or facilitate the commission of a violation of this chapter, except that:

(A) No real property shall be forfeited under this paragraph by reason of an act or omission established by the owner to have been committed or omitted without the knowledge and consent of the owner;

(B) Real property shall not be subject to forfeiture for a violation of § 48-904.01(d); and

(C) The forfeiture of real property encumbered by a bona fide security interest shall be subject to the interest of the secured party if the secured party had no knowledge and did not consent to the act or omission that constituted a violation of this chapter.

(a-1) All moneys, coins and currency forfeited pursuant to this chapter shall be deposited as provided in § 23-527 [sic].

(b) Property subject to forfeiture under this chapter may be seized by law enforcement officials, as designated by the Mayor, or designated civilian employees of the Metropolitan Police Department, upon process issued by the Superior Court of the District of Columbia having jurisdiction over the property, or without process if authorized by other law.

(c) In the event of seizure pursuant to subsection (b) of this section, proceedings under

subsection (d) of this section shall be instituted promptly.

(d) (1) All controlled substances, the lawful possession of which is not established or the title to which cannot be ascertained, which come into the custody of law-enforcement officials of the District of Columbia, or any designated civilian employees of the Metropolitan Police Department, shall be delivered promptly to the United States Department of Justice or its delegate for disposal, except that controlled substances which may be needed as evidence in any criminal or administrative proceeding pursuant to the provisions of this chapter or the provisions of any federal controlled substances law shall, upon delivery to the United States Department of Justice, not be so disposed of until the public official in charge of prosecuting any violation under this chapter shall certify that such controlled substances are no longer needed as evidence.

(2) Property, other than controlled substances, taken or detained under this section shall not be subject to replevin, but is deemed to be in the custody of the Mayor. When property is seized under this chapter, the Mayor shall:

(A) Place the property under seal;

(B) Remove the property to a place designated by the Mayor; or

(C) Remove the property to an appropriate location for disposition in accordance with law.

(3) (A) After a proper showing of probable cause for the seizure is made, the Mayor shall cause notice of the seizure of property, other than controlled substances, and the Mayor's intention to forfeit and sell or otherwise dispose of the property in accordance with this chapter to be published for at least 2 successive weeks in a local newspaper of general circulation. In addition, the Mayor shall provide written notice of the seizure together with information on the applicable procedures for claiming the property to each party who is known or in the exercise of reasonable diligence should be known by the Mayor to have a right of claim to the seized property. Notice to each party shall be by registered or certified mail, return receipt requested.

(B) Any person claiming the property may, at any time within 30 days from the date of receipt of notice of seizure, file with the Mayor a claim stating his or her interest in the property. Upon the filing of a claim, the claimant shall give a bond to the District government in the penal sum of \$ 2,500 or 10% of the fair market value of the claimed property (as appraised by the Chief of the Metropolitan Police Department), whichever is lower, but not less than \$ 250, with sureties to be approved by the Mayor. In case of forfeiture of the claimed property, the costs and expenses of the forfeiture proceedings shall be deducted from the bonds. Any costs that exceed the amount of the bond shall be paid by the claimant. In determining the fair market value of the property seized, the Chief of the Metropolitan Police Department shall consider any verifiable and reasonable evidence of value that the claimant may present. The

balance of the proceeds shall be transferred to the Drug Interdiction and Demand Reduction Fund ("Fund") created by subchapter VII of this chapter. The Fund shall remain available until expended regardless of the expiration of the fiscal year in which the proceeds were collected. The Fund shall be distributed in the following descending order of priority:

- (i) To fund law enforcement activities of the Metropolitan Police Department of the District of Columbia, except that, beginning October 1, 1990, not more than 49% of the total amount deposited to the Fund in the immediately preceding quarter-year period shall be used for this purpose in the next succeeding quarter-year period; and
- (ii) To provide grants to fund community-based drug education, prevention, and demand reduction programs;

(C) If a claim and bond (or application for a waiver of bond) are not filed within 30 days of receipt of notice, and if either the property seized has a value of less than \$ 250,000 or the property seized is a conveyance subject to forfeiture under the provisions of paragraph (a)(4) of this section, the Mayor, after determining that the property is forfeitable under this chapter, shall declare the property forfeited and shall dispose of the property in accordance with the provisions of paragraph (4) of this subsection. If the Mayor determines that the seized property is not forfeitable under this chapter and is not otherwise subject to forfeiture, the Mayor shall return the property to its rightful owner.

(D) If it appears to the Mayor that any property seized under this paragraph is liable to perish, waste, or be greatly reduced in value by the keeping, or that the expense of keeping is disproportionate to the value of the property, the Mayor may proceed to advertise and sell the property at auction or otherwise dispose of the property under rules promulgated by the Mayor.

(E) If the property seized is not forfeited or disposed of in accordance with subparagraphs (C) and (D) of this paragraph, the Mayor shall request the Corporation Counsel to apply to the Superior Court of the District of Columbia for forfeiture of the property in accordance with the rules of the Superior Court of the District of Columbia.

(F) Whenever any person who has an interest in forfeited property files with the Mayor, either before or after the sale or disposition of property, a petition for remission or mitigation of the forfeiture, the Mayor shall remit or mitigate the forfeiture upon the terms and conditions as the Mayor deems reasonable if the Mayor finds:

- (i) That the forfeiture was incurred without willful negligence or

without any intention on the part of the petitioner to violate the law; or

(ii) That mitigating circumstances justify the remission or mitigation of the forfeiture.

(G) In all suits or actions brought for forfeiture of any property seized under this chapter when the property is claimed by any person, the burden of proof shall be on the claimant once the Mayor has established probable cause as provided in subsection (a) of this section.

(H) The Mayor shall, pursuant to subchapter I of Chapter 5 of Title 2, issue proposed rules to implement the provisions of this paragraph. The proposed rules shall be submitted to the Council for a 45-day period of review, excluding Saturdays, Sundays, legal holidays, and days of Council recess. If the Council does not approve or disapprove the proposed rules, in whole or in part, by resolution within this 45-day review period, the proposed rules shall be deemed approved. Nothing in this section shall affect any requirements imposed upon the Mayor by subchapter I of Chapter 5 of Title 2.

(4) When property, other than controlled substances, is forfeited under this chapter, the Mayor shall:

(A) Retain it for official use;

(B) Sell that which is not required by law to be destroyed and which is not harmful to the public. All proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody, advertising, and court costs shall be deducted from the proceeds. The balance of the proceeds shall be used, and shall remain available until expended regardless of the expiration of the fiscal year in which they were collected, to finance law enforcement activities of the Metropolitan Police Department of the District of Columbia, with any remaining balance used to finance programs which shall serve to rehabilitate drug addicts, educate citizens, or prevent drug addiction;

(C) Remove the property for disposition in accordance with law; or

(D) Forward it to the D.E.A. for disposition.

(e) During the course of any civil forfeiture proceeding pursuant to this section, which involves real property, the Mayor shall file a notice of the proceeding with the Recorder of Deeds. The notice shall include the legal description of the property and indicate that civil forfeiture is being sought. The Recorder of Deeds shall record the notice against the title of any real property for which civil forfeiture is being sought. Upon resolution of the proceeding, the Recorder of Deeds shall be notified of the disposition of the action.

### § 48-905.03. Burden of proof

(a) It is not necessary for the prosecution to negate any exemption or exception in this chapter in any complaint, information, indictment, or other pleading or in any trial, hearing, or other proceeding under this chapter. The burden of proof of any exemption or exception is upon the person claiming it.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this chapter, he or she is presumed not to be the holder of the registration or form. The burden of proof is upon him or her to rebut the presumption.

#### **§ 48-905.04. Educational programs; research purposes**

(a) The Mayor shall establish and operate an educational program consisting of films, lectures, panel discussions, or whatever other educational device the Mayor deems necessary and appropriate to enlighten persons on the habitual use of controlled substances in general and to instill in persons participating in such a program a respect for the law and legal institutions.

(b) The Mayor shall cooperate with the Board of Education in preparing similar programs for school children with the purpose of preventing their abuse of controlled substances.

(c) The Mayor shall prepare and operate similar and appropriate programs for children found to be delinquent for violation of the provisions of this chapter.

(d) The Mayor may authorize the possession and distribution of controlled substances by persons engaged in research. Possession and distribution of controlled substances by such persons, in the course of their research and to the extent of the authorization, does not violate the provisions of this chapter.

#### **§ 48-905.05. Administrative inspections**

(a) The Mayor may make administrative inspections of controlled premises in accordance with the following provisions:

(1) For purposes of this section only, the term "controlled premises" means:

(A) Places where persons registered or exempted from registration requirements under this chapter are required to keep records; and

(B) Places including factories, warehouses, establishments, and conveyances in which persons registered or exempted from registration requirements under this chapter are permitted to hold, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled substance.

(2) When authorized by an administrative inspection warrant issued pursuant to

subsection (b) of this section, an officer, an employee designated by the Mayor, or a designated civilian employee of the Metropolitan Police Department, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.

(3) When authorized by an administrative inspection warrant, an officer or employee designated by the Mayor may:

(A) Inspect and copy records required by this chapter to be kept;

(B) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and, except as provided in paragraph (5) of this subsection, all other things therein, including records, files, papers, processes, controls, and facilities bearing on violation of this chapter; and

(C) Inventory any stock of any controlled substance therein and obtain samples thereof.

(4) This section does not prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with § 48-905.07 nor does it prevent entries and administrative inspections, including seizures of property, without a warrant:

(A) If the owner, operator, or agent in charge of the controlled premises consents;

(B) In situations presenting imminent danger to health or safety;

(C) In situations involving inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant;

(D) In any other exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking; or

(E) In all other situations in which a warrant is not constitutionally required.

(5) 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.

(b) Issuance and execution of administrative inspection warrants shall be as follows:

(1) A judge of the Superior Court of the District of Columbia, upon proper oath or

affirmation showing probable cause, may issue warrants for the purpose of conducting administrative inspections authorized by this chapter or rules hereunder, and seizures of property appropriate to the inspections. For purposes of the issuance of administrative inspection warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this chapter or rules hereunder, sufficient to justify administrative inspection of the area, premises, building, or conveyance in the circumstances specified in the application for the warrant.

(2) A warrant shall issue only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the issuance of the warrant exist or that there is probable cause to believe they exist, a warrant shall be issued identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected, if any. The warrant shall:

- (A) State the grounds for its issuance and the name of each person whose affidavit has been taken in support thereof;
- (B) Be directed to a person authorized and designated by the Mayor to execute it;
- (C) Command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified;
- (D) Identify the item or types of property to be seized, if any; and
- (E) Direct that it be served during normal business hours and designate the judge to whom it shall be returned.

(3) A warrant issued pursuant to this section must be executed and returned within 10 days of its date unless, upon a showing of a need for additional time, the Court orders otherwise. If property is seized pursuant to a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.

#### **§ 48-905.06. Chemist reports**

In a proceeding for a violation of this chapter, the official report of chain of custody and of

analysis of a controlled substance performed by a chemist charged with an official duty to perform such analysis, when attested to by that chemist and by the officer having legal custody of the report and accompanied by a certificate under seal that the officer has legal custody, shall be admissible in evidence as evidence of the facts stated therein and the results of that analysis. A copy of the certificate must be furnished upon demand by the defendant or his or her attorney in accordance with the rules of the Superior Court of the District of Columbia or, if no demand is made, no later than 5 days prior to trial. In the event that the defendant or his or her attorney subpoenas the chemist for examination, the subpoena shall be without fee or cost and the examination shall be as on cross-examination.

#### **§ 48-905.07. Mayoral subpoenas**

(a) In any investigation relating to the Mayor's functions under this subchapter with respect to controlled substances, the Mayor may subpoena witnesses, compel the attendance and testimony of witnesses, and require the production of any records (including books, papers, documents, and other tangible things which constitute or contain evidence) which the Mayor finds relevant or material to the investigation. The attendance of witnesses and the production of records may be required from any place in the District of Columbia. Witnesses summoned under this section shall be paid the same fees and mileage that are paid witnesses in the Superior Court of the District of Columbia.

(b) A subpoena issued under this section may be served by any person designated in the subpoena to serve it. Service upon a natural person may be made by personal delivery of the subpoena to that person. Service may be made upon a domestic or foreign corporation or upon a partnership or other unincorporated association which is subject to suit under a common name, by delivering the subpoena to an officer, to a managing or general agent, or to any other agent authorized by appointment or by law to receive service of process. The affidavit of the person serving the subpoena entered on a true copy thereof by the person serving it shall be proof of service.

(c) In the case of contumacy by or refusal to obey a subpoena issued to any person, the Mayor may invoke the aid of any District of Columbia court within the jurisdiction of which the investigation is carried on or of which the subpoenaed person is an inhabitant, or in which the subpoenaed person carries on business or may be found, to compel compliance with the subpoena. The court may issue an order requiring the subpoenaed person to appear before the Mayor to produce records, if so ordered, or to give testimony touching the matter under investigation. Any failure to obey the order of the court may be punished by the court as a contempt thereof.

## SUBCHAPTER VI. MISCELLANEOUS

### § 48-906.01. Pending proceedings

- (a) Prosecution for any violation of the laws repealed by D.C. Law 4-29, pursuant to § 604, which were initiated prior to August 5, 1981, is not affected or abated by this chapter. If the offense being prosecuted is similar to an offense set out in subchapter IV of this chapter, then the penalties under subchapter IV of this chapter apply if they are less than those under prior law.
- (b) Civil seizures or forfeitures commenced prior to August 5, 1981, are not affected by this chapter.
- (c) All administrative proceedings pending under prior laws which are superseded by this chapter shall be continued and brought to a final determination in accord with the laws and rules in effect prior to August 5, 1981.
- (d) The Mayor shall initially permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dispensing of any controlled substance prior to August 5, 1981, and who are registered or licensed by the District of Columbia on August 5, 1981, pursuant to laws and rules in effect immediately prior thereto.
- (e) This chapter applies to violations of law, seizures and forfeiture, administrative proceedings, and investigations which occur following its effective date.

### § 48-906.02. Continuation of orders and rules

Any orders and rules issued under any law affected by this chapter and in effect on August 5, 1981, and not in conflict with it, continue in effect until modified, superseded, or repealed.

### § 48-906.03. Severability

If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

## SUBCHAPTER VII. DRUG INTERDICTION AND DEMAND REDUCTION FUND

### § 48-907.01. Establishment of Fund

There is established within the District of Columbia Treasury a nonlapsing revolving fund to be known as the Drug Interdiction and Demand Reduction Fund ("Fund"), to be operated as

an enterprise fund controlled by the Chief of the Metropolitan Police Department to receive all funds generated from fines collected and assets derived from the enforcement of § 48-904.03a or § 48-905.02.

**§ 48-907.02. Funding and disbursements**

Any funds from whatever source derived shall be deposited as soon as practicable into the Fund. Any deposit of funds shall be secured in a manner consistent with deposit of revenues by the District of Columbia government. The Fund shall be distributed in the following descending order of priority:

- (1) To fund law enforcement activities of the Metropolitan Police Department of the District of Columbia, except that, beginning October 1, 1990, not more than 49% of the total amount deposited to the Fund in the immediately preceding quarter-year period shall be used for this purpose in the next succeeding quarter-year period; and
- (2) To fund substance abuse education, prevention, and treatment activities of the Alcohol and Drug Abuse Administration.

**§ 48-907.03. Grant Award Committee**

[Repealed.]

**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE III. ILLEGAL DRUGS**  
**CHAPTER 9. CONTROLLED SUBSTANCES**  
**UNIT B. GENERAL**

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SUBCHAPTER VIII. SEARCHES INVOLVING CONTROLLED SUBSTANCES

- § 48-921.01. Arrests, searches and seizures without warrant
- § 48-921.02. Search warrants; issuance, execution and return; property inventory; filing of proceedings; interference with service

SUBCHAPTER IX. PHYSICIANS AND CONTROLLED SUBSTANCES

- § 48-931.01. Physician privilege
  - § 48-931.02. Supervision by licensed practitioner
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**SUBCHAPTER VIII. SEARCHES INVOLVING CONTROLLED SUBSTANCES**

**§ 48-921.01. Arrests, searches and seizures without warrant**

(a) Repealed.

(b) Arrests without a warrant, and searches of the person and seizures pursuant thereto, may be made for a violation of subsection (a) of this section hereof by police officers, as in the case of a felony, upon probable cause that the person arrested is violating such subsection at the time of his arrest.

(c) No evidence discovered in the course of any such arrest, search, or seizure authorized by subsection (b) of this section hereof shall be admissible in any criminal proceeding against the person arrested unless at the time of such arrest he was violating the provisions of this section.

**§ 48-921.02. Search warrants; issuance, execution and return; property inventory; filing of proceedings; interference with service**

(a) A search warrant may be issued by any judge of the Superior Court of the District of Columbia or by a United States Magistrate for the District of Columbia when any controlled substances are manufactured, possessed, controlled, sold, prescribed, administered, dispensed, or compounded, in violation of the provisions of the District of Columbia Uniform Controlled Substances Act of 1981, and any such controlled substances and any other property designed for use in connection with such unlawful manufacturing, possession, controlling, selling, prescribing, administering, dispensing, or compounding may be seized thereunder, and shall be subject to such disposition as the Court may make thereof and such

controlled substances may be taken on the warrant from any house or other place in which they are concealed.

(b) A search warrant cannot be issued but upon probable cause supported by affidavit particularly describing the property and the place to be searched.

(c) The judge or Magistrate must, before issuing the warrant, examine on oath the complainant and any witnesses he may produce, and require their affidavits or take their depositions in writing and cause them to be subscribed by the parties making them.

(d) The affidavits or depositions must set forth the facts tending to establish the grounds of the application or probable cause for believing that they exist.

(e) If the judge or Magistrate is thereupon satisfied of the existence of the grounds of the application or that there is probable cause to believe their existence, he must issue a search warrant, signed by him, to the Chief of Police of the District of Columbia or any member of the Metropolitan Police Department or to the Chief or any member of the United States Park Police, stating the particular grounds or probable cause for its issue and the names of the persons whose affidavits have been taken in support thereof, and commanding the Chief of Police or member of the Metropolitan Police Department or to the Chief or any member of the United States Park Police forthwith to search the place named for the property specified and to bring it before the judge or Magistrate.

(f) A search warrant may in all cases be served by any of the officers mentioned in its direction, but by no other person, except in aid of the officer on his requiring it, he being present and acting in its execution.

(g) The officer may break open any outer or inner door or window of a house, or any part of a house, or anything therein, to execute the warrant, if, after notice of his authority and purpose, he is refused admittance.

(h) The judge or Magistrate shall insert a direction in the warrant that it may be served at any time in the day or night.

(i) A search warrant must be executed and returned to the judge or Magistrate who issued it within 10 days after its date; after the expiration of this time the warrant, unless executed, is void.

(j) When the officer or the designated civilian employee of the Metropolitan Police Department takes property under the warrant, he must give a copy of the warrant together with a receipt for the property taken (specifying it in detail) to the person from whom it was taken by him, or in whose possession it was found; or in the absence of any person, he must leave it in the place where he found the property.

(k) The officer or the designated civilian employee of the Metropolitan Police Department, the District of Columbia Housing Authority Police Department, or the United States Park

Police must forthwith return the warrant to the judge or Magistrate and deliver to him a written inventory of the property taken, made publicly or in the presence of the person from whose possession it was taken, and of the applicant for the warrant, if they are present, verified by the affidavit of the officer at the foot of the inventory and taken before the judge or Magistrate at the time, to the following in effect: "I, \_\_\_\_\_, the officer by whom this warrant was executed, do swear that the above inventory contains a true and detailed account of all the property taken by me on the warrant."

(l) The judge or Magistrate must thereupon, if required, deliver a copy of the inventory to the person from whose possession the property was taken and to the applicant for the warrant.

(m) The judge or Magistrate must annex the affidavits, search warrant, return, inventory, and evidence, and at once file the same, together with a copy of the record of his proceedings, with the Clerk of the Superior Court of the District of Columbia.

(n) Whoever shall knowingly and willfully obstruct, resist, or oppose any such officer or person in serving or attempting to serve or execute any such search warrant, or shall assault, beat, or wound any such officer or person, knowing him to be an officer or person so authorized, shall be fined not more than \$ 1,000 or imprisoned not more than 2 years.

## SUBCHAPTER IX. PHYSICIANS AND CONTROLLED SUBSTANCES

### § 48-931.01. Physician privilege

Information communicated to a physician in an effort unlawfully to procure controlled substances, or unlawfully to procure the administration of any such controlled substances, shall not be deemed a privileged communication.

### § 48-931.02. Supervision by licensed practitioner

A licensed practitioner, in good faith and in the course of professional practice only, may cause controlled substances to be administered by a nurse, certified emergency medical technician/paramedic, certified emergency medical technician/intermediate paramedic, or intern under the licensed practitioner's direction and supervision.

**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE III. ILLEGAL DRUGS**  
**CHAPTER 10. DRUG FREE ZONES**

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- § 48-1001. Definitions
  - § 48-1002. Procedure for establishing a drug free zone
  - § 48-1003. Notice of a drug free zone
  - § 48-1004. Prohibition
  - § 48-1005. Penalties
- 

**§ 48-1001. Definitions**

For the purposes of this chapter, the term:

- (1) "Chief of Police" means the Chief of the Metropolitan Police Department as the designated agent of the Mayor.
- (2) "Disperse" means to depart from the designated drug free zone and not to reassemble within the drug free zone with anyone from the group ordered to depart for the duration of the zone.
- (3) "Drug free zone" means public space on public property in an area not to exceed a square of 1000 feet on each side that is established pursuant to § 48-1002.
- (4) "Illegal drug" means the same as the term "controlled substance" § 48-901.02.
- (5) "Police Department" means the Metropolitan Police Department.

**§ 48-1002. Procedure for establishing a drug free zone**

(a) The Chief of Police may declare any public area a drug free zone for a period not to exceed 120 consecutive hours. The Chief of Police shall inform each of the 7 Police District Commanders and the Council of the District of Columbia of the declaration of a drug free zone.

(b) In determining whether to designate a drug free zone, the Chief of Police shall consider the following:

- (1) The occurrence of a disproportionately high number of arrests for the possession or distribution of illegal drugs in the proposed drug free zone within the preceding 6-month period;
- (2) Any number of homicides related to the possession or distribution of illegal drugs that were committed in the proposed drug free zone within the preceding 6-month

period;

(3) Objective evidence or verifiable information that shows that illegal drugs are being sold and distributed on public space on public property within the proposed drug free zone; and

(4) Any other verifiable information from which the Chief of Police may ascertain whether the health or safety of residents who live in the proposed drug free zone are endangered by the purchase, sale, or use of illegal drugs or other illegal activity.

### **§ 48-1003. Notice of a drug free zone**

Upon the designation of a drug free zone, the Police Department shall mark each block within the drug free zone by using barriers, tape, or police officers that post the following information in the immediate area of, and borders around, the drug free zone:

(1) A statement that it is unlawful for a person to congregate in a group of 2 or more persons for the purposes of participating in the use, purchase, or sale of illegal drugs within the boundaries of a drug free zone, and to fail to disperse after being instructed to disperse by a uniformed officer of the Police Department who reasonably believes the person is congregating for the purpose of participating in the use, purchase, or sale of illegal drugs;

(2) The boundaries of the drug free zone;

(3) A statement of the effective dates of the drug free zone designation; and

(4) Any other additional notice to inform the public of the drug free zone.

### **§ 48-1004. Prohibition**

(a) It shall be unlawful for a person to congregate in a group of 2 or more persons in public space on public property within the perimeter of a drug free zone established pursuant to § 48-1002 and to fail to disperse after being instructed to disperse by a uniformed officer of the Police Department who reasonably believes the person is congregating for the purpose of participating in the use, purchase, or sale of illegal drugs.

(b) In making a determination that a person is congregating in a drug free zone for the purpose of participating in the use, purchase, or sale of illegal drugs, the totality of the circumstances involved shall be considered. Among the circumstances which may be considered in determining whether such purpose is manifested are:

(1) The conduct of a person being observed, including, but not limited to, that such person is behaving in a manner raising a reasonable belief that the person is engaging or is about to engage in illegal drug activity, such as the observable distribution of

small packages to other persons, the receipt of currency for the exchange of a small package, operating as a lookout, warning others of the arrival of police, concealing himself or herself or any object which reasonably may be connected to unlawful drug-related activity, or engaging in any other conduct normally associated by law enforcement agencies with the illegal distribution or possession of drugs;

(2) Information from a reliable source indicating that a person being observed routinely distributes illegal drugs within the drug free zone;

(3) Information from a reliable source indicating that the person being observed is currently engaging in illegal drug-related activity within the drug free zone;

(4) Such person is physically identified by the officer as a member of a gang or association which engages in illegal drug activity;

(5) Such person is a known unlawful drug user, possessor, or seller. For purposes of this chapter, the phrase a "known unlawful drug user, possessor, or seller" means a person who has, within the knowledge of the arresting officer, been convicted in any court of any violation involving the use, possession, or distribution of any of the substances referred to in § 48-902.04, § 48-902.06, § 48-902.08, § 48-902.10 or § 48-902.12; or is a person who displays physical characteristics of drug use, including, but not limited to, "needle tracks";

(6) Such person has no other apparent lawful reason for congregating in the drug free zone, such as waiting for a bus or being near one's own residence; and

(7) Any vehicle involved in the observed circumstances is registered to a known unlawful drug user, possessor, or seller, or a person for whom there is an outstanding arrest warrant for a crime involving drug-related activity.

### **§ 48-1005. Penalties**

Any person who violates § 48-1004 shall, upon conviction, be subject to a fine of not more than \$ 300, imprisonment for not more than 180 days, or both.

**TITLE 48. FOOD AND DRUGS**  
**SUBTITLE III. ILLEGAL DRUGS**  
**CHAPTER 11. DRUG PARAPHERNALIA**

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SUBCHAPTER I. GENERAL

- § 48-1101. Definitions
- § 48-1102. Factors to be considered in determining whether object is paraphernalia
- § 48-1103. Prohibited acts
- § 48-1103.01. Needle Exchange Program
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SUBCHAPTER II. PROHIBITION ON DISTRIBUTION OF NEEDLES AND SYRINGES NEAR SCHOOLS

- § 48-1121. Distribution of needle or syringe near schools prohibited
- 

**SUBCHAPTER I. GENERAL**

**§ 48-1101. Definitions**

For purposes of this chapter, the term:

- (1) "Controlled substance" has the same meaning as that provided in § 48-901.02(4).
- (2) "Court" means the Superior Court of the District of Columbia and the District of Columbia Court of Appeals.
- (3) "Drug paraphernalia" means:
  - (A) Kits or other objects used, intended for use, or designed for use in planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived;
  - (B) Kits or other objects used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing a controlled substance;
  - (C) Isomerization devices or other objects used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance;
  - (D) Testing equipment or other objects used, intended for use, or designed for

- use in identifying or analyzing the strength, effectiveness, or purity of a controlled substance;
- (E) Scales and balances or other objects used, intended for use, or designed for use in weighing or measuring a controlled substance;
- (F) Diluents and adulterants, including, but not limited to: quinine, hydrochloride, mannitol, mannite, dextrose, and lactose, used, intended for use, or designed for use in cutting a controlled substance;
- (G) Separation gins and sifters or other objects used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, Cannabis or any other controlled substance;
- (H) Blenders, bowls, containers, spoons, and other mixing devices used, intended for use, or designed for use in compounding a controlled substance;
- (I) Capsules, balloons, envelopes, glassy plastic bags, or zip-lock bags that measure 1 inch by 1 inch or less, and other containers used, intended for use, or designed for use in packaging small quantities of a controlled substance;
- (J) Containers and other objects used, intended for use, or designed for use in storing or concealing a controlled substance;
- (K) Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting a controlled substance into the human body; and
- (L) Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing Cannabis, cocaine, hashish, hashish oil, or any other controlled substance into the human body, including, but not limited to:
- (i) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls;
  - (ii) Water pipes;
  - (iii) Carburetion tubes and devices;
  - (iv) Smoking and carburetion masks;
  - (v) Roach clips;
  - (vi) Miniature spoons with level capacities of one-tenth cubic

- centimeter or less;
- (vii) Chamber pipes;
- (viii) Carburetor pipes;
- (ix) Electric pipes;
- (x) Air-driven pipes;
- (xi) Bongs;
- (xii) Ice pipes or chillers;
- (xiii) Wired cigarette papers; or
- (xiv) Cocaine freebase kits.

The term "drug paraphernalia" shall not include any article that is 50 years of age or older.

**§ 48-1102. Factors to be considered in determining whether object is paraphernalia**

(a) In determining whether an object is drug paraphernalia, a court or other authority shall consider, in addition to all other logically and legally relevant factors, the following factors:

- (1) Statements by an owner or by anyone in control of the object concerning its use;
- (2) The proximity of the object, in time and space, to a violation of § 48-1103(a) or to a controlled substance;
- (3) The existence of any residue of a controlled substance on the object;
- (4) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he or she knows, or should reasonably know, intends to use the object to facilitate a violation of § 48-1103(a); the innocence of an owner, or of anyone in control of the object, as to a violation of § 48-1103(a) shall not prevent a finding that the object is intended for use, or designed for use as drug paraphernalia;
- (5) Instructions, oral or written, provided with the object concerning its use;
- (6) Descriptive materials accompanying the object which explain or depict its use;
- (7) National and local advertising concerning the use of the object;
- (8) The manner in which the object is displayed for sale;

(9) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, including, but not limited to, a licensed distributor or dealer of tobacco products;

(10) Direct or circumstantial evidence of the ratio of sales of the object or objects to the total sales of the business enterprise;

(11) The existence and scope of legitimate uses for the object in the community; and

(12) Expert testimony concerning its use.

(b) Where the alleged violation of the act included the sale of glassy plastic bags or zip-lock bags that measure 1 inch by 1 inch or less and occurred at a commercial retail or wholesale establishment, the court or other authority may infer that the item sold is drug paraphernalia, based on the size of the bags, the packaging of the bags, and a consideration of the factors in subsection (a) of this section.

### **§ 48-1103. Prohibited acts**

(a) It is unlawful for any person to use, or to possess with intent to use, drug paraphernalia to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inhale, ingest, or otherwise introduce into the human body a controlled substance. Whoever violates this subsection shall be imprisoned for not more than 30 days or fined for not more than \$ 100, or both.

(b) It is unlawful for any person to deliver or sell, possess with intent to deliver or sell, or manufacture with intent to deliver or sell drug paraphernalia, knowingly, or under circumstances where one reasonably should know, that it will be used to plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, conceal, inject, ingest, inhale, or otherwise introduce into the human body a controlled substance. Whoever violates this subsection shall be imprisoned for not more than 6 months or fined for not more than \$ 1,000, or both, unless the violation occurs after the person has been convicted in the District of Columbia of a violation of this chapter, in which case the person shall be imprisoned for not more than 2 years, or fined not more than \$ 5,000, or both.

(c) Any person 18 years of age or over who violates subsection (b) of this section by delivering drug paraphernalia to a person under 18 years of age who is at least 3 years his or her junior is guilty of a special offense and upon conviction may be imprisoned for not more than 8 years, fined not more than \$ 15,000, or both.

(d) Where the violation of the section involves the selling of drug paraphernalia by a commercial retail or wholesale establishment, the court shall revoke the license of any licensee convicted of a violation of this section and the certificate of occupancy for the

premises.

### **§ 48-1103.01. Needle Exchange Program**

(a) The Mayor is authorized to establish within the Department of Human Services a Needle Exchange Program ("Program"), which may provide clean hypodermic needles and syringes to injecting drug users. Counseling on substance abuse addiction and information on appropriate referrals to drug treatment programs shall be made available to each person to whom a hypodermic needle and syringe is provided. Counseling and information on the Human Immunodeficiency Virus ("HIV") and appropriate referrals for HIV testing and services shall be made available to each person to whom a hypodermic needle and syringe is provided.

(b) The Program authorized by subsection (a) of this section shall be administered by the Commission on Public Health in the Department of Human Services. Only qualified medical officers, registered nurses, counselors, community based organizations, or other qualified individuals specifically designated by the Commissioner of Public Health shall be authorized to exchange hypodermic needles and syringes under the provisions of subsections (c) through (i) of this section.

(c) The Commissioner of Public Health shall provide all persons participating in the Program authorized by subsection (a) of this section with a written statement of the person's participation in the Program, signed by the Commissioner of Public Health, or the Commissioner's designee. No person participating in the Program shall be required to carry such a statement.

(d) Notwithstanding the provisions of § 48-1103 or § 48-904.10, it shall not be unlawful for any person who is participating in the Program authorized by subsection (a) of this section to possess, or for any person authorized by subsection (b) of this section, to deliver any hypodermic syringe or needle distributed as part of the Program.

(e) The District of Columbia, its officers, or employees shall not be liable for any injury or damage resulting from use of, or contact with, any needle exchanged as part of the Program authorized by subsection (a) of this section.

(e-1) A community based organization or other qualified individuals designated by the Commissioner of Public Health under subsection (b) of this section shall not be liable for any injury or damage resulting from the use of, or contact with, any needle exchanged as part of the Program authorized by subsection (a) of this section, unless such injury or damage is a direct result of the gross negligence or intentional misconduct of such community based organization or other qualified individuals.

(f) All needles and syringes distributed by the Commission of Public Health as part of the Program shall be made identifiable through the use of permanent markings, or color coding, or any other method determined by the Commissioner to be effective in identifying the needles and syringes.

(g) The Mayor shall issue an annual evaluation report on the Program. The report shall address the following components:

- (1) Number of Program participants served daily;
- (2) Demographics of Program participants, including age, sex, ethnicity, address or neighborhood of residence, education, and occupation;
- (3) Impact of Program on behaviors which put the individual at risk for HIV transmission;
- (4) Number of materials distributed, including needles, bleach kits, alcohol swabs, and educational materials;
- (5) Impact of Program on incidence of HIV infection in the District. In determining this, the Mayor shall take into account the following factors:
  - (A) Annual HIV infection rates among injecting drug users entering drug treatment programs in the District;
  - (B) Estimates of the HIV infection rate among injecting drug users in the District at the start of the Program year as compared to the rate at the end of the third Program year;
  - (C) The annual number of HIV-positive mothers giving birth in the District;
  - (D) Annual estimates of the HIV infection rate among newborns; and
- (6) Costs of the Program versus direct and indirect costs of HIV infection and Acquired Immunodeficiency Syndrome ("AIDS") in the District.

(h) Data on Program participants shall be obtained through interviews. The interviews shall be used to obtain the following information:

- (1) Reasons for participating in Program;
- (2) Drug use history, including type of drug used, frequency of use, method of ingestion, length of time drugs used, and frequency of needle sharing;
- (3) Sexual behavior and history, including the participant's self-described sexual identity, number of sexual partners in the past 30 days or 6 months, number of sexual partners who were also intravenous drug users, frequency of condom use, and number of times sex was used in exchange for money or drugs;
- (4) Health assessment, including whether the participant has been tested for HIV

infection and whether the results were negative or positive; and

(5) Impact of Program on the participant's behavior and attitudes, including any increase or decrease in drug use or needle sharing, changes in high-risk sexual behaviors, or willingness to follow through with drug treatments.

(i) The Mayor shall explore the feasibility of establishing a system to test used needles and syringes received by the Commission of Public Health for HIV antibody contamination. The Mayor shall prepare a feasibility report on needle and syringe testing and shall submit this report to the Council for review no later than 120 days after June 30, 1992. If the report finds that needles and syringe testing would be beneficial and feasible to implement, such a system shall be incorporated into the Program.

#### **§ 48-1104. Property subject to forfeiture**

The following shall be subject to forfeiture immediately, and no property right shall exist in them after a final conviction by a court:

- (1) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this chapter;
- (2) All money or currency which shall be found in close proximity to drug paraphernalia or which otherwise has been used or intended for use in connection with the manufacture, distribution, delivery, sale, use, dispensing, or possession of drug paraphernalia in violation of § 48-1103; and
- (3) All drug paraphernalia as defined in §§ 48-1101 and 48-1102 and prohibited in § 48-1103.

### **SUBCHAPTER II. PROHIBITION ON DISTRIBUTION OF NEEDLES AND SYRINGES NEAR SCHOOLS**

#### **§ 48-1121. Distribution of needle or syringe near schools prohibited**

(a) (1) Effective 120 days after November 22, 2000, it shall be unlawful for any person to distribute any needle or syringe for the hypodermic injection of any illegal drug in any area of the District of Columbia which is within 1,000 feet of a public or private elementary or secondary school (including a public charter school).

(2) It is stipulated that based on a survey by the Metropolitan Police Department of the District of Columbia that sites at 4th Street Northeast and Rhode Island Avenue Northeast, Southern Avenue Southeast and Central Avenue Southeast, 1st Street

Southeast and M Street Southeast, 21st Street Northeast and H Street Northeast, Minnesota Avenue Northeast and Clay Place Northeast, and 15th Street Southeast and Ives Street Southeast are outside the 1,000-foot perimeter. Sites at North Capitol Street and New York Avenue Northeast, Division Avenue Northeast and Foote Street Northeast, Georgia Avenue Northwest and New Hampshire Avenue Northwest, and 15th Street Northeast and A Street Northeast are found to be within the 1,000-foot perimeter.

(b) The Public Housing Police of the District of Columbia Housing Authority shall prepare a monthly report on activity involving illegal drugs at or near any public housing site where a needle exchange program is conducted, and shall submit such reports to the Executive Director of the District of Columbia Housing Authority, who shall submit them to the Committees on Appropriations of the House of Representatives and Senate. The Executive Director shall ascertain any concerns of the residents of any public housing site about any needle exchange program conducted on or near the site, and this information shall be included in these reports. The District of Columbia Government shall take appropriate action to require relocation of any such program if so recommended by the police or by a significant number of residents of such site.

**DISTRICT OF COLUMBIA OFFICIAL CODE**  
**TITLE 4. PUBLIC CARE SYSTEMS**  
**CHAPTER 13. CHILD ABUSE AND NEGLECT**  
**SUBCHAPTER II. REPORTS OF NEGLECTED CHILDREN**

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- § 4-1321.01. Purpose
  - § 4-1321.02. Persons required to make reports; procedure
  - § 4-1321.03. Nature and contents of reports
  - § 4-1321.04. Immunity from liability
  - § 4-1321.05. Privileges; waiver
  - § 4-1321.06. Exceptions for treatment solely by spiritual means
  - § 4-1321.07. Failure to make report
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**§ 4-1321.01. Purpose**

It is the purpose of this subchapter to require a report of a suspected neglected child in order to identify neglected children; to assure that protective services will be made available to a neglected child to protect the child and his or her siblings and to prevent further abuse or neglect; and to preserve the family life of the parents and children, to the maximum extent possible, by enhancing the parental capacity for adequate child care.

**§ 4-1321.02. Persons required to make reports; procedure**

(a) Notwithstanding § 14-307, any person specified in subsection (b) of this section who knows or has reasonable cause to suspect that a child known to him or her in his or her professional or official capacity has been or is in immediate danger of being a mentally or physically abused or neglected child, as defined in § 16-2301(9), shall immediately report or have a report made of such knowledge or suspicion to either the Metropolitan Police Department of the District of Columbia or the Child Protective Services Division of the Department of Human Services.

(b) Persons required to report such abuse or neglect shall include every physician, psychologist, medical examiner, dentist, chiropractor, registered nurse, licensed practical nurse, person involved in the care and treatment of patients, law-enforcement officer, school official, teacher, social service worker, day care worker, and mental health professional. Whenever a person is required to report in his or her capacity as a member of the staff of a hospital, school, social agency or similar institution, he or she shall immediately notify the person in charge of the institution or his or her designated agent who shall then be required to make the report. The fact that such a notification has been made does not relieve the person who was originally required to report from his or her duty under subsection (a) of this section of having a report made promptly to the Metropolitan Police Department of the District of Columbia or the Child Protective Services Division of the Department of Human Services.

(c) In addition to those persons who are required to make a report, any other person may

make a report to the Metropolitan Police Department of the District of Columbia or the Child Protective Services Division of the Department of Human Services.

(d) In addition to the requirements in subsections (a) and (b) of this section, any health professional licensed pursuant to Chapter 12 of Title 3, or a law enforcement officer, except an undercover officer whose identity or investigation might be jeopardized, shall report immediately, in writing, to the Child Protective Services Division of the Department of Human Services, that the law enforcement officer or health professional has reasonable cause to believe that a child is abused as a result of inadequate care, control, or subsistence in the home environment due to exposure to drug-related activity. The report shall be in accordance with the provisions of § 4-1321.03.

#### **§ 4-1321.03. Nature and contents of reports**

(a) Each person required to make a report of a known or suspected neglected child shall:

(1) Immediately make an oral report of the case to the Child Protective Services Division of the Department of Human Services or the Metropolitan Police Department of the District of Columbia; and

(2) Make a written report of the case if requested by said Division or Police or if the abuse involves drug-related activity.

(b) The report shall include, but need not be limited to, the following information if it is known to the person making the report:

(1) The name, age, sex, and address of the following individuals:

(A) The child who is the subject of the report;

(B) Each of the child's siblings and other children in the household; and

(C) Each of the child's parents or other persons responsible for the child's care;

(2) The nature and extent of the abuse or neglect of the child and any previous abuse or neglect, if known;

(3) All other information which the person making the report believes may be helpful in establishing the cause of the abuse or neglect and the identity of the person responsible for the abuse or neglect; and

(4) If the source was required to report under this subchapter, the identity and occupation of the source, how to contact the source and a statement of the actions taken by the source concerning the child.

**§ 4-1321.04. Immunity from liability**

Any person, hospital, or institution participating in good faith in the making of a report pursuant to this subchapter shall have immunity from liability, civil or criminal, that might otherwise be incurred or imposed with respect to the making of the report. Any such participation shall have the same immunity with respect to participation in any judicial proceeding involving the report. In all civil or criminal proceedings concerning the child or resulting from the report good faith shall be presumed unless rebutted.

**§ 4-1321.05. Privileges; waiver**

Notwithstanding the provisions of §§ 14-306 and 14-307, neither the husband-wife privilege nor the physician-patient privilege shall be grounds for excluding evidence in any proceeding in the Family Division of the Superior Court of the District of Columbia concerning the welfare of a neglected child; provided, that a judge of the Family Division of the Superior Court of the District of Columbia determines such privilege should be waived in the interest of justice.

**§ 4-1321.06. Exceptions for treatment solely by spiritual means**

Notwithstanding any other provision of this subchapter, no child who in good faith is under treatment solely by spiritual means through prayer in accordance with the tenets and practices of a recognized church or religious denomination by a duly accredited practitioner thereof shall, for that reason alone, be considered to have been neglected within the purview of this subchapter.

**§ 4-1321.07. Failure to make report**

Any person required to make a report under this subchapter who willfully fails to make such a report shall be fined not more than \$ 100 or imprisoned for not more than 30 days or both. Violations of this subchapter shall be prosecuted by the Corporation Counsel of the District of Columbia or his or her agent in the name of the District of Columbia.

**DISTRICT OF COLUMBIA OFFICIAL CODE  
TITLE 2. GOVERNMENT ADMINISTRATION  
CHAPTER 5. ADMINISTRATIVE PROCEDURE  
SUBCHAPTER I. ADMINISTRATIVE PROCEDURE**

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§ 2-502. Definitions  
§ 2-509. Contested cases  
§ 2-510. Judicial Review

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**§ 2-502. Definitions**

As used in this subchapter:

- (1) (A) The term "Mayor" means the Mayor of the District of Columbia, or his or her designated agent.  
  
(B) The term "Council" means the Council of the District of Columbia established by § 1-204.01(a) unless the term "District of Columbia Council" is used in which event it shall mean the District of Columbia Council established by subsection (a) of § 201 of Reorganization Plan No. 3 of 1967 (81 Stat. 948).
- (2) The term "District" means the District of Columbia.
- (3) The term "agency" includes both subordinate agency and independent agency.
- (4) The term "subordinate agency" means any officer, employee, office, department, division, board, commission, or other agency of the government of the District, other than an independent agency or the Mayor or the Council, required by law or by the Mayor or the Council to administer any law or any rule adopted under the authority of a law.
- (5) The term "independent agency" means any agency of the government of the District with respect to which the Mayor and the Council are not authorized by law, other than this subchapter, to establish administrative procedures, but does not include the several courts of the District and the Tax Division of the Superior Court.
- (6) (A) The term "rule" means the whole or any part of any Mayor's or agency's statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure, or practice requirements of the Mayor or of any agency.  
  
(B) The term "rule" does not include any statement for guiding, directing or otherwise regulating vehicular or pedestrian traffic, including any statement controlling parking, standing, stopping or a construction detour; provided, that:

(i) The contents of the statement are indicated to the public on one or more signs, signals, meters, markings or other similar devices located on or adjacent to a street, avenue, road, highway or other public space;

(ii) The proposed installation, modification or removal of the statement is based on engineering or other technical considerations;

(iii) The proposed installation, modification or removal of the statement does not involve substantial policy considerations; and

(iv) The Council and the affected Advisory Neighborhood Commissions ("ANC") are provided with 30-days written notice, excluding Saturdays, Sundays and legal holidays, of an agency's intent to install, modify or remove any of these statements, and any ANC recommendation, if provided, is given great weight pursuant to § 1-309.10.

(7) The term "rulemaking" means Mayor's or agency's process for the formulation, amendment, or repeal of a rule.

(8) The term "contested case" means a proceeding before the Mayor or any agency in which the legal rights, duties, or privileges of specific parties are required by any law (other than this subchapter), or by constitutional right, to be determined after a hearing before the Mayor or before an agency, but shall not include:

(A) Any matter subject to a subsequent trial of the law and the facts de novo in any court;

(B) The selection or tenure of an officer or employee of the District;

(C) Proceedings in which decisions rest solely on inspections, tests, or elections; and

(D) Cases in which the Mayor or an agency act as an agent for a court of the District.

(9) The term "person" includes individuals, partnerships, corporations, associations, and public or private organizations of any character other than the Mayor, the Council, or an agency.

(10) The term "party" includes the Mayor and any person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in any proceeding before the Mayor or an agency, but nothing herein shall be construed to prevent the Mayor or an agency from admitting the Mayor or any person or agency as a party for limited purposes

(11) The term "order" means the whole or any part of the final disposition (whether affirmative, negative, injunctive, or declaratory in form) of the Mayor or of any agency in any matter other than rulemaking, but including licensing.

(12) The term "license" includes the whole or part of any permit, certificate, approval, registration, charter, membership, statutory exemption, or other form of permission granted by the Mayor or any agency.

(13) The term "licensing" includes process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license by the Mayor or an agency.

(14) The term "relief" includes the whole or part of any Mayor's or agency's:

(A) Grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) Recognition of any claim, right, immunity, privilege, exemption, or exception; and

(C) Taking of any other action upon the application or petition of, and beneficial to, any person.

(15) The term "proceeding" means any process of the Mayor or an agency as defined in paragraphs (6), (11), and (12) of this section.

(16) The term "sanction" includes the whole or part of any Mayor's or agency's:

(A) Prohibition, requirement, limitation, or other condition affecting the freedom of any person;

(B) Withholding of relief;

(C) Imposition of any form of penalty or fine;

(D) Destruction, taking, seizure, or withholding of property;

(E) Assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees

(F) Requirement, revocation, or suspension of a license; and

(G) Taking of other compulsory or restrictive action.

(17) The term "regulation" means the whole or any part of any District of Columbia Council statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure, or practice requirements of the Mayor, District of Columbia Council, or any agency

(18) The term "public record" includes all books, papers, maps, photographs, cards, tapes, recordings, or other documentary materials, regardless of physical form or characteristics prepared, owned, used in the possession of, or retained by a public body. Public records include information stored in an electronic format.

(18A) The term "public body" means the Mayor, an agency, or the Council of the District of Columbia.

(19) The term "adjudication" means the agency process, other than rulemaking, for the formulation, issuance, and enforcement of an order.

### **§ 2-509. Contested cases.**

(a) In any contested case, all parties thereto shall be given reasonable notice of the afforded hearing by the Mayor or the agency, as the case may be. The notice shall state the time, place, and issues involved, but if, by reason of the nature of the proceeding, the Mayor or the agency determines that the issues cannot be fully stated in advance of the hearing, or if subsequent amendment of the issues is necessary, they shall be fully stated as soon as practicable, and opportunity shall be afforded all parties to present evidence and argument with respect thereto. The notice shall also state that if a party or witness is deaf, or because of a hearing impediment cannot readily understand or communicate the spoken English language, the party or witness may apply to the agency for the appointment of a qualified interpreter. Unless otherwise required by law, other than this subchapter, any contested case may be disposed of by stipulation, agreed settlement, consent order, or default.

(b) In contested cases, except as may otherwise be provided by law, other than this subchapter, the proponent of a rule or order shall have the burden of proof. Any oral and any documentary evidence may be received, but the Mayor and every agency shall exclude irrelevant, immaterial, and unduly repetitious evidence. Every party shall have the right to present in person or by counsel his case or defense by oral and documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as may be required for a full and true disclosure of the facts. Where any decision of the Mayor or any agency in a contested case rests on official notice of a material fact not appearing in the evidence in the record, any party to such case shall on timely request be afforded an opportunity to show the contrary.

(c) The Mayor or the agency shall maintain an official record in each contested case, to include testimony and exhibits, but it shall not be necessary to make any transcription unless a copy of such record is timely requested by any party to such case, or transcription is required by law, other than this subchapter. The testimony and exhibits, together with all papers and requests filed in the proceeding, and all material facts not appearing in the evidence but with respect to which official notice is taken, shall constitute the exclusive record for order or decision. No sanction shall be imposed or rule or order or decision be issued except upon consideration of such exclusive record, or such lesser portions thereof as may be agreed upon by all the parties to such case. The cost incidental to the preparation of a

copy or copies of a record or portion thereof shall be borne equally by all parties requesting the copy or copies.

(d) Whenever in a contested case a majority of those who are to render the final order or decision did not personally hear the evidence, no order or decision adverse to a party to the case (other than the Mayor or an agency) shall be made until a proposed order or decision, including findings of fact and conclusions of law, has been served upon the parties and an opportunity has been afforded to each party adversely affected to file exceptions and present argument to a majority of those who are to render the order or decision, who, in such case, shall personally consider such portions of the exclusive record, as provided in subsection (c) of this section, as may be designated by any party.

(e) Every decision and order adverse to a party to the case, rendered by the Mayor or an agency in a contested case, shall be in writing and shall be accompanied by findings of fact and conclusions of law. The findings of fact shall consist of a concise statement of the conclusions upon each contested issue of fact. Findings of fact and conclusions of law shall be supported by and in accordance with the reliable, probative, and substantial evidence. A copy of the decision and order and accompanying findings and conclusions shall be given by the Mayor or the agency, as the case may be, to each party or to his attorney of record.

### **§ 2-510. Judicial review.**

(a) Any person suffering a legal wrong, or adversely affected or aggrieved, by an order or decision of the Mayor or an agency in a contested case, is entitled to a judicial review thereof in accordance with this subchapter upon filing in the District of Columbia Court of Appeals a written petition for review. If the jurisdiction of the Mayor or an agency is challenged at any time in any proceeding and the Mayor or the agency, as the case may be, takes jurisdiction, the person challenging jurisdiction shall be entitled to an immediate judicial review of that action, unless the Court shall otherwise hold. The reviewing Court may by rule prescribe the forms and contents of the petition and, subject to this subchapter, regulate generally all matters relating to proceedings on such appeals. A petition for review shall be filed in such Court within such time as such Court may by rule prescribe and a copy of such petition shall forthwith be served by mail by the clerk of the Court upon the Mayor or upon the agency, as the case may be. Within such time as may be fixed by rule of the Court, the Mayor or such agency shall certify and file in the Court the exclusive record for decision and any supplementary proceedings, and the clerk of the Court shall immediately notify the petitioner of the filing thereof. Upon the filing of a petition for review, the Court shall have jurisdiction of the proceeding, and shall have power to affirm, modify, or set aside the order or decision complained of, in whole or in part, and, if need be, to remand the case for further proceedings, as justice may require. Filing of a petition for review shall not in itself stay enforcement of the order or decision of the Mayor or the agency, as the case may be. The Mayor or the agency may grant, or the reviewing Court may order, a stay upon appropriate terms. The Court shall hear and determine all appeals upon the exclusive record for decision before the Mayor or the agency. The review of all administrative orders and decisions by the Court shall be limited to such issues of law or fact as are subject to review on appeal under applicable statutory law, other than this subchapter. In all other cases the review by the

Court of administrative orders and decisions shall be in accordance with the rules of law which define the scope and limitations of review of administrative proceedings. Such rules shall include, but not be limited to, the power of the Court:

- (1) So far as necessary to decision and where presented, to decide all relevant questions of law, to interpret constitutional and statutory provisions, and to determine the meaning or applicability of the terms of any action;
- (2) To compel agency action unlawfully withheld or unreasonably delayed; and
- (3) To hold unlawful and set aside any action or findings and conclusions found to be:
  - (A) Arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
  - (B) Contrary to constitutional right, power, privilege, or immunity;
  - (C) In excess of statutory jurisdiction, authority, or limitations or short of statutory jurisdiction, authority, or limitations or short of statutory rights;
  - (D) Without observance of procedure required by law, including any applicable procedure provided by this subchapter; or
  - (E) Unsupported by substantial evidence in the record of the proceedings before the Court.

(b) In reviewing administrative orders and decisions, the Court shall review such portions of the exclusive record as may be designated by any party. The Court may invoke the rule of prejudicial error.