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

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.

[1] As of March 1, 2012, the Pharmaceutical Control Division is now located at 899 North Capitol Street, N.E., 2nd Floor, Washington, D.C. 20002, 202-724-4900.
[2] As of March 1, 2012, the Department of Consumer and Regulatory Affairs in now located at1100 4th Street, S.W., Washington, D.C. 20024.[1]

§ 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, rescheduling, additions and deletions as determinedby federal law or regulation, unless otherwise contraindicated for the Districtof 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 withany controlled substance, or who proposes to engage in the manufacture,distribution, dispensing, or conducting of research with any controlled substancewithin the District of Columbia shall obtain biennially and maintain current aregistration issued by the Director in accordance with this chapter, unlessexempted by federal law, or District of Columbia law or pursuant to §§ 1002.4and 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 lawfullypossess 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 theperson:

(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 14th Street, N.W., 6th 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 reregistration, 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.[1]

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 or any controlled substances shall be the responsibility of the registrant or his or her legal representative.

1009.8 A new registration shall be required under the following circumstances:

(a) If any partners are added or deleted from the partnership;

(b) If there is a change in the president or chief executive officer of the corporation; or

(c) If there is a change in the ownership of ten percent (10%) or more of the outstanding shares of the corporation.

1009.9 No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Director may specifically consent.

§ 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 re-registration 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 re-registration 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 14th Street, N.W., 6th Floor, Washington, D.C. 20005, or to its successor agency by certified mail, return receiptrequested.

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) Re-inspection-- $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 drugfree 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.