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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

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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:

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- (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 non-narcotic 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.

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- (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

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(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.

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- (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.

§ 48-903.08. Prescriptions.

- (a) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in Schedule II may be dispensed without the written prescription of a practitioner.
- (b) In emergency situations, as defined by rule of the Mayor, Schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of § 48-903.06. No prescription for a Schedule II controlled substance may be refilled.
- (c) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV which is a prescription drug as determined under § 353(b) of Title 21, United States Code, shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than 6 months after the date thereof or be refilled more than 5 times, unless renewed by the practitioner.

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(d) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose.

(e) Whenever a practitioner dispenses any controlled substance on a written or oral prescription issued by a practitioner, the practitioner shall affix to the container in which such controlled substance is dispensed a label showing the name of the controlled substance or controlled substances contained therein unless otherwise so indicated by the prescribing practitioner; the serial number and date of initial filling; the directions for use; the practitioner's name and registry number; the name of the ultimate user, or if the ultimate user is an animal, the name of the owner and the species of the animal; the name of the practitioner issuing the prescription; and caution statements, if any, as required by law.

§ 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.