

Title 22 District of Columbia Municipal Regulations

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

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§ 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.15), 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.16) and in situations described in § 505(a)(4) of the Act (§ 33-555(a)(4), D.C. Code, 1981 ed.17).

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.18); 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.19

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

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

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

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

19 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.