

**DISTRICT OF  
COLUMBIA  
MUNICIPAL  
REGULATIONS  
for  
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, thefts, suspected diversions, significant losses of drug inventory or the inability to account for such inventory, and damage to a pharmacy or its inventory by fire, flood, or other causes shall be reported by the licensee or agent of the licensee to the Director within forty-eight (48) hours after discovery.
- 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;

- (d) Whether the pharmacy intends to engage in the compounding of sterile pharmaceuticals; and
  - (e) 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) Indicate whether the nonresident pharmacy is currently engaged in the compounding of sterile pharmaceuticals or intends to engage in the compounding of sterile pharmaceuticals after approval of a registration;
- (g) 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;
- (h) 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
- (i) Provide all website address(es) and domain registration(s) to the Department, if applicable;

(j) 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 A licensee applying for a renewal of a license shall disclose whether the licensee is currently engaged in the compounding of sterile pharmaceuticals or intends to engage in the compounding of sterile pharmaceuticals after approval of a licensee.
- 1904.5 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.
- 1904.6 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.
- 1904.7 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.
- 1904.8 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.
- 1904.9 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) Satisfy compounding space requirements as follows:

(1) For the compounding of non-sterile and sterile pharmaceuticals, 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;

- (2) Beginning six (6) months after the effective date of these regulations, for the compounding of non-sterile pharmaceuticals, satisfy all other compounding space requirements established in the current published edition of USP General Chapter 795, 800; and
  - (3) Beginning six (6) months after the effective date of these regulations, for the compounding of sterile pharmaceuticals, satisfy all compounding space requirements as established in the current published edition of USP General Chapter 797, 800;
- (c) 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;
  - (f) Have a sink and goose-neck faucet within the dispensing and compounding area for the immediate access and use of all pharmacy personnel, maintained in a sanitary condition, which shall provide hot running water no less than one hundred and ten degrees Fahrenheit (110° F) (forty-three and one-third degrees Celsius (43.3° C)), cold running water, and shall include:
    - (1) Soap or detergent from a dispenser; and
    - (2) Air-driers or single-use non shedding 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); and
  - (j) Beginning six (6) months after the effective date of these regulations, comply with all other requirements of the current published editions of USP General Chapters 795, 797, and 800 relevant to the type of compounding being undertaken.

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) Beginning six (6) months after the effective date of these regulations, includes a video surveillance system meeting the requirements set forth in § 1910.3 of this chapter;
- (d) Has an auxiliary source of power; and
- (e) Is in good repair and operating order at all times.

1910.3      Beginning six (6) months after the effective date of these regulations, all pharmacies shall be required to operate and maintain in good working order a video surveillance system on the premises in compliance with the following:

- (a) The video surveillance system shall be continuously operated twenty-four (24) hours, seven (7) days a week and shall display an accurate date and time stamp on all video recordings;
- (b) The video surveillance system shall store without recording over, at a minimum, the current day and previous thirty (30) days of video surveillance recording;
- (c) The video surveillance system shall record all pharmacy-related operations, including drug storage, dispensing, compounding, and patient consultations areas, but may exclude private patient areas and areas used for administering medications or immunizations;
- (d) The video surveillance system shall record all automated dispensing machines (ADM) utilized in institutional pharmacies, but may exclude private patient areas;
- (e) The video surveillance recordings for the current day and previous thirty (30) days shall be viewable upon request by a Department investigator or inspector;
- (f) The video surveillance system shall be capable of producing, at a minimum, a digital storage device of the current day and previous thirty (30) days of recording in a standard format that is viewable on any Windows PC and that includes any required device or software necessary for viewing;
- (g) The video surveillance recording shall be provided to the Department within

seventy-two (72) hours of a request by a Department investigator or inspector; and

- (h) The video surveillance system shall be maintained in good working order at all times and tested monthly for proper retrieval functionality. The pharmacy shall retain all documentation regarding the testing of its video surveillance system, and present that documentation upon request to a Department inspector or investigator. The pharmacy shall report any malfunctioning or inoperability of the system to the Department within seventy-two (72) hours of discovering the issue.

- 1910.4 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.
- 1910.5 Any controlled substance stored outside of the prescription drug compounding and dispensing area shall be kept in a locked storage area.
- 1910.6 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.
- 1910.7 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.
- 1910.8 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.
- 1910.9 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.
- 1910.10 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 dose 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 Pharmacopeia, and reporting of drug product defects accordingly;
- (v) Developing or ensuring the establishment of procedures for an ongoing quality assurance program of pharmaceutical services that include a mechanism for reviewing and evaluating drug related patient care, as well as an appropriate response to findings;
- (w) Notifying the Director of the occurrence of any of the following:
  - (1) Permanent closing of the pharmacy;
  - (2) Change of proprietorship, management, location, or pharmacist-in-charge of the pharmacy;

- (3) Any theft or loss of prescription drugs or medical devices from the pharmacy;
  - (4) Conviction of any employee of the pharmacy of any federal, state, or District of Columbia drug laws;
  - (5) Disasters or accidents resulting in damage to the pharmacy facility, or inventory;
  - (6) Any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;
  - (7) Occurrences of significant adverse drug reactions; or
  - (8) Illegal use or disclosure of protected patient health information; and
- (x) Ensuring the making or filing of any reports required by federal or District of Columbia laws or regulations.

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 Beginning six (6) months after the effective date of these regulations, pharmacies engaged in the practice of compounding and dispensing of any drugs shall comply with the standards set forth in the current published edition of USP General Chapters 795, 797, and 800 relevant to the type of compounding and dispensing undertaken.

1921.32 Repealed

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 Repealed.

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 Beginning six (6) months after the effective date of these regulations, pharmacies providing parenteral services shall have written policies and procedures for the disposal of infectious materials, materials containing cytotoxic residues, and all preparations and waste that may be produced or used in compounding or the final product. The procedures shall include cleanup of spills and shall conform with applicable District of Columbia and federal law and regulations as well as the current published editions of USP General Chapters 795, 797, and 800 as applicable.

1921.38 The pharmacist or their designated individual is responsible for developing and maintaining a quality assurance program that insures a clean and sanitary environment for the preparation of sterile products and ensures that the parenteral products that are produced are sterile. The pharmacist or their designated individual is required to develop and implement a training program to be completed by all sterile compounders under their supervision concerning the implementation of the quality assurance program. Documentation of these activities, including, but not limited to, a written training program and tests used to demonstrate familiarity of the quality assurance program requirements, shall be available to the Director.

1921.39 Repealed

1921.40 Repealed

1921.41 Repealed

## **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;
- (i) Developing and implementing written policies and procedures to ensure compliance with the applicable provisions of federal and District of Columbia laws and regulations;
- (j) Notifying the Director of the occurrence of any of the following:
  - (1) Permanent closing of the pharmacy;
  - (2) Change of proprietorship, management, location, or pharmacist-in-charge of the pharmacy;
  - (3) Any theft or loss of prescription drugs or medical devices from the pharmacy;
  - (4) Conviction of any employee of the pharmacy of any federal, state, or District of Columbia drug laws;
  - (5) Disasters or accidents resulting in damage to the pharmacy facility, or inventory;
  - (6) Any theft, destruction, or loss of records required to be maintained by federal or District of Columbia law or regulation;

- (7) Occurrences of significant adverse drug reactions; or
- (8) Illegal use or disclosure of protected patient health information; and
- (k) Ensuring the making or filing of any reports required by federal or District of Columbia laws or 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 Beginning six (6) months after the effective date of these regulations, 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, and all other requirements set forth in the current published editions of USP General Chapters 795, 797, 800 and 825 relevant to the type of compounding being undertaken.

## **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 may delegate to staff of the Department the authority to conduct inspections of pharmacy operations covered by this chapter. Inspections shall be conducted upon the issuance of a new license and at least annually thereafter. Inspections may be conducted more frequently as often as the Director deems necessary or useful.

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 may delegate to staff of the Department the authority 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>

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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 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.

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

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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).

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
  - (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.

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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).

- 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:
- (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.

**USP** – United States Pharmacopoeia, may also be referred to as United States Pharmacopoeia/National Formulary (USP/NF). USP/NF is a combination of two compendia, the United States Pharmacopoeia (USP) and the National Formulary (NF). The USP-NF is copyrighted by The United States Pharmacopoeial Convention and therefore is not republished here. However, a copy of the text may be obtained at <https://www.uspnf.com/purchase-usp-nf>.

**USP General Chapter** – Standard developed by United States Pharmacopoeia/National Formulary (USP/NF).