

TITLE 22. PUBLIC HEALTH AND MEDICINE

CHAPTER 13. PRESCRIPTIONS AND DISTRIBUTIONS

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1300 GENERAL PROVISIONS

- 1300.1 This chapter shall apply to all categories of prescriptions drugs.
- 1300.2 Unless otherwise prohibited in this chapter or by District or federal law, a pharmacist may accept as valid for dispensing, a written prescription, an oral prescription, a telephone facsimile prescription, or an electronic prescription, issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices.
- 1300.3 A prescription shall only be issued by a practitioner who holds a valid license issued by the District of Columbia, or other U.S. state, to prescribe drugs or medical devices. If the prescription is for a controlled substance, the practitioner must also have a valid federal Drug Enforcement Agency (DEA) registration number and if applicable, a valid District of Columbia controlled substance registration or be exempt from registration pursuant to § 302 of the District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D.C. Law 4-29, D.C. Official Code § 48-901.01).
- 1300.4 A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner only pursuant to the directions and order of the practitioner, and in conformance with the applicable federal and District of Columbia laws and regulations, and this chapter.
- 1300.5 A prescription shall only be filled by a licensed pharmacist or individual practitioner legally authorized to dispense a prescription.
- 1300.6 Pharmacists shall exercise sound professional judgment with respect to the accuracy and authenticity of any prescription they dispense. If the pharmacist questions the accuracy or authenticity of prescription, he or she shall verify the order with the practitioner prior to dispensing.
- 1300.7 Prior to dispensing a prescription, pharmacists shall determine, in the exercise of sound professional judgment, that the prescription is a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist knows that the prescription was issued without a valid patient-practitioner relationship.
- 1300.8 An internet based or telephone consultation or questionnaire evaluation is not adequate to establish a valid patient-practitioner relationship except as follows:
 - (a) In the event of a documented medical emergency;
 - (b) In an on-call or cross-coverage arrangement; or
 - (c) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.
- 1300.9 Nothing in this chapter shall be construed as authorizing or permitting any

person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he or she desires to do such act nor shall compliance with such parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

1301 WRITTEN PRESCRIPTION ORDERS

- 1301.1 In addition to conforming to all applicable federal and District requirements, a written prescription drug order shall contain the following:
- (a) The printed or typed full name, address, and telephone number of the practitioner;
 - (b) The original, legal signature of the practitioner, in ink;
 - (c) The date of issuance;
 - (d) The full name of the patient;
 - (e) The name, strength and quantity of the drug prescribed, directions for use, and number of refills, when applicable; and
 - (f) Be written in ink, indelible pencil or typewriter.
- 1301.2 In addition to the requirements of § 1301.1, a prescription drug order for a controlled substance shall also include the following:
- (a) The patient's address;
 - (b) The practitioner's Federal Drug Enforcement Administration (DEA) registration number;
 - (c) The practitioner's District of Columbia controlled substances registration number, if applicable;
 - (d) Be signed by the practitioner in the same manner as the practitioner would sign a check or legal document (for example: "J.H. Smith" or "John H. Smith").
- 1301.3 Any person who is exempted from registration under federal or District of Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.
- 1301.4 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1301.5 The service identification number for a Public Health Service employee is his or her social security identification number or, if applicable, his or her National Provider Identifier (NPI) number. Each prescription shall have the name of the individual stamped or printed on it, as well as the signature of the individual.
- 1301.6 The dispensing pharmacist shall document the following information on each prescription order that has been dispensed:

(a) The name or initials of the pharmacist who performed the final verification; and

(b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include but not be limited to, a change in quantity, directions, or number of refills.

1301.7 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1302 ORAL PRESCRIPTION ORDERS

1302.1 A pharmacist shall not dispense an oral prescription drug order for a controlled substance listed in Schedule II except as provided in § 1306.5 of this chapter.

1302.2 An oral prescription drug order from a practitioner or a practitioner's designated agent shall:

- (a) Only be received by a pharmacist; and
- (b) Be immediately reduced to writing.

1302.3 In addition to conforming to all applicable federal and District requirements, an oral prescription drug order shall contain the following:

- (a) The full name, address, and telephone number of the practitioner;
- (b) The date of issuance;
- (c) The full name and address of the patient;
- (d) The name, strength, and quantity of the drug, directions for use, and number of refills, when applicable; and
- (e) The name of the practitioner's designated agent authorized to orally communicate the prescription to the pharmacist.

1302.4 In addition to the requirements of § 1302.3, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:

- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number; and
- (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable.

1302.5 The dispensing pharmacist shall document the following information on the written record of each prescription order that has been dispensed:

- (a) The name or initials of the pharmacist who performed the final verification; and
- (b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.

1302.6 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies

authorizing such substitution.

- 1302.7 For any person who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions for controlled substances issued by the exempted practitioner the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act, in lieu of the registration number of the practitioner required by this chapter.
- 1302.8 For an official who is exempted from registration under federal or District of Columbia statute, the pharmacist shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the individual's service identification number, in lieu of the registration number of the practitioner required by this chapter.
- 1302.9 For any Public Health Service employee that is exempted from registration under federal or District of Columbia statute, the pharmacist shall include the individual's social security identification number or, if applicable, his or her National Provider Identifier (NPI) number, office, title, and business address on the prescription.

1303 TELEPHONE FACSIMILE PRESCRIPTION ORDERS

- 1303.1 A practitioner shall not transmit a prescription via telephone facsimile if in doing so it would interfere with a patient's freedom to choose a pharmacy, or without a patient's consent.
- 1303.2 A pharmacist shall not dispense a telephone facsimile prescription drug order for a controlled substance listed in Schedule II, except as permitted under § 1306 of this chapter.
- 1303.3 A telephone facsimile prescription shall be transmitted only by a practitioner or a practitioner's designated agent directly from the practitioner's office or a health care facility to the pharmacy with no intervening person having access to the prescription drug order.
- 1303.4 To maintain the confidentiality of patient records:
- (a) The pharmacy and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and telephone facsimile transmissions; and
 - (b) The pharmacy shall implement and maintain procedures, system controls and other efforts to ensure compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), federal and District laws regarding the confidentiality and protection of patient information.
- 1303.5 The pharmacy shall implement and maintain procedures to verify the authenticity of the telephone facsimile transmission and its source of origin which may include:
- (a) Maintenance of a practitioner's telephone facsimile number reference;
 - (b) Verification of the telephone number of the originating telephone facsimile equipment; and
 - (c) Telephone verification with the practitioner's office that the prescription as transmitted via telephone facsimile contains the same exact information it contained when originated by the practitioner and contains no alterations by any intervening parties.

1303.6 In addition to conforming to all applicable federal and District requirements, a telephone facsimile prescription drug order shall contain the following at the time it is transmitted:

- (a) A prescription bearing the following information:
 - (1) The printed or typed full name, address, telephone number and facsimile number of the practitioner;
 - (2) The signature of the practitioner;
 - (3) The date of issuance;
 - (4) The full name and address of the patient;
 - (5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable; and
 - (6) A statement which indicates that the prescription was transmitted via telephone facsimile;

(b) Along with the prescription, the following information shall be transmitted:

- (1) The name, address, and facsimile number of the pharmacy to which the prescription was transmitted;
- (2) The date the prescription was transmitted via facsimile to the pharmacy, if the date is different from the date of issuance of the prescription;
- (3) If transmitted by a designated agent, the full name of the designated agent; and
- (4) A clearly legible statement that:
 - (A) The telephone facsimile transmission is intended only for the recipient to which it was addressed and contains information that is confidential;
 - (B) The recipient is prohibited from distribution or dissemination of the information contained in the transmission unless permitted by federal or District law; and
 - (C) If the recipient is not the intended recipient or the authorized agent of the intended recipient, the recipient should immediately notify the sender by telephone and return the original message to the sender.

1303.7 In addition to the requirements of § 1303.6, a prescription for a controlled substance, when authorized by law for dispensing, shall also include the following:

- (a) The practitioner's federal Drug Enforcement Administration (DEA) registration number;
- (b) The practitioner's District of Columbia Controlled Substances registration number, if applicable;
- (c) Be signed by the practitioner in the same manner as the practitioner would sign a check or legal document (for example: "J.H. Smith" or "John H. Smith"); and
- (d) Any other requirements under District or federal law.

1303.8 Any person who is exempted from registration under federal or District of

Columbia statute shall include on all prescriptions for controlled substances issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in the Act or this chapter, in lieu of the registration number of the practitioner required by this chapter.

1303.9 An official exempted from registration under federal or District of Columbia statute shall include on all prescriptions issued by that individual, his or her branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and the individual’s service identification number, in lieu of the registration number of the practitioner required by this chapter.

1303.10 The service identification number for a Public Health Service employee is his or her social security identification number or, if applicable, his or her National Provider Identifier (NPI) number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

1303.11 The dispensing pharmacist shall document the following information on each facsimile prescription order that has been dispensed:

(a) The name or initials of the pharmacist who performed the final verification; and

(b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.

1303.12 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1304 ELECTRONIC PRESCRIPTION ORDERS

1304.1 A practitioner shall not electronically transmit a prescription if in doing so it would interfere with a patient’s freedom to choose a pharmacy, or without a patient’s consent.

1304.2 A pharmacist shall not dispense an electronic prescription for a controlled substance listed in any schedule, unless otherwise authorized or permitted by federal law or regulations.

1304.3 An electronic prescription may be transmitted only by a practitioner or a practitioner’s designated agent:

(a) Directly to a pharmacy through a secure computer to computer transmission;

(b) Directly to a pharmacy through a secure computer to facsimile transmission; or

(c) Processed by a commercial intermediary that is duly authorized to operate in the District of Columbia, if applicable, and which ensures the confidentiality and security of the transmission process.

1304.4 The original electronic transmission shall be readily retrievable through the pharmacy computer system and shall be immediately reduced to hardcopy and filed in accordance with District of Columbia regulations.

1304.5 To maintain the confidentiality of patient records:

(a) The pharmacy computer system and the practitioner shall both have adequate security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and electronic

transmissions; and

(b) The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, system controls, and other efforts to ensure compliance

1304.6 The Director of Pharmacy or Pharmacist in Charge shall create and maintain an ongoing security program and procedures which are capable of identifying misuse or unauthorized use of electronic signatures;

1304.7 The Director of Pharmacy or Pharmacist in Charge shall implement and maintain procedures, computer system controls, and other efforts, including contractual arrangements with commercial intermediaries, to:

(a) Verify the authenticity of the electronic transmission and its source of origin;

(b) Ensure that the electronic transmission contains the same exact information it contained when originated by the practitioner;

(c) Ensure that the electronic transmission contains no alterations by any intervening parties;

(d) Prevent unauthorized access and changes to electronically transmitted prescriptions; and

(e) Other efforts which, in the professional judgment of the pharmacist, may be necessary to ensure the validity of the transmission.

1304.8 In addition to conforming to all applicable federal and District requirements, an electronic prescription order shall conform to federally recognized national transmission standards and contain the following information at the time it is transmitted:

(a) A prescription bearing the following information:

(1) The full name, address, and telephone number of the practitioner;

(2) The electronic signature of the practitioner;

(3) The date of issuance;

(4) The full name and address of the patient; and

(5) The name and dosage of the drug, directions for use, quantity dispensed, and number of refills, when applicable.

(b) Along with the prescription, the following information shall be transmitted:

(1) The National Council on Prescription Drug Programs (NCPDP) pharmacy number of the pharmacy to which the prescription was transmitted;

(2) The date the prescription was transmitted to the pharmacy, if the date is different from the date of issuance of the prescription; and

(3) If transmitted by the prescriber's designated agent, the full name of the designated agent.

1304.9 The dispensing pharmacist shall document the following information on each electronic prescription order that has been dispensed:

(a) The name or initials of the pharmacist who performed the final verification; and

(b) Any change or alteration made to the prescription dispensed based on contact with the practitioner to show a clear audit trail. This shall include, but not be limited to, a change in quantity, directions, or number of refills.

1304.10 Authorization obtained from the practitioner to substitute a drug, shall be documented on the prescription order, except in the case of an institutional pharmacy which maintains readily retrievable, written, documented policies authorizing such substitution.

1304.11 Electronic transmission technology shall not be used to circumvent or violate any provision of District or federal laws or regulations.

1305 ISSUANCE OF CONTROLLED SUBSTANCE PRESCRIPTIONS

1305.1 The prescribing practitioner and the pharmacist shall be jointly responsible for compliance with this chapter in prescribing and dispensing a controlled substance.

1305.2 A prescription for a controlled substance shall be issued or dispensed only for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

1305.3 A prescription for a controlled substance shall be issued for treatment of individual patients. A prescription for a controlled substance shall not be issued to an individual practitioner for general dispensing purposes.

1305.4 A prescription for a controlled substance listed in any schedule shall be used for the purpose of continuing the patient's dependency only when its issuance is pursuant to authorized clinical treatment in a narcotic treatment rehabilitation program.

1305.5 Any person issuing a prescription and any person knowingly filling a prescription which is not in conformity with this chapter shall be subject to the penalties provided for violations of the Act and this chapter.

1305.6 An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Act, and a person knowingly filling such a prescription, and the person issuing it, shall both be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

1306 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

1306.1 Except as otherwise authorized in this section, a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, shall only be dispensed pursuant to a valid written prescription signed by the prescribing practitioner, unless otherwise authorized by federal law.

1306.2 A prescription for a controlled substance listed in Schedule II shall not be filled if submitted more than thirty (30) days after the date on which the prescription is written; except as follows:

(a) A pharmacist may fill a prescription for a controlled substance listed in Schedule II that was submitted to the pharmacy more than thirty (30) days after the date on which it was written, if it is clear on the face of the prescription that the individual practitioner issued multiple prescriptions authorizing the patient to receive a total of up to a ninety (90)-day supply of the Schedule II controlled substance and:

(i) Each separate prescription was issued for a legitimate medical purpose

by an individual practitioner acting in the usual course of professional practice;

(ii) The individual practitioner provided written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription; and

(iii) The prescription is presented to the pharmacy for filling not more than ninety (90) days after the date on which the prescription was written.

1306.3 A prescription for a controlled substance listed in Schedule II shall not be refilled and shall be cancelled out by a line drawn through the entire prescription order, with the date dispensed and initials of the person that dispensed the drug.

1306.4 A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via telephone facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to issuance of the controlled substance to the patient or the patient's representative. The original prescription shall be maintained in accordance with the requirements of this chapter and as required under federal and District law.

1306.5 In emergency situations, as defined under § 1306.6 of this chapter, a pharmacist may dispense Schedule II drugs upon the oral prescription of a practitioner. The pharmacist shall comply with the following requirements as set forth in 21 CFR § 1306.11(d) and failure to do so may result in suspension or revocation of a pharmacy registration:

(a) The quantity prescribed and dispensed is limited to no more than a seven (7) day supply to treat the patient during the emergency period (dispensing beyond the emergency period shall be pursuant to a written prescription signed by the prescribing individual practitioner);

(b) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required by District and federal law;

(c) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a call back to the prescribing practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure the practitioner's identity; and

(d) Within seven (7) days after authorizing an emergency oral prescription, the practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1301 of this chapter, the prescription shall:

(1) Have written on its face "Authorization for Emergency Dispensing," and the date of the oral order; and

(2) The written prescription shall be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach the written prescription to the oral emergency prescription which was previously reduced to writing. The pharmacist shall notify, in writing, the Director if the prescribing individual practitioner fails to deliver a written prescription to him or

her. Failure of the pharmacist to notify the Director shall void the authority conferred by this section to dispense without a written prescription of a prescribing practitioner.

- 1306.6 As used in this section “emergency situation” means those situations in which the prescribing practitioner determines the following:
- (a) That immediate administration of the controlled substance is necessary, for proper treatment of the intended ultimate user;
 - (b) That no appropriate alternative treatment is available, including administration of a drug which is not a controlled substance under Schedule II; and
 - (c) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.
- 1306.7 A prescription for a Schedule II controlled substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner’s agent to the institutional or home health care pharmacy by telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.
- 1306.8 A prescription for a Schedule II controlled substance for a resident of a Long Term Care Facility may be transmitted by the practitioner or the practitioner’s agent to the dispensing pharmacy by telephone facsimile. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirements of this Title and federal and District law.
- 1306.9 A prescription for a Schedule II controlled substance for a patient enrolled in a hospice care program certified or paid for by Medicare under Title XVIII or a hospice program which is licensed by the District may be transmitted by the practitioner or the practitioner’s agent to the dispensing pharmacy by telephone facsimile. The practitioner or the practitioner’s agent shall note on the prescription that the patient is a hospice patient. The telephone facsimile shall serve as the original written prescription and shall be maintained in accordance with the requirement of this Title and federal and District law.
- 1306.10 An individual practitioner may administer or dispense directly to a patient a Schedule II controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.
- 1306.11 An institutional practitioner may administer or dispense directly, (but not prescribe) a controlled substance listed in Schedule II only pursuant to:
- (a) A valid written prescription signed by the prescribing individual practitioner;
- or
- (b) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.

1307 PARTIAL FILLING OF PRESCRIPTIONS LISTED IN SCHEDULE II

- 1307.1 The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity for a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription (or written record of the

emergency oral prescription).

- 1307.2 The remaining portion of the prescription may be filled within seventy-two (72) hours of the partial filling, however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.
- 1307.3 A Prescription for Schedule II controlled substance for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units and in accordance with federal law. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist shall also observe the following:
- (a) Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient;
 - (b) The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient";
 - (c) A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the federal and District law;
 - (d) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist;
 - (e) The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed; and
 - (f) Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

1308 LABELING OF SUBSTANCES LISTED IN SCHEDULE II

- 1308.1 The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label meeting the requirements set forth in § 1912.2 of this title.
- 1308.2 The label of a drug listed in Schedules II, III, IV, and V shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient. When the size of the label space requires a reduction in type, the reduction shall be made to a size no smaller than necessary and in no event to a size no smaller than six (6) point type.
- 1308.3 The requirements of § 1308.1 do not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, if the following limitations are observed:
- (a) Not more than a seven (7) day supply of the controlled substance listed in Schedule II is dispensed at one time;
 - (b) The controlled substance listed in Schedule II is not in the possession of the ultimate user before the administration;

(c) The institution maintains appropriate safeguards and records regarding the proper administration, control dispensing, and storage of the controlled substance listed in Schedule II; and

(d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

1308.4 When dispensed to or for a patient, the label of a drug listed in Schedules II, III, IV, or V shall contain a clear and concise warning that it is a crime to transfer the drug to any person other than the patient.

1309 PRESCRIPTIONS FOR CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV AND V

1309.1 Unless otherwise permitted under federal law, a pharmacist shall dispense directly a controlled substance listed in Schedule III, IV or V, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act only pursuant to:

(a) A valid written prescription signed by the prescribing practitioner;

(b) A telephone facsimile of a written prescription, signed by the prescribing practitioner, transmitted by the practitioner or the practitioner's designated agent to the pharmacy; or

(c) An oral prescription of a practitioner immediately reduced to writing by the pharmacist containing all information required under § 1302 of this chapter.

1309.2 An individual practitioner may administer or dispense directly to a patient a Schedule III, IV or V controlled substance in the course of his or her professional practice without a prescription, subject to the conditions set forth in 21 CFR § 1306.07.

1309.3 An institutional practitioner may administer or dispense directly, but not prescribe, a controlled substance listed in Schedule III, IV, or V only pursuant to:

(a) A valid written prescription signed by an individual practitioner;

(b) A telephone facsimile of a written prescription or order for medication transmitted by the individual practitioner or the practitioner's designated agent to the institutional practitioner or pharmacist;

(c) An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required under § 1302 of this chapter; or

(d) An order for medication made by an individual practitioner which is dispensed for immediate administration to the patient, subject to § 21 CFR 1306.07.

1310 REFILLING OF PRESCRIPTIONS LISTED IN SCHEDULES III, IV OR V

1310.1 A prescription for a controlled substance listed in Schedule III, IV, or V may not be filled or refilled more than six (6) months after the date on which the prescription was issued.

1310.1 A prescription authorized to be refilled may not be refilled more than five (5)

1310.3 Each refilling of a prescription shall be entered on the back of the prescription, or on another appropriate, uniformly maintained, readily retrievable record such as a

patient profile. The following information must be retrievable by the prescription number:

- (a) The name of the controlled substance, or the name and manufacturer of the drug if it is a substitute or generic drug for the drug actually prescribed or filled initially;
- (b) The strength and dosage form of the controlled substance;
- (c) The date of each refilling and the quantity dispensed;
- (d) The identity or initials of the dispensing pharmacist for each refill; and
- (e) The total number of refills for that prescription.

1310.4 Each refilling of a prescription shall state the amount dispensed.

1310.5 If the pharmacist merely initials and dates the back of the prescription, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.

1310.6 The prescribing practitioner may authorize additional refills of a Schedule III, IV or V prescription controlled substance on the original prescription or through an oral refill authorization transmitted to the pharmacist provided that the following conditions are met:

- (a) The total quantity authorized, including the amount of the original prescription, does not exceed five (5) refills or extend beyond six (6) months from the date of issue of the original prescription;
- (b) The pharmacist obtaining the oral authorization shall record the date, quantity of refill, and number of additional refills authorized, on the reverse of the original prescription and initial the prescription documenting that he or she received the authorization from the prescribing practitioner who issued the original prescription; and
- (c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

1310.7 Additional quantities of prescription controlled substances listed in Schedule III, IV or V, beyond the five (5) refill, six (6) month limitation, shall only be authorized by a prescribing practitioner through the issuance of a new and separate prescription.

1310.8 As an alternative to the procedures provided under § 1310.3 of this chapter, an automated data processing system may be used for the storage and retrieval of refill information for prescription drug orders for controlled substances in Schedule III, IV, or V, subject to the conditions outlined under 21 CFR § 1306.22(b).

1311 PARTIAL FILLING OF PRESCRIPTIONS LISTED IN SCHEDULES III, IV OR V

1311.1 The partial filling of a prescription for a controlled substances listed in Schedules III, IV or V is permissible within six (6) months after date thereof provided that the following occurs:

- (a) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
- (b) Each partial filling is recorded in the same manner as a refilling.

- 1311.2 The remaining portion of a partially filled prescription may be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

1312 LABELING OF SUBSTANCES LISTED IN SCHEDULES III, IV OR V

- 1312.1 The pharmacist filling a prescription for a controlled dangerous substance listed in Schedule III, IV or V shall affix to the package a label meeting the requirements set forth in § 1912.2 of this title.
- 1312.2 The requirements of § 1312.1, do not apply when a controlled substance listed in Schedule III or IV is prescribed for administration to an ultimate user who is institutionalized; Provided, that the following occurs:
- (a) Not more than thirty (30) day supply of one hundred (100) dosage units, whichever is less, of the controlled substance listed in Schedule II, IV or V is dispensed at one time;
- (b) The controlled substance listed in Schedule III, IV or V is not in the possession of the ultimate user before administration;
- (c) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III, IV or V; and
- (d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

1313 FILING OF PRESCRIPTION ORDERS

- 1313.1 Prescription orders for controlled substances in Schedules I and II shall be maintained in a file separate from all other records of the pharmacy.
- 1313.2 Prescription orders for controlled substances in Schedules III, IV and V shall be maintained either in a separate prescription file or in such form that they are readily retrievable from the other prescription records of the pharmacy. They will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is marked in red ink in the lower right corner with the letter "C" no less than one-inch high and filed in the usual consecutively numbered prescription file for non-controlled substances.
- 1313.3 All prescription orders shall be in compliance with requirements under this section, the Act and Title 21, CFR Part 1306, where applicable.

1314 DISPENSING WITHOUT A PRESCRIPTION

- 1314.1 A controlled substance listed in Schedule II, III, IV or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail; provided, that the following occurs:
- (a) The dispensing is made only by a pharmacist (as defined in 21 CFR, § 1306.02(d)), and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);

(b) Not more than 240 cc. (8 ounces) of any controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other controlled substance, nor more than forty-eight (48) dosage units of any controlled substance containing opium, nor more than twenty-four (24) dosage units of any other controlled substance may be dispensed at retail to the same purchaser in any given forty-eight (48) hour period; except pursuant to a written or oral prescription of a duly licensed practitioner in possession of a Federal Controlled Substances Registration number;

(c) The purchaser is at least eighteen (18) years of age;

(d) The pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate);

(e) A bound record book for dispensing of controlled substances under this section is maintained by pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record-keeping requirement of 21 CFR, § 1304.04); and

(f) A prescription is not required for distribution or dispensing of the substance pursuant to any other federal or District of Columbia laws or regulations, or this chapter.

1315 DELIVERY OF PRESCRIPTION MEDICATION BY MAIL OR CARRIER

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

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

1315.3 The prescription shall contain all requirements specified for prescriptions as listed within this chapter and shall be packaged and sent in conformance with the applicable federal laws and regulations of the U.S. Department of Justice, Drug Enforcement Administration 21 CFR §§ 1300 *et seq.*, and the U.S. Postal Service 18 U.S.C. § 1716.

1315.4 A pharmacy may deliver the following by employee or courier, but shall not dispense the following by mail or common carrier:

(a) Antibiotics that have been reconstituted;

(b) Prescription drugs generally recognized to be subject to significant deterioration due to heat, cold, fermentation, or prolonged agitation unless it can be documented that the drug was shipped according to industry recognized shipping standards; or

(c) Any other drug or device which federal or District law prohibits dispensing by mail.

1315.5 A Prescription drug or device shall be shipped by U.S. Postal Service, common carrier, employee, or courier service unless the purchaser agrees in advance to another means of delivery that does not violate the provisions of this chapter.

- 1315.6 Prescription drugs and medical devices dispensed by any method shall be packaged and sent in conformance with the applicable federal and District laws and regulations and standards pertaining to temperature, light, and humidity and in containers that are resistant to breaking, denting, and tampering.
- 1315.7 A prescription medication may be delivered to:
- (a) The patient for whom the prescription is prescribed;
 - (b) Wherever the patient is located;
 - (c) An agent authorized by the patient; or
 - (d) The residence of the patient, regardless of whether the patient is present at the residence at the time of delivery.
- 1315.8 If a patient authorizes delivery of a prescription medication or device to an agent at a location other than the pharmacy or the patient's residence, the pharmacy shall document in a readily retrievable record:
- (a) The patient's authorization;
 - (b) The identity of the agent to whom the medication is sent; and
 - (c) The date, time; and location where the medication was sent.

1316 TRANSFER BETWEEN PHARMACIES OF PRESCRIPTION

INFORMATION FOR REFILL PURPOSES

- 1316.1 The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible, subject to the requirements of § 1316.3 of this chapter, between pharmacies on a one-time basis only. However, pharmacies utilizing a linked pharmacy system may transfer up to the maximum number of refills permitted by law.
- 1316.2 The transfer of original prescription information for a non-controlled substance for the purpose of refill dispensing is permissible subject to the requirements of § 1316.3 of this chapter.
- 1316.3 Any authorized transfer of original prescription information between non-linked Pharmacy systems for the purpose of refill dispensing shall be subject to the following requirements:
- (a) The transfer shall be communicated directly between two licensed Pharmacists;
 - (b) The transferring pharmacist shall record on the invalidated prescription, in hardcopy or electronically, the following information:
 - (1) The words "VOID" and "TRANSFER";
 - (2) The name, address, and telephone number of the pharmacy to which it was transferred;
 - (3) The name of the pharmacist receiving the prescription information;
 - (4) For controlled substances, the DEA registration number of the prescriber and of the pharmacy to which the prescription is being transferred and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy to which the prescription is being transferred; and

(5) The date of the transfer and the name of the pharmacist transferring the information;

(c) The pharmacist receiving the transferred prescription information shall reduce to writing the following information:

(1) Write the word "TRANSFER" on the face of the transferred prescription;

(2) All information required to be on a prescription pursuant to 21 CFR § 1306.05 and this chapter;

(3) Date of issuance of original prescription;

(4) Original number of refills authorized on original prescription;

(5) Date of original dispensing;

(6) Number of valid refills remaining ;

(7) The transferring pharmacy's name, address, and telephone number;

(8) Name of pharmacist who transferred the prescription; and

(9) For controlled substances, the DEA registration number of the prescriber and the pharmacy from which the prescription was transferred, and the District of Columbia Controlled Substances registration number, if applicable, of the prescriber and of the pharmacy from which the prescription information was transferred;

1316.4 Direct pharmacist to pharmacist communication is not required between pharmacies utilizing a linked pharmacy system to transfer prescription drug orders or information for dispensing purposes. However, the common electronic file shall contain a complete record of each prescription drug order and refill dispensed, and a hard copy record of each prescription drug order accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription drug order.

1316.5 The original and transferred prescription(s) shall be maintained for a period of two (2) years from the date of initial filling in accordance with District of Columbia regulations.

1316.6 Pharmacies electronically accessing the same prescription record shall satisfy all information requirements as required of a manual prescription transferral.

1316.7 A pharmacist at the transferring pharmacy may not refill a prescription that has been transferred to another pharmacy.

1316.8 The use of unified prescription records by more than one pharmacy through a computerized prescription database does not constitute a permanent transfer of a prescription order.

1317 ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES

1317.1 The administering or dispensing directly (but not prescribing) of controlled substances listed in any schedule to a controlled substance dependent person for the purpose of detoxification or for continuing his or her dependence upon these drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program shall be permissible; provided, that the following conditions are met:

(a) Approval is obtained before the initiation of this program by submission of a

“ Notice of Claimed Investigation Exemption for a New Drug ” to the Food and Drug Administration [which will be reviewed concurrently by FDA for scientific merit and by the Pharmaceutical Control Division, for drug control requirements]; and

(b) That the clinical investigation thereafter accords with this approval, as required by the Federal Act and Federal regulations.

- 1317.2 Any practitioner who violates any of the provisions of the federal law or regulations shall be in violation of this chapter.
- 1317.3 Nothing in this chapter shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) controlled substances to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one (1) day’s medication may be administered to the person or issued for the person’s use at one time. The emergency treatment may be carried out for not more than three (3) days and may not be renewed or extended.
- 1317.4 The rules of this chapter are not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense controlled substances in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense controlled substances to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

1318-1319 [RESERVED]

1320 DISTRIBUTION BY A DISPENSER TO ANOTHER PRACTITIONER OR A REVERSE DISTRIBUTOR

- 1320.1 A practitioner who is authorized to dispense a controlled substance may distribute (without being registered to distribute) a quantity of the substance to:
- (a) A reverse distributor who is registered to receive controlled substances under federal and District law; or
- (b) Another practitioner for the purpose of general dispensing by the practitioner to his or her patients, provided that the following conditions are satisfied:
- (1) The practitioner to whom the controlled substance is to be distributed is registered appropriately to dispense that controlled substance;
 - (2) The distribution is recorded by the distributing practitioner and by the receiving practitioner in accordance with 21 CFR § 1304.22(c);
 - (3) If the substance is listed in Schedule I or II, an order form shall be used as required by 21 CFR § 1305; and
 - (4) The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section, during the twelve (12) month period in which the practitioner is registered to dispense, does not exceed five percent (5%) of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the twelve (12) month period.
- 1320.2 If at any time during the twelve (12) month period during which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him or her to another practitioner pursuant to this section will exceed five percent (5%) of the total number of dosage units of all controlled substances distributed and

dispensed by him or her during the twelve (12) month period, the practitioner shall obtain a registration to distribute controlled substances.

1321 DISTRIBUTION TO SUPPLIER

1321.1 A person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance, to the person from whom he or she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained containing the following:

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

1321.2 An order form shall be used in the manner prescribed in 21 CFR § 1305, and shall be maintained as the written record for a controlled substance listed in Schedule I or II which is returned. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the Federal Act 21 USC § 822(c) or 957(b)(1) shall be exempt from maintaining the records required by this section.

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

1322 DISTRIBUTION UPON DISCONTINUANCE OR TRANSFER OF BUSINESS

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

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

1322.2 A registrant desiring to discontinue business activities altogether or with respect to controlled substances (by transferring those business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Director, at least fourteen (14) days before the date of the proposed transfer (unless the director waives this time limitation in individual instances) the following information:

- (a) The name, address, controlled substance registration number(s), and authorized business activity of the registrant discontinuing the business (registrant-transferor);
- (b) The name, address, controlled substance registration number(s), and authorized business activity of the person acquiring the business (registranttransferee);

(c) Whether the business activities will be continued at the location registered by the person discontinuing the business, or moved to another location (if the latter, the address of the new location shall be listed); and

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

1322.3 Unless the registrant-transferor is informed by the Director, before the date on which the transfer was stated to occur, that the transfer shall not be permitted to occur, the registrant-transferor may distribute (without being registered to distribute) controlled substances in his or her possession to the registrant transferee in accordance with the following:

(a) On the date of transfer of the controlled substances, a complete inventory of all controlled substances being transferred shall be taken in accordance with 21 CFR § 1304.11. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall not be necessary to file a copy of the inventory with the Director unless requested by the Director. Transfers of any substances listed in Schedule I or II shall require the use of order forms in accordance with CFR § 1305;

(b) On the date of transfer of the controlled substances, all records required to be kept by the registrant-transferor with reference to the controlled substances being transferred, under 21 CFR § 1304, shall be transferred to the registrant transferee. Responsibility for the accuracy of the records prior to the date of transfer shall remain with the transferor. Responsibility for the custody and maintenance of the records after the date of the transfer shall be upon the transferee; and

(c) In the case of registrants required to make reports pursuant to 21 CFR § 1304, a report marked "Final" shall be prepared and submitted by the registrant transferor showing the disposition of all the controlled substances for which a report is required; no additional report will be required from him or her, if no further transactions involving controlled substances are consummated by him or her. The initial report of the registrant-transferee shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor-registrant and the substances transferred to him or her shall be reported as recipients in his or her initial report.

1323 MANUFACTURE AND DISTRIBUTION OF CONTROLLED SUBSTANCE SOLUTIONS AND COMPOUNDS BY A PHARMACIST

1323.1 A pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion that shall not exceed twenty (20%) of the complete solution, compound, or mixture.

1324 PROCEDURE FOR DISPOSING OF LEGALLY OBTAINED CONTROLLED SUBSTANCES

1324.1 Any registrant in possession of legally obtained controlled substances and desiring or required to dispose of any of these substances shall contact Drug Enforcement Administration, Regional Office, for instructions and to request the necessary form (DEA-41).

1325 ISSUANCE OF NON-CONTROLLED SUBSTANCES

1325.1 A pharmacist shall dispense a non-controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, or medical device pursuant to a valid written, oral, facsimile, or electronic

- prescription issued in compliance with this chapter by a licensed practitioner authorized to prescribe the substance or medical device.
- 1325.2 A prescription issued by a prescribing practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner only pursuant to the directions and order of the practitioner, and in conformance with applicable federal and District of Columbia laws and regulations and this chapter.
- 1325.3 A prescription order shall be issued or dispensed only for a legitimate medical purpose by a prescribing practitioner acting in the usual course of his or her professional practice.
- 1325.4 The prescribing practitioner and the pharmacist shall be jointly responsible for compliance with this chapter in prescribing and dispensing a prescribed substance or medical device.
- 1325.5 Any person issuing a prescription and any person knowingly filling a prescription which is not in conformity with this chapter shall be subject to the penalties provided for violations of the Act and this chapter.
- 1325.6 Non-controlled substance prescriptions shall have a label affixed to the package meeting the requirements as set forth in § Chapter 19 of this Title.
- 1325.7 The label required in § 1325.6 does not apply to a prescription for a non-controlled substance that is prescribed for administration to a patient who is institutionalized if the following limitations are observed:
- (a) Not more than a thirty (30) day supply or one hundred (100) dosage units, whichever is less, of the prescription is dispensed at one time;
 - (b) The prescription controlled substance is not in the possession of the patient prior to administration;
 - (c) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the prescription substance; and
 - (d) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and sets forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
- 1325.8 A prescription for a non-controlled substance shall not be filled if presented for dispensing more than one (1) year after the date on which the prescription was issued.
- 1325.9 The total amount dispensed under one prescription order for a non-controlled substance, including refills, shall be limited to a one (1) year supply, not to exceed other applicable federal or District laws.
- 1325.10 Each refilling of a prescription shall be entered on the back of the prescription, or on another appropriate, uniformly maintained, readily retrievable record such as a medication record. The following information must be retrievable by the prescription number:
- (a) The name of the drug or the name and manufacturer of the substituted drug if different than the originally prescribed or filled drug;
 - (b) The dosage form of the drug dispensed;
 - (c) The date of each refilling and the quantity dispensed;

- (d) The identity or initials of the dispensing pharmacist for each refill; and
 - (e) The total number of refills for that prescription.
- 1325.11 If the pharmacist merely initials and dates the back of a prescription or in the electronic record, he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.
- 1325.12 The prescribing practitioner may authorize additional refills of a non-controlled substance on the original prescription through an oral refill authorization transmitted to the pharmacist provided that the following conditions are met:
- (a) The total quantity authorized, including the amount of the original prescription, does not extend beyond one year from the date of issuance of the original prescription;
 - (b) The pharmacist obtaining the oral authorization shall record the date, quantity of refill, and number of additional refills authorized, on the reverse of the original prescription and initial the prescription documenting that he or she received the authorization from the prescribing practitioner who issued the original prescription; and
 - (c) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.
- 1325.13 Additional quantities of prescription non-controlled substances beyond the one year limitation, shall only be authorized by a prescribing practitioner through the issuance of a new and separate prescription.
- 1325.14 As an alternative to the procedures provided under § 1325.10 of this chapter, an automated data processing system may be used for the storage and retrieval of refill information for prescription drug orders and prescription records.
- 1325.15 The partial filling of a prescription for a non-controlled substance is permissible, if the pharmacist is unable to supply the full quantity called for in the prescription, and he or she makes a notation of the quantity supplied on the face of the written or facsimile prescription (or written record of the oral prescription), provided that:
- (a) Each partial filling is recorded in the same manner as a refilling;
 - (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
 - (c) No dispensing occurs beyond one year after the date on which the prescription was issued.
- 1325.16 A pharmacist shall notify the prescribing physician if:
- (a) The pharmacist is unable to dispense the remaining portion of a partially filled prescription for a prescription non-controlled substance within a reasonable period of time;
 - (b) The inability to do so lies with the pharmacy; and
 - (c) In the professional judgment of the pharmacist the delay may jeopardize or alter the drug therapy of the patient.
- 1326 **GENERIC SUBSTITUTION**
- 1326.1 A pharmacist may dispense a generically equivalent drug product if:
- (a) The generic product costs the patient less than the prescribed drug product;

- (b) The patient does not refuse the substitution; and
 - (c) The prescribing practitioner does not indicate on the written, facsimile, or electronic prescription form that the specific prescribed brand is to be dispensed by marking “DISPENSE AS WRITTEN,” “BRAND NECESSARY,” “NO SUBSTITUTION,” or other similar language.
- 1326.2 If a prescription is transmitted orally, the prescribing practitioner or the practitioner’s authorized agent shall prohibit substitution by specifying “BRAND NECESSARY,” “NO SUBSTITUTION,” or other similar language.
- 1326.3 The formulary of drug products for the District of Columbia shall be the chemical and generic drugs contained in the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the Orange Book)”, and its monthly updates. This drug formulary is incorporated by reference as a part of this chapter.
- 1326.4 A copy of the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” may be obtained from the Superintendent of Documents, Government Printing Office of the United States, Washington, DC 20402. The electronic version may be accessed on line at <http://www.fda.gov/cder/ob/default.htm> This URL is subject to change.

1327 SUBSTITUTION OF DOSAGE FORMS

- 1327.1 A pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided that:
- (a) The pharmacist notifies the patient of the dosage form substitution prior to filling the prescription;
 - (b) The pharmacist documents the substitution on the prescription record;
 - (c) The pharmacist notifies the practitioner of the dosage form substitution prior to dispensing or as soon as is reasonably possible thereafter; and
 - (d) The dosage form dispensed contains the identical amount of the active ingredients as the dosage prescribed for the patients, is not an enteric-coated or time release product; and does not alter desired clinical outcomes.
- 1327.2 The notification required in § 1327.1(c) shall not apply to those circumstances where the dosage form substitution is made in order to comply with the prescriber’s intent, (i.e. physician prescribed tablets but the medication only comes in capsules.)
- 1327.3 Substitution of dosage form shall not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

1328 THERAPEUTIC INTERCHANGE

- 1328.1 This section shall not apply to generic drug substitutions. For generic drug substitutions, see the requirements of § 1326 of this chapter.
- 1328.2 As used in this section, “therapeutic interchange” means the dispensing of chemically different drugs that are considered to be therapeutically equivalent.
- 1328.3 A therapeutic interchange shall not be made without the prior approval of the prescribing practitioner.

- 1328.4 The approval required pursuant to § 1328.3 may be in the form of a readily retrievable, written, documented policy maintained by the pharmacy which clearly indicates that the provider has intended to approve the therapeutic interchange.
- 1328.5 The patient shall be notified of the therapeutic interchange prior to, or upon delivery, of the dispensed prescription to the patient. The notification shall include:
 - (a) A description of the change;
 - (b) The reason for the change; and
 - (c) Contact information indicating who the patient may contact with questions concerning the change.

1330 GENERICALLY EQUIVALENT PRESCRIPTION DRUGS

- 1330.1 The Formulary of Drug Products for the District of Columbia shall be the chemical and generic drugs contained in the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (also known as the “Orange Book”), and its monthly updates, issued by the Department of Health and Human Services of the United States, 1988. This drug formulary is incorporated by reference as a part of this chapter.
- 1330.2 The publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” shall be available for public inspection at the Commission of Public Health, Department of Human Services.
- 1330.3 A copy of the publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” may be obtained from the Superintendent of Documents, Government Printing Office of the United States, Washington, D.C. 20402.

1329 RETURN OF PRESCRIPTION DRUGS

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

1330-1331 REPEALED

1332 DRUG MANUFACTURERS AND DISTRIBUTORS FEES

- 1332.1 The licensure fees for drug manufacturers and distributors located within the District of Columbia are as follows:
 - (a) Annual Fee \$200.00
 - (b) Late Fee \$100.00
 - (c) Duplicate Certificate \$ 20.00
 - (d) License Validation \$ 20.00
- 1332.2 The registration fees for drug manufacturers and distributors located outside the boundaries of the District of Columbia are as follows:
 - (a) Annual Fee \$100.00

(b) Late Fee \$ 50.00

(c) Duplicate Certificate \$ 20.00

1333 PRESCRIPTION REQUIREMENTS FOR MEDICAID COVERED SERVICES

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

(a) The prescription pad contains one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) The prescription pad contains one or more industry-recognized features designed to prevent erasure or modification of information written on the prescription by the prescriber; or

(c) The prescription pad contains one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

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

(a) The prescription pad contains one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) The prescription pad contains one or more industry-recognized features designed to prevent erasure or modification of information written on the prescription by the prescriber; and

(c) The prescription pad contains one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

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

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

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

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

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

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

requirements of this section.

1399 DEFINITIONS

1399.1 As used in this chapter, the following words and phrases shall have the meanings ascribed:

Act--District of Columbia Uniform Controlled Substances Act of 1981, effective August 5, 1981, (D. C. Law 4-29; D.C. Official Code § 48-901.01).

Administer--the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Adulterated drug or medical device--as defined in § 501 of the Federal Food, Drug and Cosmetic Act, (Pub. L. 96-354, 21 USC § 351) as amended.

Automated data processing system--a system utilizing computer software and hardware for the purpose of recordkeeping.

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

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

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

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