

**DISTRICT OF COLUMBIA  
BOARD OF ELECTIONS AND ETHICS**

**NOTICE OF FINAL RULEMAKING**

The District of Columbia Board of Elections and Ethics pursuant to the authority set forth in D.C. Code §1-1001.05 (a) (14) hereby gives notice of the adoption of the following amendments to 3 DCMR Chapter 4, "Hearings"; 3 DCMR Chapter 5, "Voter Registration"; and 3 DCMR Chapter 6, "Eligibility of Candidates". The Board took final rulemaking action with respect to these amendments at a regular meeting on Thursday, June 11, 2009

The proposed amendments: 1) ensure that the Board's regulations conform to the District of Columbia Election Code of 1955, as amended, and other federal and local rules and regulations in force and in practice in the District of Columbia; 2) reflect Board policy that Board minutes will be available on the Board's website; 3) correct technical and typographical errors.

No changes have been made to the text of the proposed rules, as published with the Notice of Proposed Rulemaking in the D.C. Register on April 10, 2009 at 56 DCR 2732. These amendments will be effective upon publication of this notice in the D.C. Register.

*Section 402 of Chapter 4 of 3 DCMR, "Hearings," shall be amended as follows:*

- 1) By deleting the phrase "include the following" in subsection 402.2
- 2) By striking the word "Time" in paragraph 402.2(a) and inserting the phrase "Provide the time" in its place;
- 3) By striking the phrase "References to" in paragraph 402.2(b) and inserting the word "Reference" in its place;
- 4) By striking the phrase "The purpose" in paragraph 402.2(c) and inserting the phrase "State the purpose" in its place;
- 5) By striking the phrase "Advise to" in paragraph 402.2(d) and inserting the word "Advise" in its place; and
- 6) By striking the phrase "Advise to parties" in paragraph 402.2(e) and inserting the phrase "Advise the party or parties" in its place.

*Section 405 of Chapter 4 of 3 DCMR, "Hearings," shall be amended as follows:*

- 1) By inserting the phrase "and the minutes available on the Board's website" after the word "Counsel" and before the word "." in subsection 405.5.

*Section 406 of Chapter 4 of 3 DCMR, "Hearings," shall be amended as follows:*

- 1) By striking the phrase "except that a meeting to consider personnel matters, litigation, or other matters that are privileged or sensitive and are not required to

- be open by applicable law may be closed at the discretion of the Board.” in subsection 406.1 and inserting the phrase “with the exception of executive sessions, as that term is defined and explained in Section 103 in Chapter 1 of this title.” in its place;
- 2) By striking the phrase “or the schedule for each hearing shall be posted in the office of the Board and available to the public at least twenty-four (24) hours prior to a meeting or hearing” in subsection 406.2 and inserting the phrase “and the minutes from the previous regular Board meeting shall be posted in the office of the Board and on its website at least twenty-four (24) hours prior to a regular Board meeting” in its place; and
  - 3) By inserting the phrase “and the minutes from the previous regular Board meeting” after the word “agenda” and before the word “shall” in subsection 406.3.

*Section 428 of Chapter 4 of 3 DCMR, “Hearings,” shall be amended as follows:*

- 1) By striking the number “431” in subsection 428.9 and inserting the number “432” in its place.

*Section 500 of Chapter 5 of 3 DCMR, “Voter Registration,” shall be amended as follows:*

- 1) By striking the phrase “Federal Election Commission” in subsection 500.1 and inserting the phrase “Election Assistance Commission” in its place; and
- 2) By adding two new subsections 500.13 and 500.14 to read as follows:

“500.13 An elector may vote in the primary election of a political party only if he or she is a duly registered voter whose voter registration application indicates an affiliation with the party holding the primary election.

500.14 A person who is otherwise qualified to vote may pre-register on or after his or her 17th birthday and may vote in any election occurring on or after his or her 18th birthday.”

*Section 503 of Chapter 5 of 3 DCMR, “Voter Registration,” shall be amended as follows:*

- 1) By inserting the phrase “, pursuant to the Uniformed and Overseas Citizens Absentee Voting Act of 1986,” after the word “may” and before the word “obtain” in subsection 503.1;
- 3) By striking the phrase “Federal Government Post Card Application” in subsection 503.1 and inserting the phrase “Federal Post Card Application” in its place;
- 4) By inserting the word “or” after the word “;” in paragraph 503.2 (b);
- 5) By striking the phrase “; or” in paragraph 503.2 (c) and inserting the word “.” in its place; and
- 6) By deleting paragraph 503.2(d) in its entirety.

*Section 507 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in the title of subsection 507 and replacing it with the phrase "Department of Motor Vehicles";
- 2) By deleting the phrase "Bureau of Motor Vehicle Services (BMVS)" in subsection 507.1 and inserting the phrase "Department of Motor Vehicles (DMV)" in its place;
- 3) By deleting the word "original" in subsection 507.4;
- 4) By deleting the phrase "Bureau of Motor Vehicle Services (BMVS)" in subsection 507.6 and inserting the phrase "DMV" in its place;
- 5) By deleting the phrase "Bureau of Motor Vehicle Services (BMVS)" in subsection 507.7 and inserting the phrase "DMV" in its place;
- 6) By deleting the phrase "Bureau of Motor Vehicle Services (BMVS)"; wherever it appears in subsection 507.8 and inserting the phrase "DMV" in its place;
- 7) By deleting the phrase "voter registration form" in subsection 507.8 and inserting the phrase "request for voter registration or notice of change of a name, address, or party" in its place;
- 8) By deleting the phrase "Chief Administrative Officer of the Bureau of Motor Vehicle Services (BMVS)" in subsection 507.9 and inserting the phrase "Director of the DMV" in its place; and
- 9) By deleting the phrase "and of the National Voter Registration Act Conforming Amendment Act of 1994" in subsection 507.9 and inserting the phrase ", the National Voter Registration Act Conforming Amendment Act of 1994, and the Help America Vote Act of 2002" in its place.

*Section 508 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) Inserting the phrase "Parks and" after the word "of" and before the word "Recreation".

*Section 509 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in subsection 509.9 and inserting the phrase "DMV" in its place.

*Section 510 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in subsection 510.6 and inserting the phrase "DMV" in its place.

*Section 513 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in paragraph

513.1 (c) and inserting the phrase "DMV" in its place.

*Section 514 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in paragraph 514.1 (c) and inserting the phrase "DMV" in its place.

*Section 516 of Chapter 5 of 3 DCMR, "Voter Registration," shall be amended as follows:*

- 1) By deleting the phrase "Bureau of Motor Vehicle Services" in subsection 516.1 and inserting the phrase "DMV" in its place; and
- 2) By adding a new subsection 516.7 to read as follows:

"516.7 The Board's Executive Director may enter into agreements with other Chief State Election Officials for the purpose of verifying information on its statewide voter registration list to ensure the accuracy of the District's voter registry."

*Section 604 of Chapter 6 of 3 DCMR, "Eligibility of Candidates," shall be amended as follows:*

- 1) By deleting the phrase "not later than twenty-four hours (24 hrs.) following receipt of notice of the election results" in subsection 604.3 and inserting the phrase "not later than 4:45 p.m. on the third (3<sup>rd</sup>) day immediately following the election" in its place; and
- 2) By deleting the phrase "not later than five (5) days following receipt of notice of election results" in subsection 604.4 and inserting the phrase "not later than 4:45 p.m. on the seventh (7<sup>th</sup>) day immediately following the election" in its place.

**DEPARTMENT OF HEALTH**

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**NOTICE OF FINAL RULEMAKING**

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The Director of the Department of Health, pursuant to the authority set forth in section 19(a)(3) of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980, (D.C. Law 3-98; D.C. Official Code § 47-2885.18.01(a)(3)); 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); Mayor's Order 98-48, dated April 15, 1998, Section 4902 of the Fiscal Year 2002 Budget Support Act of 2001, effective October 3, 2001, (D.C. Law 14-28; D.C. Official Code § 7-731); Section 15 of the District of Columbia Drug Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990, (D.C. Law 8-137; D.C. Official Code § 48-714(a)); and Mayor's Order 98-88, dated May 29, 1998; hereby gives notice of the adoption of the following amendments to Chapter 13 (Prescriptions and Distribution) of Title 22 of the District of Columbia Municipal Regulations (DCMR).

The purpose of the amendments is to clarify the requirements for dispensing prescription by mail, to set forth the requirements for delivering prescriptions to patients, to set forth the requirements for dispensing non-controlled substances, to clarify and consolidate the requirements for distribution to another practitioner, supplier or a reverse distributor, to amend the regulations concerning generic substitutions and dosage form substitutions, to set forth the requirements for making therapeutic drug interchanges, and to prohibit a pharmacy from accepting any unused prescription or drug after it has been dispensed or sold, for the purpose of re-dispensing or resale to any person.

This rulemaking was previously published as proposed rulemaking on May 25, 2007 at 54 DCR 5300. The Department received written comments from the National Association of Chain Drugs Stores and Kaiser Permanente.

The Department subsequently amended the proposed rulemaking §§ 1315.4 - 1315.6, 1315.8, 1325.16, 1326, 1327, 1399.1, and added new § 1328. The amended rulemaking was then republished as proposed rulemaking on May 16, 2008 at 55 DCR 5741 to provide thirty (30) days to receive comments on the revised rulemaking. In response to the revised rulemaking the Department received public comments from the National Association of Chain Drug Stores. The Department subsequently amended §§ 1306.2, 1310.1, 1326.1(a) of the proposed rulemaking.

The Department subsequently amended and published the proposed rulemaking on April 24, 2009 at 56 DCR 3147. Written comments were received from CVS Caremark on May 31, 2009 in response to the notice. The comments were considered. However, no further changes were made to the regulations. These regulations will become effective upon publication of this notice in the D.C. Register.

**The following rulemaking action is proposed:**

**CHAPTER 13 (PRESCRIPTIONS AND DISTRIBUTION) is amended as follows:**

**Section 1306.2 is amended to read as follows:**

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 dated.

**Section 1308.1 is amended to read as follows:**

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.

**Section 1310.1 is amended to read as follows:**

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.

**Section 1312.1 is amended to read as follows:**

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.

**The section heading for 1315 is amended to read as follows:**

**1315            DELIVERY OF PRESCRIPTION MEDICATION BY MAIL OR CARRIER**

**Section 1315 is amended to read as follows:**

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.

**Section 1320 is amended to read as follows:**

**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.

**Section 1321 is amended to read as follows:**

**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.

**Section 1322 is amended to read as follows:**

**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 (registrant-transferee);
- (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.

**Section 1323 is amended to read as follows:**

**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.

**A new section 1325 is added to read as follows:**

**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.

**A new section 1326 is added to read as follows:**

**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.

**A new section 1327 is added to read as follows:**

**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.

**A new section 1328 is added to read as follows:**

**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.

**A new section 1329 is added to read as follows:**

**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 re-dispensing or resale to any person.

**Section 1330 is repealed.**

**Section 1331 is repealed.**

**Section 1399.1 is amended as follows:**

**a) The following terms with the ascribed meanings are added as follows:**

**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.

**Courier**— An individual or entity that is hired to take parcels directly from one place to another.

**DEA**— The United States Drug Enforcement Administration

**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.

**Dispensing pharmacist**— A pharmacist who, in the process of dispensing a prescription medication after the complete preparation of the prescription medication and before delivery of the prescription medication to a patient or patient's agent, verifies, checks, and initials the medication record.

**Non-Prescription drug**— A drug which may be sold without a prescription and which is labeled for use by the consumer in accordance with the requirements of the laws and rules of the District of Columbia and the federal government and includes both the classifications over-the-counter drugs and restricted drugs.

**Restricted drug**— A drug for which a prescription is not required that pursuant to District of Columbia or federal law or regulation must be stored behind the pharmacy counter and which shall not be directly accessible to the public.

**Therapeutic interchange**— The dispensing of chemically different drugs that are considered to be therapeutically equivalent.

**Therapeutically equivalent drugs**- Drug products that are chemically dissimilar but produce essentially the same therapeutic outcome and have similar toxicity profiles. Usually these drugs are within the same pharmacologic class. They frequently differ in chemistry, mechanism of action, and pharmacokinetic properties, and may possess different adverse reaction, toxicity, and drug interaction profiles.

## DEPARTMENT OF HEALTH CARE FINANCE

## NOTICE OF FINAL RULEMAKING

The Director of the Department of Health Care Finance, pursuant to the authority set forth in Section 7a of the Health Care Privatization Amendment Act of 2001, effective July 12, 2001 (D.C. Law 14-18; D.C. Official Code §7-1405.01), as amended, and the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code §7-771.05(6)), hereby gives notice of the adoption of an amendment to Section 3304, of Title 22 of the District of Columbia Municipal Regulations (DCMR), entitled "Eligibility Criteria Effective June 1, 2006." The purpose of these final rules is to amend the eligibility requirements of the D.C. HealthCare Alliance (Alliance) program to exclude individuals who have third party insurance, including Medicare, from enrollment in the Alliance program.

The Alliance program was designed to be a safety net for District residents without any health insurance. The program currently provides health benefits for more than 45,000 low-income residents. Alliance enrollment has expanded rapidly since the program was implemented. The District remains committed to this safety net. However, in the current fiscal climate, the District can not sustain the Alliance without thoughtful policies to ensure the program's long term viability. Individuals with third party insurance, including Medicare, have alternate means of accessing health care. Additionally, the Alliance operates exclusively in a managed care environment, thereby creating significant benefit coordination issues (and limited capacity to leverage cost savings) when it is used as a wrap-around for other forms of health insurance. In order to ensure adequate funding to keep pace with the demand for Alliance benefits among the growing low-income populations, it is not financially feasible at this time to permit individuals with third party insurance to enroll in the Alliance program.

A notice of proposed rulemaking was published in the *DC Register* on April 24, 2009 (56 DCR 003160). Comments were received but no substantive changes have been made. The proposed rules were approved on June 2, 2009 by the Council of the District of Columbia (See Resolution 18-149). These rules shall become effective upon publication of this notice in the *DC Register*.

**Section 3304.2 (Eligibility Criteria Effective June 1, 2006) of Title 22 of the DCMR (Public Health and Medicine) is amended to read as follows:**

- 3304.2 Eligibility for the D.C. HealthCare Alliance is limited to residents of the District of Columbia who are not eligible for Medicaid or Medicare or are not enrolled in any other third party health insurance program, and who live in households:
- (a) With a countable income of less than 200 percent of the Federal Poverty Level; and
  - (b) With countable resources less than \$ 4,000 (or \$ 6,000 if the individual lives with a spouse or cares for a child who is residing in the home).

## DEPARTMENT OF HEALTH CARE FINANCE

NOTICE OF FINAL RULEMAKING

The Director of the Department of Health Care Finance, pursuant to the authority set forth in An Act to enable the District of Columbia to receive federal financial assistance under Title XIX of the Social Security Act for a medical assistance program, and for other purposes, approved December 27, 1967 (81 Stat. 774; D.C. Official Code § 1-307.02) and the Department of Health Care Finance Establishment Act of 2007, effective February 27, 2008 (D.C. Law 17-109; D.C. Official Code § 7-771.05(6)), hereby gives notice of the adoption of an amendment to Chapter 41 of Title 29 of the District of Columbia Municipal Regulations (“DCMR”), entitled “Ticket to Work Demonstration Project for Individuals with HIV.” This amendment repeals Chapter 41 of Title 29 DCMR because the Ticket to Work Demonstration Project for individuals with HIV (“Demonstration Project”) is no longer in existence.

A notice of proposed rulemaking was published for comment in the *D.C. Register* on April 24, 2009 (56 DCR 3162). No comments were received and no changes were made to the proposed rule. This rule shall become effective on the date of publication of this notice in the *D.C. Register*.

**Chapter 41 of Title 29 of the DCMR is amended to read as follows:**

**CHAPTER 41 Repealed.**

**THE DISTRICT OF COLUMBIA HOUSING AUTHORITY****NOTICE OF FINAL RULEMAKING**

The Board of Commissioners of the District of Columbia Housing Authority (DCHA) hereby gives notice of the following amendments to selected provisions of Title 14 of the District of Columbia Municipal Regulations. The DCHA's rulemaking authority is found in the District of Columbia Housing Authority Act of 1999 at D.C. Code § 6-202. A Notice of Proposed Rulemaking was published in the D.C. Register on May 1, 2009 at 56 DCR 003504.

The amendments are to Section 9311.4 of Chapter 93 of Title 14 of the District of Columbia Municipal Regulations and contain the rules governing the term of a Housing Assistance Payment Contract under DCHA's Partnership Program for Affordable Housing. Final action to adopt this rule was taken at the Board of Commissioners regular meeting on June 10, 2009. These final rules will be effective upon publication of this notice in the D.C. Register.

9311.4 Once the Partnership Program units are occupied, DCHA will enter into a HAP Contract with the Owner based on the FMRs in place at the time the HAP Contract is executed. Upon commencement of the contract term, DCHA will make monthly Housing Assistance Payments in accordance with the HAP Contract for each unit occupied by an eligible family. The initial term of the HAP Contract is up to fifteen (15) years, subject to future availability of appropriations, and the HAP Contract may be extended for an indefinite period thereafter. To obtain the current FMRs, see Section 9303.5 of this Title.

**D.C. DEPARTMENT OF HUMAN RESOURCES****NOTICE OF FINAL RULEMAKING**

The Director, D.C. Department of Human Resources, with the concurrence of the City Administrator, pursuant to Mayor's Order 2008-92, dated June 26, 2008, and in accordance with Title XIX of the District of Columbia Government Comprehensive Merit Personnel Act of 1978, effective March 3, 1979 (D.C. Law 2-139; D.C. Official Code § 1-619.01 *et seq.*) (2006 Repl.), hereby gives notice that final rulemaking action was taken to adopt these rules. The main purpose of this Notice of Proposed Rulemaking is to amend subsection 1904.3 (e) of Chapter 19, Incentive Awards, of **Title 6 of the District of Columbia Municipal regulations (DCMR)**, to specify that a *Special Act or Service Award* may be given to an employee with a satisfactory performance rating. Subsection 1904.3 (b) is also being amended. No comments were received and no changes were made to the Notice of Proposed Rulemaking published in the *D.C. Register* on May 1, 2009 (56 DCR 003525). Final rulemaking action was taken on June 9, 2009.

**CHAPTER 19****INCENTIVE AWARDS**

*Chapter 19, Incentive Awards, of Title 6 of the District of Columbia Municipal Regulations, is amended as follows:*

*Subsections 1904.3 (b) and (e) are amended to read as follows:*

- (b) Such special act or service may include but is not necessarily limited to the performance of a temporary assignment of the duties of a position, in addition to the employee's position, and with a performance level of the duties of both positions within prescribed criteria in this chapter; performance of unusual duties for limited periods; exemplary or courageous handling of an emergency situation in connection with the performance of assigned duties; and any such other special acts or services as may be specified in criteria established by the personnel authority. This award category shall not be used to reward year round exemplary performance, which is covered under the Exemplary Performance Awards in section 1904.2 of this section.
- (e) For the purpose of determining the amount of a Special Act or Service Award for an employee, the amount of the award shall be calculated using the employee's rate of basic pay during the performance rating period in which the performance contribution was made. The amount of this award may be in the range between 1% and 10% of the employee's rate of basic pay; the exact percentage to be determined by the agency, with the approval of the appropriate Agency Incentive Awards Committee as specified in section 1903.2 of this chapter. The performance rating of an employee considered for a Special Act or Service Award shall be at least satisfactory.

WASHINGTON CONVENTION CENTER AUTHORITY

NOTICE OF FINAL RULEMAKING

The Board of Directors of the Washington Convention Center Authority (“Authority”), pursuant to section 203 of the Washington Convention Center Authority Act of 1994, D.C. Law 10-188, D.C. Code § 10-1201.03 as amended, hereby gives notice of its adoption, on March 5, 2009, of the following amendments to Chapters 1 and 3 of Title 19 of the District of Columbia Municipal Regulations. No comments have been received and no changes have been made to the text of the proposed rulemaking published on April 24, 2009 at 56 DCR 3189-3190.

This rulemaking shall take effect immediately upon publication in the *District of Columbia Register*.

Chapter 1 of Title 19 of the District of Columbia Municipal Regulations is amended as follows:

**CHAPTER 1. WASHINGTON CONVENTION CENTER AUTHORITY: BY LAWS**

\* \* \*

114. Approval of Certain Contracts.

114.1 Before the Authority awards any contract that requires the approval of the District of Columbia Council in accordance with D.C. Code § 2-301.05a, and prior to the submission of any such contract to the Council, the Board shall first approve the contract by a resolution passed by a majority of the Members.

\* \* \*

Chapter 3 of Title 19 of the District of Columbia Municipal Regulations is amended as follows:

**CHAPTER 3. WASHINGTON CONVENTION CENTER AUTHORITY: PROCUREMENT**

300. General Requirements: Procurement Authority.

\* \* \*

300.7 No contract requiring the submission to, and approval by, the District of Columbia Council in accordance with D.C. Code § 2-301.05a shall be awarded unless first approved by a majority of the Board by resolution prior to submission to the Council.