

DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Director of the Department of Health (“Department”), pursuant to the District of Columbia Health Occupations Revision Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1203.02(14)), Mayor's Order 98-140, dated August 20, 1998, the SafeRx Amendment Act of 2008, effective March 26, 2008 (D.C. Law 17-0131; 55 DCR 4462, published on April 25, 2008) (the Act), and Mayor’s Order 2008-94, dated July 3, 2008, hereby gives notice of his intent to take final rulemaking action to adopt the following amendments to chapter 83 of Title 17 (Business, Occupations and Professions) of the District of Columbia Municipal Regulations (DCMR),(Pharmaceutical Detailers) in not less than thirty (30) days from the date of publication of this notice in the D.C. Register.

The purpose of these amendments is to further clarify the requirements and scope of this chapter. These amendments will further clarify which individuals are subject to the licensure requirement, provide a time line for the Board of Pharmacy (“Board”) to make decisions on licensure applications, clarify that practices that are in compliance with the FDA’s policy and regulations will not be deemed a violation of this chapter, set forth the types of documents and information that should be maintained by pharmaceutical detailers, provide further clarification regarding health professionals’ requests not to receive any further sales calls, and create a supervised practice authorization that will allow applicants with licensure applications pending before the Board of Pharmacy to practice under supervision for a period of sixty (60) days.

Chapter 83 (Pharmaceutical Detailers) of Title 17 (Business Occupations and Professions) is amended as follows:

New sections 8300.5 to 8300.9 are added to read as follows:

- 8300.5 For purposes of this chapter, an individual shall be deemed as engaging in the practice of pharmaceutical detailing if:
- (a) He or she is acting as a representative of a pharmaceutical manufacturer or labeler; and
 - (b) Communicating in person with a licensed health professional or an employee or representative of a licensed health professional located in the District of Columbia;
 - (c) In a non-conference setting, as defined in this chapter;
 - (d) For the purpose of selling, marketing, or promoting a prescription or over-the-counter pharmaceutical product for use in humans, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such product.

- 8300.6 The scope of this chapter shall not apply to representatives who only sell, market, or promote veterinary drugs.
- 8300.7 The scope of this chapter shall not apply to the act of providing information about a pharmaceutical product solely for the purpose of conducting or pertaining to clinical trials, investigational drugs, or a Risk Evaluation and Mitigation Strategy pursuant to the Federal Food, Drug and Cosmetic Act.
- 8300.8 The scope of this chapter shall not apply to activities taking place at a conference, as defined in this chapter.
- 8300.9 The scope of this chapter shall not apply to health professionals participating in a conference, as defined in this chapter, including conferences targeting a local audience, solely as a speaker or presenter with respect to his or her area of expertise.

Section 8304.1(c) is amended to read as follows:

- 8304.1(c) Submit an official certificate of graduation or transcript in a sealed envelope from the educational institution(s) to the Board, which shall verify that the applicant meets the educational requirements set forth under § 8302 of this chapter;

New sections 8304.2 and 8304.3 are added to read as follows:

- 8304.2 The Board shall make a decision whether to approve or to initiate the process to deny an application for licensure within sixty (60) days after receipt of a completed application package containing all required materials, information, and supporting documents.
- 8304.3 If the Board initiates the process to deny an application, the Board shall send a written notice to the Applicant of the Board's decision to initiate the process within sixty (60) days. However, the formal denial process under the Administrative Procedures Act shall not be included within the sixty (60) day requirement.

Section 8305.1 is amended to read as follows:

- 8305.1 A pharmaceutical detailer shall not engage in any deceptive or misleading marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact. Practices and conduct in compliance with the Food and Drug Administration's laws, regulations, policies and guidelines shall not be deemed a violation of this subsection.

Sections 8305.7 to 8305.10 are amended to read as follows:

- 8305.7 For purposes of § 8305.6, unless the person continuing to make the sales calls has actual knowledge of the request, a pharmaceutical manufacturer or labeler's employees and representatives will not be deemed to have knowledge of a health care provider's request until thirty (30) days after the health care provider submits the written request to the pharmaceutical detailer or his or her employer.
- 8305.8 A pharmaceutical detailer shall not offer a gift or remuneration of any kind to a member of a medication advisory committee; except that a pharmaceutical detailer may give medication samples to a member of a medication advisory committee that is also a licensed physician engaged in the practice of medicine.
- 8305.9 A pharmaceutical detailer shall not employ any inducement or misleading statements to gain access to a healthcare professional.
- 8305.10 A pharmaceutical detailer shall provide information to healthcare professionals That is accurate and fairly balanced in compliance with FDA policy and practices on the provision of information to health care professionals. However, nothing in this section shall be construed to require a pharmaceutical detailer to promote a competitor's product.

A new section 8305.11 is added to read as follows:

- 8305.11 In addition to the regulations set forth under this section, any holder of a license under this chapter or any person authorized to practice pharmaceutical detailing functions under this chapter shall comply with the standards of ethical and professional conduct established by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its publication entitled "PhRMA Code on Interactions With Healthcare Professionals" as it may be amended or republished from time to time. Where there is a conflict between this publication and the regulations set forth in this Chapter or the provisions of the Act, the regulations and/or Act shall control.

Sections 8308.1 to 8308.2 are amended to read as follows:

- 8308.1 A minimum of fifty (50) minutes shall constitute one (1) contact hour.
- 8308.2 For approved undergraduate courses, each semester hour of credit shall constitute fifteen (15) contact hours of continuing education credit.

A new section 8309.6 is added to read as follows:

- 8309.6 For purposes of complying with this section, a pharmaceutical detailer shall

maintain documents and information relating to his or her communications with licensed health professionals or with employees or representatives of licensed health professionals that include but are not limited to:

- (a) The name, business address, and telephone number of the healthcare professional the detailer visited;
- (b) The date, time and location of the visit;
- (c) The products discussed;
- (d) Whether samples were provided; and
- (e) The type of materials provided to the health care professional, if applicable.

A new section 8311 is added to read as follows:

8311 SUPERVISED PRACTICE

8311.1 An applicant for a pharmaceutical detailer license may engage in the supervised practice of pharmaceutical detailing under the supervision of a licensed pharmaceutical detailer for a period not to exceed sixty (60) days under the following conditions:

- (a) The applicant has an initial application for licensure pending before the Board;
- (b) Has received a supervised practice letter from the Board; and
- (c) Has not previously received a supervised practice letter from the Board.

8311.2 The supervising pharmaceutical detailer shall be fully responsible for the supervised practice of the supervisee during the period of supervision, and is subject to disciplinary action for any violation of the Act or this chapter by the person being supervised.

8311.3 A supervisee shall be subject to all applicable provisions of the Act and this chapter.

8311.4 If the Board finds that a person practicing under supervision has violated the Act or this title, the Board may, in addition to any other disciplinary actions permitted by the Act, deny, revoke, suspend, or restrict the privilege of the supervisee to practice.

Section 8399.1 is amended as follows:

a) **The following terms are repealed:**

Marketing Representative- an individual who is employed by or is under contract to represent a manufacturer or labeler and engages in the marketing of pharmaceutical products in the District to any person or entity licensed to provide health care in the District.

Prescriber- a person who is licensed, registered, or otherwise authorized by the District to prescribe and administer prescription drugs in the course of a professional practice.

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

Conference- A meeting, symposium, expo, exhibit, convention, assembly, or like gathering for the discussion of health-related issues consisting of multi-pharmaceutical company or labeler representation and targeting a regional, national or international audience.

Multi-pharmaceutical or labeler representation- at least three or more pharmaceutical companies or labelers which shall not be subsidiaries, or affiliations of the same company or parent company.

Pharmaceutical Detailer: a person licensed under the Act to engage in the practice of pharmaceutical detailing.

Sales Call- any in person communication with a health care professional or his or her employees or representatives for the direct purpose of selling marketing, or promoting a pharmaceutical product, or providing information about a pharmaceutical product for the purpose of selling, marketing, or promoting such pharmaceutical product on behalf of a pharmaceutical manufacturer or labeler.

All persons desiring to comment on the subject matter of this proposed rulemaking action shall submit written comments, not later than thirty (30) days after the date of publication of this notice in the D.C. Register, to Kenneth Campbell, General Counsel, the Department of Health, Office of the General Counsel, 825 North Capitol Street, N.E., 4th Floor, Washington, D.C. 20002. Copies of the proposed rules may be obtained between the hours of 9:00 a.m. and 5:00 p.m. at the address listed above.

OFFICE OF THE STATE SUPERINTENDENT OF EDUCATION

NOTICE OF PROPOSED RULEMAKING

The State Superintendent of Education, pursuant to the authority set forth in Section 3(b)(3) of the District of Columbia State Education Office Establishment Act of 2000 (D.C. Law 13-176; D.C. Official Code § 38-2602(b)(3)) (2008 Supp.), and Title IV, Section 403 of the Public Education Reform Amendment Act of 2007 (D.C. Law 17-9; D.C. Official Code § 38-2652)(2008 Supp.), and Section 9 of the District of Columbia Non resident Tuition Act of 1960, 74 St. 853, P.L. 86-725, as added by the Truth in Student Residency in Public and Public Charter Schools Act of 2004 (D.C. Law 15-205; D.C. Official Code § 38-301 *et seq.* gives notice of the intent to amend Chapter 50 of Title 5, of the District of Columbia Municipal Regulations (DCMR), entitled "Residency Verification for the District of Columbia Public Schools and Public Charter Schools" in a new Chapter A50, in not less than thirty (30) days from the date of publication of this notice in the D.C. Register. Upon final adoption of Title 5, Chapter A50, Chapter 50 will be repealed.

In June 2008 the State Board of Education approved a revision to one portion of the regulations enabling the District of Columbia Public schools system and public charter schools to begin the residency verification process as early as May 1. See, *55 District of Columbia Register* 6498 (June 13, 2008). The rule was put into effect as an emergency rule which expired in October 2008. The proposed regulations also enable schools to begin the residency verification process as early as April 1.

CHAPTER A50

RESIDENCY VERIFICATION FOR PUBLIC SCHOOLS
AND PUBLIC CHARTER SCHOOLS**A5000. General Policy.**

A5000.1 Public education in the District of Columbia includes the District of Columbia Public Schools system and all public charter schools. All students in such schools must have proof of residency in the District of Columbia or pay tuition. A determination of residency status shall be made annually for each student.

A5000.2 District residency shall be determined pursuant to the District of Columbia Nonresident Tuition Act of 1960, effective September 8, 1960 (74 Stat. 853; D.C. Official Code § 38-301 *et seq.*).

A5001. Students Entitled to Enrollment without Payment of Non-Resident Tuition.

A5001.1 Students entitled to enrollment without payment of non-resident tuition are either:

(a) A student under eighteen (18) years of age who is otherwise eligible for

admission to the District of Columbia Public School system (DCPS) or a public charter school, and who qualifies for free instruction under one of the following categories:

- (1) A student who is in the care or control of a parent, guardian, custodian, or primary caregiver who is a resident of the District of Columbia;
 - (2) A student who is a resident of the District of Columbia and does not have a living parent, guardian, custodian, or other primary caregiver;
 - (3) A student who is a ward of the District of Columbia;
 - (4) A student who is homeless;
 - (5) A student who is living with his or her spouse, when the spouse is eighteen (18) years of age or older and is a resident of the District of Columbia; or
- (b) An adult student who is otherwise eligible for admission to DCPS or a public charter school and a resident of the District of Columbia. For the purposes of this chapter, the residence of an adult student is the address of the adult student, not the address of the adult student's parent, custodian, guardian or other primary caregiver.

A5002 Establishment or Verification of Residency: Timing

A5002.1 The residency status of each student enrolled in a public school in the District of Columbia shall be verified annually at the school attended by the student no earlier than April 1 and no later than October 5 for the school year that begins on or after July 1 of each year.

A5002.2 The residency status of each student enrolling in a public school after the beginning of a school year shall be established by October 5, or no later than ten (10) days following enrollment, whichever is later.

A5002.3 The residency status of a student, who attends a school other than a public school in the District of Columbia and whose tuition is paid by the District of Columbia, shall be verified in conformance with the procedures set forth in Sections A5002.1 and A5002.2 above.

A5002.4 A student shall be permitted to attend and remain enrolled in a school while his or her residency verification is pending.

A5003 Establishment or Verification of Residency: Documentation

A5003.1 A parent, guardian, custodian, other primary caregiver, or adult student shall provide documentation in compliance with District of Columbia laws, including Title 38 of the District of Columbia Code §§ 38-308 through 38-310.

A5003.2 Documentation to establish or verify residency may be presented in the following manner:

- (a) Provided to the school by the parent, guardian, custodian, primary care giver, an adult student, in person or through other appropriate means specified by the LEA; or
- (b) Subject to implementation of an interagency data sharing process, pursuant to such a process with the consent of the parent, guardian, primary caregiver, or adult student.

A5004. Other Primary Caregiver: Documentation of Status

A5004.1 An other primary caregiver seeking to enroll a student in school shall provide documentation that establishes his or her status as an other primary caregiver in addition to documentation that establishes the caregiver's residency status.

A5004.2 The primary caregiver status of each person other than a parent, custodian, or guardian seeking to enroll a student in a school shall be established through the use of documentation set forth in D.C. Code § 38-310.

A5005 Exceptional Circumstances

A5005.1 Exceptional circumstances exist when documentation to establish or verify residency or status of “other primary caregiver” pursuant to District of Columbia law and Sections A5003 and A5004 above is not available.

A5005.2 Policies and procedures shall address and verify residency and caregiver status in exceptional circumstances in conformance D.C. Code §§ 38-311, when documentation set forth in D.C. Code §§ 38- 309 and 38-310 is unavailable.

A5005.3 The policies and procedures for exceptional circumstances shall be designed to facilitate rather than hinder the residency verification process and may include home visits. These policies shall designate one or more individuals authorized to determine residency and primary caregiver status in the event of exceptional circumstances in conformance with District law.

A5005.4 The policies and procedures for exceptional circumstances shall be submitted to and approved or disapproved by the Office of the State Superintendent of Education thirty days after submission, no later than July 1, 2009 or within 30 days after any material revision to a previously approved policy and procedure.

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An LEA shall amend policies in conformance with comments from the OSSE for approval.

A5005.5 Upon evidence satisfactory to the OSSE, that a child is self-supporting or that care, custody and substantial support are supplied by a person(s) with whom a child is residing in the District of Columbia, and that the parent or guardian of such child is unable to supply such care, custody, and support, such child shall be considered a resident of the District of Columbia for purposes of this Chapter.

A5099. Definitions

“Adult student” means a student who is eighteen (18) years of age or older, or who has been emancipated from parental control by marriage, operation of statute, or the order of a court of competent jurisdiction.

“Chartering Authority” means a District of Columbia entity authorized to grant charters for the establishment of charter schools, pursuant to either the District of Columbia School Reform Act of 1995, approved April 26, 1996 (110 Stat. 1321; D.C. Official Code § 38-1802.01 (2001) et seq.), or the Public Charter School Act of 1996, effective May 29, 1996 (D.C. Law 11-135; D.C. Official Code § 1701.01 (2001) et seq.).

“Custodian” means a person to whom physical custody has been granted by a court of competent jurisdiction.

“District of Columbia Public Schools system” (DCPS) means the District of Columbia Public School system, not including public charter schools.

“District law” in this chapter refers to the specific provisions of Title 38 of the District of Columbia Code, including without limitation Sections 38-301 through 312 and other applicable law.

“Enroll and enrollment” include attending classes and participating fully in school activities.

“Guardian” means a person who has been appointed legal guardian of a student by a court of competent jurisdiction.

“Homeless” means an individual who lacks a fixed, regular, and adequate nighttime residence. These individuals shall include children and youth who are between the ages of five (5) and eighteen (18) years of age:

- (a) sharing the housing of other persons due to loss of housing, economic hardship or similar reasons;
- (b) living in motels, hotels, trailer parks, or camping grounds due to lack of alternative adequate accommodation;

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- (c) living in emergency or transitional shelters, (including D.C. transitional housing);
- (d) in a primary nighttime residence that is a public or private place not designed for or ordinarily used as a regular sleeping accommodation for human beings;
- (e) living in cars, parks, public spaces, abandoned buildings, substandard housing, bus or train stations, or similar settings;
- (f) living in a hospital due to abandonment;
- (g) awaiting foster care placement;
- (h) migratory children, as defined in section 1309 of the Elementary and Secondary Education Act of 1965, who qualify as homeless because they live in circumstances described above;
- (i) unaccompanied youth, including youths who are not in physical custody of a parent or guardian, who qualify as homeless because they live in circumstances described above.

“Local Education Agency or LEA” means the District of Columbia Public School system and/or any individual or group of public charter schools operated under a single charter in the District of Columbia.

“Other primary caregiver” means a caregiver to a student who submits evidence, pursuant to §§ A5004 or A5005, that he or she is the primary caregiver of the student.

“Parent” means a natural parent, stepparent, or parent by adoption that has custody or control of a student, including joint custody.

“Public Charter School” means a District of Columbia public school authorized by a chartering authority.

“School” means a public charter school, a school within the District of Columbia Public School system, a school in another state or a non public school in the District of Columbia enrolling a student funded by the District of Columbia.



Repeal of Chapter 50.

Chapter 50 of Title 5 DCMR is repealed. Residency regulations will now be governed by Chapter A50.

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Persons wishing to comment on this proposed rule should submit their comments in writing to Deborah Gist, State Superintendent of Education, 441 4th Street, NW, Room 350N, Washington, D.C. 20001, Attn: Kristin Yochum. All comments must be received by the Office of the State Superintendent of Education not later than thirty (30) days after publication of this notice in the D.C. Register. Copies of this rulemaking amendment and related information may be obtained by writing to the above address, by calling the Office of the State Superintendent of Education at (202) 727-6436, or on the OSSE website at www.osse.dc.gov.