

A BILL

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IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

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To amend the Health Occupations Revisions Act of 1985 to regulate the practice of pharmaceutical detailing, to prohibit certain actions by pharmaceutical detailers, and to set licensure qualifications for pharmaceutical detailers; to amend the Department of Health Functions Clarification Act of 2001 to establish the Pharmaceutical Education Fund for the purpose of supporting the needs of the Board of Pharmacy and establishing and funding an academic detailing program within the Department of Health; to require a prescriber to make efforts to provide a patient with information about off-label use of medication; to prohibit the use of prescribing data for marketing purposes without the consent of a physician; and, to prohibit gifts or remuneration of any kind from a pharmaceutical company to a member of a medication advisory committee.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, that this act may be cited as the “SafeRx Act of 2007”.

TITLE I - LICENSURE OF PHARMACEUTICAL DETAILERS

Sec. 101. The District of Columbia Health Occupations Revisions Act of 1985 (D.C. Law 6-99; D.C. Official Code § 3-1201 *et seq.*) is amended as follows:

(a) The table of contents is amended by adding the following after “Sec. 722. Waiver of license requirements - Meeting educational requirements.”

“TITLE VII-C”

“PHARMACEUTICAL DETAILERS; SCOPE OF PRACTICE; PROHIBITED ACTS;

QUALIFICATIONS; WAIVER OF REQUIREMENTS; CONTINUING EDUCATION.” 1

“Sec. 741. Scope of practice. 2

“Sec. 742. Prohibited acts. 3

“Sec. 743. Qualifications for licensure. 4

“Sec. 744. Waiver of licensure requirements. 5

“Sec. 745. Continuing education.” 6

(b) Section 102 (D.C. Official Code § 3-1201.02) is amended by adding a new paragraph  
11A to read as follows: 7  
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“(11A)(A) “Practice of Pharmaceutical Detailing” means the practice by a representative  
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of a pharmaceutical manufacturer or labeler of contacting or engaging a licensed health  
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professional located in the District of Columbia, or an employee or representative of a licensed  
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health professional located in the District, for purposes of selling, educating or in any way  
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promoting a pharmaceutical product. 13

“(B) Within the meaning of this paragraph, the term: 14

“(i) “Labeler” means an entity or person that receives pharmaceutical  
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products from a manufacturer or wholesaler and repackages them for later retail sale and that has  
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a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20. 17

“(ii) “Manufacturer” means a manufacturer of pharmaceutical products  
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and includes a subsidiary or affiliate of a manufacturer. 19

“(iii) “Pharmaceutical product” means a drug regulated by the federal  
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Food and Drug Administration.” 21

(c) Section 208(b) (D.C. Official Code § 3-1202.08) is amended as follows: 22

(1) Designate the existing text as paragraph (1) and insert the phrase “and the practice of pharmaceutical detailing” at the end of the sentence. 1  
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(2) A new paragraph (2) is added to read as follows: 3

“(2) The Board is authorized to: 4

“(A) Establish a code of ethics for the practice of pharmaceutical detailing; and 5  
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“(B) Collect reports from licensed pharmaceutical detailers as to interactions with licensed health professionals located in the District of Columbia, or with employees or representative of a licensed health professionals located in the District, for purposes of selling, educating or in any way promoting a pharmaceutical product. 7  
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(d) Section 409 (D.C. Official Code § 3-1204.09) is amended to read as follows: 11

“(a) The Mayor is authorized to establish a fee schedule for all services related to the regulation of all health occupations under this chapter, in accordance with the requirements of District law. 12  
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“(b) Notwithstanding subsection (a): 15

“(1) The fee for the issuance of a medical license shall be set by the Board of Medicine, provided that the fee shall be no less than \$500 and shall be sufficient to fund the programmatic needs of the Board; and 16  
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“(2) The fee for the issuance of a license to practice pharmaceutical detailing shall be set by the Board of Pharmacy, provided that the fee shall be no less than \$250.” 19  
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(e) Section 501 (D.C. Official Code § 3-1205.01) is amended by striking the word “pharmacy” and inserting the phrase “pharmacy, pharmaceutical detailing,” in its place. 21  
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(f) A new Title VII-C is added to read as follows: 1

“TITLE VII-C” 2

“PHARMACEUTICAL DETAILERS; SCOPE OF PRACTICE; PROHIBITED ACTS,  
PENALTIES; QUALIFICATIONS; WAIVER OF REQUIREMENTS; CONTINUING  
EDUCATION.” 3  
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“Sec. 741. Scope of practice. 6

“A pharmaceutical detailer shall be licensed by the Board of Pharmacy before engaging  
in the practice of pharmaceutical detailing in the District of Columbia. 7  
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“Sec. 742. Prohibited acts. 9

“A pharmaceutical detailer shall not: 10

“(1) 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. For purposes of this section, it shall be considered an act of  
deceptive or misleading marketing to provide information regarding an off-label use of a  
pharmaceutical product without explaining that the off-label use has not been approved by the  
federal Food and Drug Administration. 11  
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“(2) Use a title or designation that may cause a licensed health professional to believe  
that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry,  
pharmacy, or other similar health occupation, in the District of Columbia unless the  
pharmaceutical detailer has been granted such a license; or 17  
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“(3) Give medical advice to patients or attend patient examinations without the consent 21

of the patient.” 1

“Sec. 743. Qualifications for licensure. 2

“In addition to the general qualifications for licensure as set forth in this Act, an 3  
individual applying for a license to practice pharmaceutical detailing shall: 4

“(1) Establish to the satisfaction of the Board of Pharmacy that the individual is a 5  
graduate of a recognized institution of higher education; 6

“(2) Pay the required licensure fee; and 7

“(3) Submit to the Board of Pharmacy a notarized statement that the applicant 8  
understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, 9  
including adherence to the code of ethics as established by the Board, as set forth in this Title. 10

“Sec. 744. Waiver of licensure requirements. 11

“The Board of Pharmacy shall waive the educational requirements for any applicant for 12  
licensure as a pharmaceutical detailer who can demonstrate, to the satisfaction of the Board, that 13  
he or she has been performing the functions of a pharmaceutical detailer, as defined in this 14  
chapter, on a full-time or substantially full time basis continually at least 12 months immediately 15  
preceding the effective date of this section. 16

“Sec. 745. Continuing education. 17

“The Mayor shall establish by rule continuing education requirements as a condition for 18  
renewal of the license to practice pharmaceutical detailing. 19

“Sec. 746. Penalties 20

“In addition to the penalties set forth in this chapter, any person who practices pharmaceutical detailing without a license shall be subject to a fine of \$10,000.”

Sec. 102. The Department of Health Functions Clarification Act of 2001 (D.C. Law 14-28; D.C. Official Code § 7-731 *et seq.*) is amended by adding a new section 4904a to read as follows:

“Sec. 4904a. Pharmaceutical Education Fund.

“(a) There is established, as a non-lapsing, revolving fund in the Department of Health, the Pharmaceutical Education Fund (“Fund”), to be administered by the Mayor as an agency fund as defined in § 47-373(2)(I), to which all licensing fees, civil fines, and interest earned relating to the practice of pharmaceutical detailing, any subscription fees collected pursuant to subsection (c) of this section, or any other funds as directed by law, shall be deposited.

“(b) Revenues deposited into the Fund shall not revert to the General Fund at the end of any fiscal year or at any other time, but shall be continually available to the Department of Health for the uses and purposes set forth in subsection (c) of this section.

“(c) Subject to the applicable laws relating to the appropriation of District of Columbia funds, monies received by and deposited in the Fund shall be for the following:

“(1) Administration of the duties of the Board of Pharmacy; and

“(2) The establishment and funding an evidence-based research, outreach and education program within the Department of Health designed to provide information on the therapeutic and cost-effective utilization of pharmaceutical products to health professionals in the District of Columbia. This program shall:

“(A) Inform prescribers about pharmaceutical product marketing that is intended to circumvent competition from generic or other therapeutically equivalent alternatives or other evidence based treatment options;

“(B) Provide outreach to health professionals who participate in state Medicaid and other publicly funded, contracted or subsidized healthcare programs in the District, to academic medical centers, and to other prescribers;

“(C) Utilize or incorporate other independent educational resources or models proven effective in promoting high quality, evidenced based, cost-effective information regarding the effectiveness and safety of pharmaceutical products; and

“(D) Be made available to private payers on a subscription basis.”

## TITLE II - INFORMED CONSENT

### Sec. 201. Definitions.

For purposes of this act, the term:

(1) “Off-label use” means the use of a prescription drug in order to treat a condition that is not within the indications for that medication as approved by the federal Food and Drug Administration (“FDA”).

(2) “Prescriber” means a person who is licensed, registered or otherwise authorized by the District to prescribe and administer prescription drugs in the course of professional practice.

### Sec. 202. Off-label use of medication.

Before prescribing, administering, or furnishing a prescription medication for an off-label

use, a prescriber shall make every effort to:

(1) Explain to the patient, in easily understood terms, that the medication is not within the indications for that medication as approved by the FDA; and

(2) Provide the patient with information commonly known by the medical profession regarding potential risks and side effects associated with using the prescription for an off-label purpose.

Sec. 203. Penalties.

Failure to comply with this title may be used by a health occupation board as a factor when determining licensure status for a prescriber.

TITLE III - PROHIBITION ON DATA-MINING

Sec. 301. Definitions.

For purposes of this title, the term:

(1) "Marketing purpose" means advertising, promoting, or other activity that could influence the sale or market share of a pharmaceutical product, including influencing or evaluating the prescribing behavior of an individual health care professional and evaluating the effectiveness of a professional pharmaceutical sales force.

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

(3) "Prescription information" means information regarding the use of prescription drugs as part of an individualized course of treatment.

Sec. 302. Prohibition on the use of prescription drug information.

Except as provided for in section 303, it shall be unlawful to use, sell, transfer, license or exchange for value, any prescription information that identifies the patient or the prescriber for any marketing purpose, unless consent for such use is affirmatively provided by the prescriber in a manner set forth by the Department of Health prior to the use of the information.

Sec. 303. Activities not included in prohibition.

Nothing in this act shall prohibit the following:

(1) The transmission of prescription information for the purpose of providing direct care to a patient, including the dispensation of prescription drugs by a licensed pharmacy, or the development of an individualized treatment plan by a licensed health professional;

(2) The transfer of prescription information for the purpose of pharmacy reimbursement, formulary compliance, or utilization review by the District, by a healthcare provider, or by the patient's insurance provider;

(3) The transfer of prescription information that may occur when there is change of ownership of a pharmacy;

(4) The use of prescription information for patient educational purposes or for clinical trials;

(5) The collection, use or disclosure of information as required by federal or District of Columbia law; and

(6) The use, sale, transfer or exchange for value of prescription drug information by zip code, geographic region, or medical specialty for marketing purposes so long as the prescription

information does not identify the patient or the prescriber. 1

Sec. 304. Prescriber data-sharing. 2

(a) The Department of Health shall establish a prescriber data-sharing program to allow a 3  
prescriber to give consent for the use of prescription information for marketing purposes. The 4  
Department shall solicit consent on licensing applications or renewal forms and shall provide a 5  
prescriber with a method for revoking his consent. 6

(b) The Department shall make publicly available the list of prescribers who have 7  
consented to sharing prescription information. 8

Sec. 305. Penalties; remedies. 9

(a) A violation of this title shall be subject to a fine of not less than \$10,000. 10

(b) All fines collected pursuant to this act shall be deposited in the Pharmaceutical 11  
Education Fund and shall not revert to the General Fund. 12

(c) In addition to any other remedy provided by law, the Attorney General of the District 13  
of Columbia may file an action in Superior Court for violation of this act. The Attorney General 14  
of the District of Columbia shall have the same authority to investigate and to obtain remedies as 15  
if the action were brought under the D.C. Consumer Protection Procedures Act of 1976 (D.C. 16  
Law 1-76; D.C. Official Code § 28-3901 *et seq.*). Each violation of this section or of any rules 17  
adopted under this section by the attorney general constitutes a separate civil violation for which 18  
the attorney general may obtain relief. 19

TITLE IV - MEDICATION ADVISORY COMMITTEES 20

Sec. 401. Definitions. 21

For purposes of this title, the term:

(1) "Medication advisory committee" means any committee or panel that is responsible for making recommendations and decisions regarding a formulary to be used by the government of the District of Columbia.

(2) "Pharmaceutical company" means any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biological product.

Sec. 402. Prohibition on gifts, remuneration.

(a) A pharmaceutical company shall not offer a gift or remuneration of any kind to a member of a medication advisory committee.

(b) A member of a medication advisory committee shall not accept a gift or remuneration of any kind from a pharmaceutical company.

(c) Nothing in this section shall prohibit the offering or acceptance of medication samples to members of a medication advisory committee who are licensed physicians engaged in the practice of medicine.

Sec. 403. Penalties.

A violation of this title shall be punishable by a fine of \$1,000 per violation.

TITLE V - FISCAL IMPACT; EFFECTIVE DATE

Sec. 501. Fiscal impact.

The Council adopts the fiscal impact statement in the committee report as the fiscal

impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act,  
approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)).

Sec. 502. Effective date.

This act shall take effect following approval by the Mayor (or in the event of veto by the  
Mayor, action by the Council to override the veto), a 30-day period of Congressional review, as  
provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December  
24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of  
Columbia Register.