

Councilmember David A. Catania

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A BILL

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IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

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Councilmember David A. Catania introduced the following bill which was referred to the  
Committee on \_\_\_\_\_

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To amend the Health Occupations Revisions Act of 1985 to create licensing standards and  
continuing education requirements for pharmaceutical detailers, to authorize the Board of  
Pharmacy to establish a code of ethics for the practice of pharmaceutical detailing, to  
require pharmaceutical detailers to disclose all related clinical trials and scientific  
evidence related to the drug detailed, to prohibit pharmaceutical detailers from  
misrepresenting their credentials to licensed health professionals, to prohibit  
pharmaceutical detailers from giving medical advice to a patient without consent, and to  
require pharmaceutical detailers to include a disapproval statement with information  
provided for off-label use; to amend the Department of Health Functions Clarification  
Act of 2001 to establish the Pharmaceutical Education Fund as the nonlapsing repository  
for all fees and penalties assessed pursuant to this act; to require a prescribing physician  
to obtain written consent from the patient before prescribing an off-label use; to require  
the timely disclosure by pharmaceutical companies of all clinical trial results and FDA  
correspondence, and to create a SafeRx Registry and delineate the specific information  
that pharmaceutical companies must submit to the Registry; to prohibit the use of  
prescribing data for commercial purposes without the consent of a physician, and to  
create penalties for violations of the act; to prohibit gifts or remuneration of any kind  
from a pharmaceutical company to a member of a medication advisory committee.

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

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TITLE I - LICENSURE OF PHARMACEUTICAL DETAILERS

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Sec. 101. The District of Columbia Health Occupations Revisions Act of 1985 (D.C.

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Law 6-99; D.C. Official Code § 3-1201 *et seq.*) is amended as follows: 1

(a) The table of contents is amended by adding the following after “Sec. 722. 2

Waiver of license requirements - Meeting educational requirements.” 3

“TITLE VII-C” 4

“PHARMACEUTICAL DETAILERS; SCOPE OF PRACTICE; PROHIBITED ACTS; 5

QUALIFICATIONS; WAIVER OF REQUIREMENTS; CONTINUING EDUCATION.” 6

“Sec. 741. Scope of practice. 7

“Sec. 742. Prohibited acts. 8

“Sec. 743. Qualifications for licensure. 9

“Sec. 744. Waiver of licensure requirements. 10

“Sec. 745. Continuing education.” 11

(b) Section 102 (D.C. Official Code § 3-1201.02) is amended by adding a new 12  
paragraph 11A to read as follows: 13

“(11A)(A) “Practice of Pharmaceutical Detailing” means the practice by a 14  
representative of a pharmaceutical manufacturer or labeler of contacting or engaging a licensed 15  
health professional located in the District of Columbia, or an employee or representative of a 16  
licensed health professional located in the District, for purposes of selling, educating or in any 17  
way providing information on a pharmaceutical. 18

“(B) Within the meaning of this paragraph, the term: 19

“(i) “Labeler” means an entity or person that receives 20  
pharmaceuticals from a manufacturer or wholesaler and repackages them for later retail sale and 21  
that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20. 22

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

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

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

(1) Designate the existing text as paragraph (1) and insert the phrase “and the practice of pharmaceutical detailing” at the end of the sentence.

(2) A new paragraph (2) is added to read as follows:

“(2) The Board is authorized to establish a code of ethics for the practice of pharmaceutical detailing.”

(d) Section 409 (D.C. Official Code § 3-1204.09) is amended to read as follows:

“(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.

“(b) Notwithstanding subsection (a):

“(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

“(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.”

(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.

(f) A new Title VII-C is added to read as follows:

“TITLE VII-C”

“PHARMACEUTICAL DETAILERS; SCOPE OF PRACTICE; PROHIBITED ACTS,  
PENALTIES; QUALIFICATIONS; WAIVER OF REQUIREMENTS; CONTINUING  
EDUCATION.”

“Sec. 741. Scope of practice.

“(a) A pharmaceutical detailer shall be licensed by the Board of Pharmacy before  
engaging in the practice of pharmaceutical detailing in the District of Columbia.

“(b) When providing information on pharmaceuticals to a licensed health professional or  
to an employee or representative of a licensed health professional, a pharmaceutical detailer must  
fully disclose all related clinical trials and scientific evidence pertaining to the pharmaceutical  
which is the subject of the contact. Such information may be presented in a manner as set forth  
by the Department of Health.”

“Sec. 742. Prohibited acts.

“A pharmaceutical detailer shall not:

“(1) 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;

“(2) Give medical advice to patients or attend patient examinations without the  
consent of the patient;

“(3) Provide information to a licensed health professional or to an employee or representative of a licensed health professional regarding an off-label use of pharmaceuticals unless such information is accompanied by a statement that the off-label use has not been approved by the federal Food and Drug Administration. For purposes of this section, “off-label use” means the use of pharmaceuticals in order to treat a condition that is not within the indications as approved by the federal Food and Drug Administration; or

“(4) Provide misleading information to a licensed health professional or to an employee or representative of a licensed health professional.”

“Sec. 743. Qualifications for licensure.

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

“(1) Establish to the satisfaction of the Board of Pharmacy that the individual is a graduate of a recognized institution of higher education with at least a bachelor's degree in pharmacy or a chemical, physical or biological science;

“(2) Pay the required licensure fee; and

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

“Sec. 744. Waiver of licensure requirements.

“The Board of Pharmacy shall waive the educational requirements for any applicant for licensure as a pharmaceutical detailer who can demonstrate, to the satisfaction of the Board, that

he or she has been performing the functions of a pharmaceutical detailer, as defined in this chapter, on a full-time or substantially full time basis continually at least 12 months immediately preceding the effective date of this section.

“Sec. 745. Continuing education.

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

“Sec. 746. Penalties

“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 nonlapsing, 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 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 sole use of establishing 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 prescription drugs to health professionals authorized to prescribe and dispense prescription drugs in the District of Columbia. This program shall:

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

“(2) Provide outreach to physicians and other health care practitioners 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;

“(3) 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 prescription drugs; and

“(4) 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”). 1

(2) “Prescriber” means a person who is licensed, registered or otherwise authorized by the 2  
District to prescribe and administer prescription drugs in the course of professional practice. 3

Sec. 202. Off-label use of medication. 4

Before prescribing, administering, or furnishing a prescription medication for an off-label 5  
use, a prescriber shall: 6

(1) Explain to the patient, in easily understood terms, that the medication is not within the 7  
indications for that medication as approved by the FDA; 8

(2) Provide the patient with information commonly known by the medical profession 9  
regarding potential risks and side effects associated with using the prescription for an off-label 10  
purpose; and 11

(3) Obtain the written informed consent of patient. 12

Sec. 203. Penalties. 13

Any person who violates any provision of this title shall be subject to a civil fine not to 14  
exceed \$1,000 for each violation. 15

### TITLE III - DISCLOSURE OF CLINICAL TRIALS AND FDA LETTERS 16

Sec. 301. Definitions. 17

For purposes of this title, the term: 18

(1) “Clinical Trial” means any trial or study of the safety or efficacy of a drug or 19  
biological product, or any other trial or study where any information regarding a drug or 20

biological product is used or intended to be used for marketing or educational purposes, whether 1  
or not completed in full, and whether marketing approval is received before or after completion. 2

(2) “Department” means the Department of Health. 3

(3) “Pharmaceutical company” means any entity that is engaged in, either directly or 4  
indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or 5  
processing of a drug or biological product. 6

Sec. 302. Establishment of SafeRx Registry. 7

(a) There is established within the Department of Health a SafeRx Registry for the public 8  
disclosure of clinical trials and FDA correspondence. 9

(b) The SafeRx Registry shall be made available to the public on the Department’s 10  
website. 11

Sec. 303. Disclosure of clinical trials. 12

(a) For each clinical trial conducted or sponsored, in whole or in part, by a pharmaceutical 13  
company for a drug or biological product sold, delivered, dispensed, offered for sale or given 14  
away in the District of Columbia, that pharmaceutical company shall submit the following 15  
information to the Department: 16

(1) The name of the clinical trial; 17

(2) The names of all participating organizations and funding sources of the 18  
clinical trial, including the name and contact information, including institutional affiliation, of all 19  
sponsors, co-sponsors and administrators, including the name of the principal investigators and 20

study centers, of the clinical trial; 1

(3) A summary of the purpose of the clinical trial, including the name of the drug 2  
or biological product being tested and their active ingredients, dosages to be tested, the overall 3  
design of the clinical trial including statistical method to be employed, FDA phase type of the 4  
trial, inclusion and exclusion criteria, treatment methods to be used, all hypotheses tested by the 5  
trial, and the medical condition or conditions being studied and outcomes that were evaluated; 6

(4) Initiation and expected completion date of the trial; 7

(5) Number of participants enrolled; 8

(6) Information concerning the results and outcomes of the clinical trial, which 9  
shall include potential or actual adverse effects, including the frequency, severity and nature of 10  
adverse events for any trial participant, and numbers of participants who discontinued 11  
participation in the trial and the reasons for such discontinuance; and 12

(7) In the case that the clinical trial was terminated prior to completion, an 13  
explanation for the termination of the trial, including but not limited to potential or actual 14  
adverse effects, and the number of participants who discontinued participation in the trial and the 15  
reasons for such discontinuance. 16

(b) The requirements of subsection (a) of this section shall apply to all clinical trials 17  
completed or terminated on or after January 1, 2008. 18

(c) A manufacturer shall submit the information set forth in subsection (a) within 30 days 19  
of completion or termination of a clinical trial or within 30 days of the effective date of this Act, 20  
whichever is later. 21

Sec. 304. Disclosure of FDA correspondence.

Within 30 days of receipt, a pharmaceutical company shall submit to the Department any FDA notice of violation, also known as an untitled letter, or FDA Warning letter regarding a prescription drug sold, delivered, dispensed, offered for sale or given away in the District of Columbia.

Sec. 305. Fees and penalties.

(a) The Department of Health shall establish an annual SafeRx Registry registration fee of no less than \$2,000.

(b) A pharmaceutical company who fails to meet the requirements set forth in this Act shall be liable for a civil penalty of at minimum \$10,000 per violation. Additionally, each day of each violation shall be considered a separate violation for which the manufacturer is liable.

(c) Funds collected pursuant to this subsection shall be used solely to cover the cost of implementation and maintenance of the SafeRx Registry.

TITLE IV - PROHIBITION ON DATA-MINING

Sec. 401. Definitions.

For purposes of this title, the term:

(1) “Commercial purpose” means advertising, marketing, 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. 402. Prohibition on the use of prescription drug information.

Except as provided for in section 403, 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 commercial 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. 403. 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 commercial purposes so long as the prescription information does not identify the patient or the prescriber.

Sec. 404. Prescriber data-sharing.

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

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

Sec. 405. Penalties; remedies.

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

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

(c) In addition to any other remedy provided by law, the Attorney General of the District of Columbia may file an action in Superior Court for violation of this act. The Attorney General of the District of Columbia shall have the same authority to investigate and to obtain remedies as

if the action were brought under the D.C. Consumer Protection Procedures Act of 1976 (D.C. Law 1-76; D.C. Official Code § 28-3901 *et seq.*). Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

## TITLE V - MEDICATION ADVISORY COMMITTEES

### Sec. 501. Definitions.

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.

### Section 502. 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. 1

Section 503. Penalties. 2

A violation of this title shall be punishable by a fine of \$1,000 per violation. 3

TITLE VI - FISCAL IMPACT; EFFECTIVE DATE 4

Sec. 601. Fiscal impact. 5

The Council adopts the fiscal impact statement in the committee report as the fiscal 6  
impact statement required by section 602(c)(3) of the District of Columbia Home Rule Act, 7  
approved December 24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(3)). 8

Sec. 602. Effective date. 9

This act shall take effect following approval by the Mayor (or in the event of veto by the 10  
Mayor, action by the Council to override the veto), a 60-day period of Congressional review, as 11  
provided in section 602(c)(1) of the District of Columbia Home Rule Act, approved December 12  
24, 1973 (87 Stat. 813; D.C. Official Code § 1-206.02(c)(1)), and publication in the District of 13  
Columbia Register. 14