ENROLLED ORIGINAL

AN ACT

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IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

To amend the District of Columbia 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 Board of Pharmacy Fund for the purpose of supporting the administration of the Board of Pharmacy; to require a prescriber to make every reasonable effort to provide a patient with information about off-label use of medication; to prohibit gifts or remuneration of any kind from a pharmaceutical company to a member of a medication advisory committee; to establish a pharmaceutical education program within the Department of Health; and to require the Department of Health to submit a comprehensive evaluation on the effectiveness of this act to the Council in 2010.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA, That this act may be cited as the "SafeRx Amendment Act of 2008".

TITLE I - PHARMACEUTICAL DETAILERS

Sec. 101. Short title.

This title may be cited as the "Pharmaceutical Detailers Amendment Act of 2008".

Sec. 102. The District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.01 *et seq.*), is amended as follows:

(a) The table of contents is amended by adding the following after "Sec. 702. Waiver of examination.".

"TITLE VII-A. QUALIFICATIONS FOR LICENSURE TO PRACTICE PROFESSIONAL COUNSELING; TRANSITION OF PROFESSIONAL COUNSELORS; WAIVER OF LICENSURE REQUIREMENTS.

"Sec. 710. Qualifications for licensure.

"Sec. 711. Transition of professional counselors.

"Sec. 712. Waiver of licensure requirements.

(b) Section 102 (D.C. Official Code § 3-1201.02) is amended by adding a new paragraph (10A) to read as follows:

Amend § 3-1201.02

"(10A)(A) "Practice of pharmaceutical detailing" means the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purposes of selling, providing information about, or in any way promoting a pharmaceutical product.

"(B) For the purposes of this paragraph, the term:

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

"(ii) "Manufacturer" means a maker of pharmaceutical products and includes a subsidiary or affiliate of a manufacturer.

"(iii) "Pharmaceutical product" means a drug or biologic regulated by the federal Food and Drug Administration.".

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

(1) Designate the existing text as paragraph (1).

Amend § 3-1202.08

(2) The newly designated paragraph (1) is amended by striking the phrase "of pharmacy" and inserting the phrase "of pharmacy and the practice of pharmaceutical detailing" in its place.

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

"(2) The Board is authorized to:

"(A) Establish a code of ethics for the practice of pharmaceutical detailing; and

"(B) Collect information from licensed pharmaceutical detailers relating to their communications with licensed health professionals, or with employees or representatives of licensed health professionals, located in the District.".

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

Amend § 3-1204.09

"(a) Except as provided in subsection (b) of this section, the Mayor is authorized to establish a fee schedule for all services related to the regulation of all health occupations under this act, in accordance with the requirements of District law.

"(b)(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.

"(2) The fee for the issuance of a license to practice pharmaceutical detailing shall be set by the Board of Pharmacy.".

(e) Section 501 (D.C. Official Code § 3-1205.01) is amended by striking the word "pharmacy" and inserting the phrase "pharmaceutical detailing, pharmacy " in its place.

Amend § 3-1205.01

(f) Section 510(b) (D.C. Official Code § 3-1205.10(b)) is amended to read as follows:

Amend § 3-1205.10

"(b) The Mayor may establish by rule continuing education requirements as a condition for renewal of licenses under this section; provided, that the Mayor shall:

"(1) Require that any continuing-education requirements for the practice of medicine include instruction on pharmacology, which shall:

"(A) Be evidence-based;

"(B) Provide physicians with information regarding the cost-effectiveness of pharmacological treatments; and

"(C) Not be financially supported by any pharmaceutical company or manufacturer; and

"(2) Establish continuing-education requirements for the practice of pharmaceutical detailing, in accordance with section 745.".

(g) A new Title VII-D is added to read as follows:

"TITLE VII-D

"PHARMACEUTICAL DETAILERS; SCOPE OF PRACTICE; QUALIFICATIONS FOR LICENSURE; WAIVER OF LICENSURE REQUIREMENTS; CONTINUING EDUCATION; PENALTIES.

"Sec. 741. Scope of practice.

"(a) An individual shall be licensed by the Board of Pharmacy before engaging in the practice of pharmaceutical detailing in the District of Columbia.

"(b) A pharmaceutical detailer shall not:

"(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;

"(2) Use a title or designation that might lead a licensed health professional, or an employee or representative of 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 currently holds such a license; or

"(3) Attend patient examinations without the consent of the patient.

"Sec. 742. Qualifications for licensure.

"In addition to the general qualifications for licensure 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 he or she is a graduate of a recognized institution of higher education;

"(2) Pay the required licensure fee; and

"(3) Submit to the Board of Pharmacy a notarized statement that he or she understands and agrees to abide by the requirements for the practice of pharmaceutical detailing, including the code of ethics, as established by the Board pursuant to section 208 and in accordance with this title.

"Sec. 743. Waiver of licensure requirements.

"The Board of Pharmacy shall waive the educational requirements for an 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 title, on a full-time, or substantially full-time, basis for at least 12 months immediately preceding the effective date of this title.

"Sec. 744. Continuing education.

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

"Sec. 745. Penalties.

"In addition to the penalties set forth in this act, a person who practices pharmaceutical detailing without a license shall be subject to a fine of up to $10,000.".

Sec. 103. The Department of Health Functions Clarification Act of 2001, effective October 3, 2001 (D.C. Law 14-28; D.C. Official Code § 7-731 *et seq.*), is amended by adding a new section 4904b to read as follows:

"Sec. 4904b. Board of Pharmacy Fund.

"(a)(1) There is established, as a nonlapsing fund in the Department of Health, the Board of Pharmacy Fund ("Fund"), to be administered by the Mayor as an agency fund, as defined in § 47-373(2)(I), into which all licensing fees, civil fines, and interest earned relating to the practice of pharmaceutical detailing, and any other funds, as directed by law, shall be deposited and used for the administration of the Board of Pharmacy.

"(2) For the purposes of this subsection, the term "practice of pharmaceutical detailing" shall have the same meaning as provided in section 102(11A) of the District of

Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.02(11A)).

"(b) All funds deposited into the Fund shall not revert to the unrestricted fund balance of the General Fund of the District of Columbia at the end of a 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 (a) of this section, subject to authorization by Congress.".

TITLE II - INFORMED CONSENT

Sec. 201. Short title

This title may be cited as the "Off-Label Informed Consent Act of 2008".

Sec. 202. Definitions.

For the purposes of this title, the term:

(1) "FDA" means the federal Food and Drug Administration.

(2) "Off-label use" means the use of a prescription drug to treat a condition that is not included in the labeling for that medication, as approved by the federal Food and Drug Administration.

(3) "Prescriber" means 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.

Sec. 203. Off-label use of medication.

Before prescribing, administering, or furnishing a prescription medication for an off-label use, a prescriber shall make every reasonable effort to:

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

(2) Provide the patient with information regarding the potential risks and side effects associated with using the medication for the off-label use.

Sec. 204. 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; provided, that a prescriber shall not be subject to an adverse licensure action if the Board of Medicine determines that the prescribing, administering, or furnishing of the prescription medication for the off-label use was clearly evidence-based and the common practice within the medical community.

TITLE III - MEDICATION ADVISORY COMMITTEES

Sec. 301. Short title.

This title may be cited as the "Medication Advisory Committee Receiving Gifts or Remuneration Prohibition Act of 2008".

Sec. 302. Definitions.

For the purposes of this title, the term:

(1) "Medication advisory committee" means any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by a health program administered 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, including any person acting as its agent or representative.

Sec. 303. Prohibition on gifts and 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. 304. Penalties.

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

TITLE IV - PHARMACEUTICAL EDUCATION

Sec. 401. Short title.

This title may be cited as the "Pharmaceutical Education Program Establishment Act of 2008".

Sec. 402. Definitions.

For the purposes of this title, the term "pharmaceutical product" shall have the same meaning as provided in section 102(10A)(B)(iii) of the District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.02(10A)(B)(iii)).

Sec. 403. Establishment of the Pharmaceutical Education Program.

(a) There is established an evidence-based Pharmaceutical Education Program ("Program") within the Department of Health. The Program shall:

(1) Educate prescribers who participate in the District of Columbia Medicaid

program, and other publicly funded, contracted, or subsidized health-care programs, on the therapeutic and cost-effective utilization of pharmaceutical products;

(2) Inform prescribers about pharmaceutical product marketing practices that are intended to circumvent competition from generic, other therapeutically-equivalent alternatives, or other evidence-based treatment options; and

(3) Utilize, or incorporate into the Program, 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.

(b) The Program shall be made available to prescribers who do not participate in the District of Columbia Medicaid program or other publicly funded, contracted, or subsidized health-care programs on a subscription basis.

(c) If approved by the Board of Medicine, the PE program may be used to satisfy continuing education requirements for the practice of medicine.

Sec. 404. Applicability.

This title shall apply upon inclusion of its fiscal effect in an approved budget and financial plan.

TITLE V. EVALUATION

Sec. 501. Short title.

This title may be cited as the “SafeRX Evaluation Act of 2008".

Sec. 502. Definitions.

For the purposes of this title, the term:

(1) “Pharmaceutical product” shall have the same meaning as provided in section 102(10A)(B)(iii) of the District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.02(10A)(B)(iii)).

(2) “Practice of pharmaceutical detailing” shall have the same meaning as provided in section 102(10A) of the District of Columbia Health Occupations Revisions Act of 1985, effective March 25, 1986 (D.C. Law 6-99; D.C. Official Code § 3-1201.02(10A)).

Sec. 503. Evaluation.

(a) Within 60 days of September 30, 2010, the Department of Health shall submit to the Council a comprehensive evaluation on the effectiveness of this act, which shall include:

(1) The number of individuals licensed to engage in the practice of pharmaceutical detailing since the effective date of this act;

(2) The number of applicants for licensure to engage in the practice of pharmaceutical detailing not approved by the Board of Pharmacy;

(3) The number of applicants for licensure to engage in the practice of pharmaceutical detailing for whom the educational requirements were waived;

(4) An assessment of the appropriateness and efficacy of the continuing

education requirements established pursuant to this act;

(5) The number of individuals identified as engaging in the practice of pharmaceutical detailing without a license;

(6) The amount of fines levied against persons charged with engaging in the practice of pharmaceutical detailing without a license;

(7) The total amount and origin of revenue deposited into the Board of Pharmacy Fund;

(8) The total amount of funds deposited into the Board of Pharmacy Fund that were used for the administration of the duties of the Board of Pharmacy;

(9) The number and types of penalties levied for failure to comply with the requirements of off-label use of medication as set forth in section 203;

(10) The number and amount of fines levied for violations as a result of pharmaceutical companies offering gifts or remuneration in violation of section 303;

(11) The number of persons who participated in the Pharmaceutical Education Program established by section 403;

(12) An assessment of the quality and effectiveness of the Pharmaceutical Education Program based on an assessment of data gathered from those who participated in the program. The data may be gathered by surveying those who participated in the program, using an evaluative instrument developed for that purpose;

(13) An assessment of the extent to which regulation of the practice of pharmaceutical detailing has improved the practice of selling, providing information about, or promoting a pharmaceutical product.

(b) The evaluation may be used to determine if this act should be repealed or amended.

TITLE VI - FISCAL IMPACT; EFFECTIVE DATE

Sec. 601. Fiscal impact statement.

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. 602. 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.

Chairman
Council of the District of Columbia

Mayor
District of Columbia