DEPARTMENT OF HEALTH

NOTICE OF PROPOSED RULEMAKING

The Acting Director of the Department of Health ("Department"), pursuant to § 201 of the District of Columbia 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 new chapter 17 of Title 22 (Public Health and Medicine) of the District of Columbia Municipal Regulations (DCMR), entitled "Pharmaceutical Education Program," in not less than thirty (30) days from the date of publication of this notice in the D.C. Register. The adoption of Chapter 17, which had until now been reserved, is necessary to implement Titles II through V of the Act, which require a prescriber to make reasonable efforts to obtain the informed consent of patients when prescribing medications for off-label uses; prohibits pharmaceutical companies from giving gifts or other remuneration to members of a medication advisory committee; establishes a pharmaceutical education program within the Department of Health; and requires the Department to provide an evaluation report to the Council of regarding the effectiveness of the Act.

Chapter 17 (Pharmaceutical Education Program) of Title 22 (Public Health and Medicine) is added as follows:

1700 INFORMED CONSENT FOR OFF-LABEL USE

1700.1 Before prescribing, administering, or furnishing, a prescription medication for an off-label use, a prescriber shall make every reasonable effort to:

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

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

(c) Document the consultation in the patient chart if the off-label use is not clearly evidence-based and common practice within the medical community.

1700.2 Failure to comply with this section 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.

1701 PROHIBITION ON GIFTS TO MEDICATION ADVISORY COMMITTEE MEMBERS

1701.1 A pharmaceutical company shall not offer a gift or remuneration of any kind to a member of a medication advisory committee.

1701.2 A member of a medication advisory committee shall not accept a gift or remuneration of any kind from a pharmaceutical company.

1701.3 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.

1701.4 A fine of one thousand dollars ($1,000), may be adjudged for each violation of this section.

1702 PHARMACEUTICAL EDUCATION PROGRAM

1702.1 The Department of Health's Pharmaceutical Education Program ("Program) shall:

(a) 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;

(b) 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

(c) 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.

1702.2 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.

1702.3 If approved by the District of Columbia Board of Medicine, the Program may be used to satisfy continuing education requirements for the practice of medicine for the number of credits approved by the board.

1702.4 If approved by a health occupations board, the Program may be used to satisfy the board's continuing education requirements for the number of credits approved by the board.

1702.5 In carrying out this Program, the Department shall ensure that the persons providing the services set forth in § 1702.1 of this chapter meet the following qualifications:

(a) Have at least three years background or experience in a clinical field, biological science, or healthcare profession;

(b) Have received training in quality improvement and health communications;

(c) Participate in ongoing training with respect to each clinical guideline that is being promoted by the Program; and

(d) Are not affiliated with, employed by, or otherwise paid by any pharmaceutical manufacturer or labeler.

1703 DEPARTMENT EVALUATION REPORT

1703.1 Within sixty (60) days of September 30, 2010, the Department shall submit to the Council a comprehensive evaluation on the effectiveness of the Act, which shall include:

(a) The number of individuals licensed to engage in the practice of pharmaceutical detailing since the effective date of the Act;

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

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

(d) An assessment of the appropriateness and efficacy of the continuing education requirements established pursuant to the Act;

(e) The number of individuals identified as engaging in the unlicensed practice of pharmaceutical detailing;

(f) The amount of fines levied against persons charged with engaging in the unlicensed practice of pharmaceutical detailing;

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

(h) 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;

(i) 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 of the Act;

(j) The number and amount of fines levied for violations as a result of pharmaceutical companies offering gifts or remuneration in violation of section 203 of the Act;

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

(l) 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 evaluation instrument developed for that purpose;

(m) 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.

1703.2 The Department evaluation report required in section § 1703.1 of this chapter, may be used by the Council to determine whether the Act should be repealed or amended.

1799 DEFINITIONS

1799.1 As used in this Chapter the following terms shall have the meanings ascribed:

Act- 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-XXX, dated May XX, 2008.

Board – the Board of Pharmacy, established by § 208 of the Act, D.C. Official Code § 3-1202.08 (2001).

Council- Council of the District of Columbia

Department- Department of Health

Director- Director of the Department

FDA- the federal Food and Drug Administration

Labeler- An entity or person that receives pharmaceutical products from a

manufacturer or wholesaler and repackages those pharmaceuticals for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 C.F.R. § 207.20.

Manufacturer- a manufacturer of pharmaceutical products and includes subsidiary or affiliate of a manufacturer.

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.

Medication advisory committee- 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.

Off-label use- 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.

Pharmaceutical Company- any entity that is engaged in, either directly or indirectly, the production, preparation, propagation, compounding, manufacturing, conversion or processing of a drug or biologic product, including any person acting as its agent or representative.

Pharmaceutical Product- a drug or biologic regulated by the federal Food and Drug Administration.

Practice of Pharmaceutical Detailing- 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 purpose of selling, providing information about, or in any way promoting a pharmaceutical product.

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.

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 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.