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DISTRICT OF COLUMBIA OFFICIAL CODE TITLE 48. FOOD AND DRUGS SUBTITLE II. PRESCRIPTION DRUGS CHAPTER 8A. AFFORDABILITY OF PRESCRIPTION DRUGS-ACCESSRX PROGRAM

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SUBCHAPTER III. FULL DISCLOSURE OF PRESCRIPTION DRUG MARKETING COSTS

§ 48-833.01. Requirement to disclose prescription drug marketing costs.

A manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District shall report marketing costs for prescription drugs in the District. These marketing costs shall be reported to the Department for the purposes of assisting the District in its role as a purchaser of prescription drugs and as an administrator of prescription drug programs, enabling the District to determine the scope of prescription drug marketing costs and their effect on the cost, utilization, and delivery of health care services, and furthering the role of the District as guardian of the public interest.

§ 48-833.02. Manner of reporting.

By July 1st of each year, a manufacturer or labeler of prescription drugs that directly or

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indirectly distributes prescription drugs for dispensation to residents of the District shall file a report with the Department in the form and manner provided by the Department. The report shall be accompanied by payment of a fee, as set by the Department in rule, to support the work of the Department under this subchapter.

§ 48-833.03. Content of annual report by manufacturer or labeler.

- (a) Except as provided in subsection (b) of this section, the annual report filed pursuant to § 48-853.02 shall include the following information as it pertains to marketing activities conducted within the District in a form that provides the value, nature, purpose, and recipient of the expense:
 - (1) All expenses associated with advertising, marketing, and direct promotion of prescription drugs through radio, television, magazines, newspapers, direct mail, and telephone communications as they pertain to District residents;
 - (2) With regard to all persons and entities licensed to provide health care in the District, including health care professionals and persons employed by them in the District, carriers licensed under Title 31, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:
 - (A) All expenses associated with educational or informational programs, materials, and seminars, and remuneration for promoting or participating in educational or informational sessions, regardless of whether the manufacturer or labeler provides the educational or informational sessions or materials;
 - (B) All expenses associated with food, entertainment, gifts valued at more than \$ 25, and anything provided to a health care professional for less than market value;
 - (C) All expenses associated with trips and travel; and
 - (D) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and
 - (3) The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (1) and (2) of this subsection, including all forms of payment to those employees. The cost reported under this paragraph shall reflect only that portion of payment to employees or contractors that pertains to activities within the District or to

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recipients of the advertising or promotional activities who are residents of or are employed in the District.

- (b) The following marketing expenses are not subject to the requirements of this subchapter:
 - (1) Expenses of \$ 25 or less;
 - (2) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, or treatment; and
 - (3) Scholarships and reimbursement of expenses for attending a significant educational, scientific, or policy-making conference or seminar of a national, regional, or specialty medical or other professional association if the recipient of the scholarship is chosen by the association sponsoring the conference or seminar.

§ 48-833.04. Department reports.

By November 30th of each year, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Council and the Corporation Counsel. By January 1, 2005, and every 2 years thereafter, the Department shall provide a report to the Council and the Corporation Counsel, providing information in aggregate form, containing an analysis of the data submitted to the Department, including the scope of prescription drug marketing activities and expenses and their effect on the cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

§ 48-833.05. Confidentiality; public information.

Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this subchapter is confidential and is not a public record. Data compiled in aggregate form by the Department for the purposes of reporting required by this subchapter is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

§ 48-833.06. Penalty.

This subchapter may be enforced in a civil action brought by the Corporation Counsel. A manufacturer or labeler that fails to provide a report as required by this subchapter commits a civil violation for which a fine of \$ 1,000 plus costs and attorney's fees may be adjudged.

§ 48-833.07. Rulemaking.

The Mayor is authorized to issue any rules necessary to implement the provisions of this

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subchapter.

§ 48-833.08. Report.

The Department shall report to the committee of the Council having jurisdiction over health and human services matters on or before January 1, 2005 and on or before July 1, 2005 on the assessment of fees on manufacturers and labelers of prescription drugs.

§ 48-833.09. Applicability date.

This subchapter shall apply as of July 1, 2004.