

Chapter 18 PRESCRIPTION DRUG MARKETING COSTS

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1800 MANNER OF REPORTING AND FILING FEE

- 1800.1 Beginning July 1, 2007, each manufacturer or labeler of prescription drugs, directly or indirectly distributed for dispensation in the District, that employs, directs or utilizes marketing representatives in the District shall file the annual report required by section 302 of the Act (“annual report”) in the form and manner provided by the Director.
- 1800.2 The annual report shall be filed with the Department by July 1st of each year and shall contain, for the previous calendar year, all of the information required by the Act and be accompanied by payment of the required filing fee.
- 1800.3 Manufacturers and labelers shall use the date of the activity to assign a reporting period and where the activity spans between more than one reporting period the cost shall be prorated by each applicable reporting period.
- 1800.4 Manufacturer and labeler grant amounts shall be reported for the period in which the money is provided and are not required to be allocated over the life of the grant.
- 1800.5 For purposes of the annual report due July 1, 2007 only, manufacturers and labelers shall report the required information by quarters. If any or all of the data for the first three quarters of 2006 is not available, then the manufacturers and labelers may substitute an explanation of why the data is not available for the data itself.
- 1800.6 In conjunction with filing the required annual report, each manufacturer or labeler shall pay to the Department the required filing fee of five thousand dollars (\$5,000), by mailing a check, made out to “D.C. Treasurer,” to District of Columbia Department of Health, Chief Financial Officer, 825 North Capitol Street, N.E., Room 5100, Washington, D.C. 20002.
- 1800.7 The Department may reduce the amount of the filing fee through rulemaking if the Department finds that its administrative costs are less than anticipated.

1801

CONTENT OF ANNUAL REPORT

1801.1 The annual report shall include the following information as it pertains to prescription drug marketing costs and activities expended by the manufacturer or labeler in the District in a form that provides the value, nature, purpose, and recipient of the expense:

- (a) 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;
- (b) 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 of the D.C. Official Code (Insurance and Securities), health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in the District, the following information:
 - (1) 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. This includes but is not limited to:
 - (i) Support for independent or continuing medical education programs (IME or CME) to the extent of participation by such persons and entities, including payments to medical education companies;
 - (ii) Printing costs of patient education materials and disease management materials distributed to such persons and entities. Design and other production costs also must be reported for materials designed specifically for District users;
 - (iii) Payment of consulting fees and expenses directly or indirectly to such persons and entities, subject to exceptions in § 1801.2 of this chapter;
 - (iv) Payments made directly or indirectly to such persons and entities for participation in speakers' bureaus and honoraria or other payments for time while speaking at or attending meetings, lectures or conferences;
 - (v) Payments made directly or indirectly to such persons or entities for writing articles or publications;
 - (vi) Charitable grants, either directly or earmarked, to such persons and entities, even if unrestricted; and

(vii) Payments made directly or indirectly to such persons or entities in connection with market research surveys or other activities undertaken in support of developing advertising and/or marketing strategies.

(2) 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;

(3) All expenses associated with trips and travel; and

(4) All expenses associated with product samples, except for samples that will be distributed free of charge to patients; and

(c) The aggregate cost of, including all forms of payment to, all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (a) and (b), limited to that portion of payment to the employees or contractors that pertains to activities within the District or to recipients of the advertising or promotional activities who are residents of or are employed in the District.

1801.2 The following expenses are not subject to the reporting requirements of this chapter:

(a) Marketing expenses of twenty-five dollars (\$25) or less per day and per health care provider or entity;

(b) Reasonable compensation and reimbursement for expenses in connection with a bona fide clinical trial of a new vaccine, therapy, treatment, or indication;

(c) 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; and

(d) Expenses associated with advertising and promotional activities purchased for a regional or national market that includes advertising in the District if the portion of the costs pertaining to or directed at the District or cannot be reasonably allocated, distinguished, determined or otherwise separated out.

1801.3 All costs reported in the annual report must be determined using Generally Accepted Accounting Principles (GAAP).

1801.4 Each manufacturer or labeler subject to the provisions of the Act shall, as part of

- (a) Report the name and contact information of the individual responsible for the company's compliance with the provisions of this chapter, and accuracy of the annual report;
- (b) Identify by name and position title the individual submitting the report; and
- (c) Submit separately in conjunction with the filing of the report under § 1802.1, a wet signature certification that "under penalty of law the information contained in the report is to the best of his or her knowledge after due diligence to inquire about the truthfulness and accuracy of the report," and an acknowledgment that providing false information or omitting required information on the report is unlawful.

1801.5 The individual identified in § 1801.4(a) of this chapter shall be a member of senior management or senior level company official within the manufacturer's or labeler's company or corporate structure.

1802 SUBMISSION OF ANNUAL REPORT

1802.1 Each manufacturer or labeler subject to reporting under the Act, shall submit the required annual report to the Department in an electronic format that is satisfactory to the Director.

1802.2 For each gift which was provided during the reporting period, that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the following information:

- (a) Name of manufacturer or labeler;
- (b) Date of payment or gift;
- (c) Name of recipient;
- (d) Type of recipient (e.g., clinic, doctor, hospital, pharmacist, university, other prescriber, benefits manager, health plan, nursing facility, psychiatric hospital, other healthcare provider);
- (e) Credentials of recipient, if applicable (e.g., APRN, DDS, MD, DO, DPM, DVM);
- (f) Nature of payment (e.g., book, cash or check, donation, food, grant, lodging, transportation, samples);
- (g) Primary purpose of payment (e.g., consulting, professional education,

charitable grant, speaker fee or payment); and

(h) Monetary value of payment.

- 1802.3 For each advertising, marketing, or direct promotion activity which occurred during the reporting period, that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the following information:
- (a) Name of manufacturer or labeler;
 - (b) Date(s) of activity;
 - (c) Type of activity (e.g., advertising, marketing, direct promotion, market research survey, patient education including materials such as disease management information; materials/consulting to promote new uses of drugs);
 - (d) Medium (e.g., radio, television, magazines, newspapers, direct mail, telephone);
 - (e) Name of medium, if applicable (e.g., television or radio station, newspaper, magazine);
 - (f) Product marketed (e.g., name of drug, general brand/company awareness);
 - (g) Target audience (e.g., general public, prescribers); and
 - (h) Cost of activity.

- 1802.4 For all employees and/or contractors of the manufacturer or labelers that that meets the requirements for mandated reporting, the manufacturer or labeler shall provide the aggregate costs, including all forms of payment, for these services as determined using GAAP.

1803 CONFIDENTIALITY AND PUBLIC INFORMATION

- 1803.1 Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this title shall be confidential and not a public record.
- 1803.2 A manufacturer or labeler subject to reporting under the Act, as part of its annual report, may identify any information that it claims is a trade secret and if so identified, shall certify in writing the reasons for its claim that the information is a trade secret.
- 1803.3 Data compiled in aggregate form by the Department for purposes of the reporting required by the Act is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

1803.4 The Director shall designate a person to review the reports required in § 1805 of this chapter before publication of the reports to ensure against disclosure of a trade secret of any manufacturer or labeler that has filed a report in compliance with the Act and this chapter. As part of such determination, such person may contact the manufacturer or labeler.

1804 ENFORCEMENT AND FINE

1804.1 These rules may be enforced in a civil action brought by the Office of the Attorney General for the District of Columbia.

1804.2 Failure to timely file a complete annual report in accordance with the Act and the provisions of this chapter constitutes a civil violation.

1804.3 Each submission of false information or omission of required information on the annual report shall constitute a separate civil violation.

1804.4 A fine of one thousand dollars (\$1,000), plus costs and attorney's fees, may be adjudged for each civil violation.

1804.5 When a manufacturer or labeler fails to timely file a complete annual report in accordance with the Act and provisions of this chapter, the District's costs for enforcement shall include all costs expended by the Director and/or the Attorney General during the course of the investigation of noncompliance, subsequent enforcement and resolution of the enforcement action, including staff time, equipment use, hearing records, expert assistance, and such other items as the Department determines to be a cost of the action which shall be calculated at the higher of the actual costs or \$1000 per day for each day that the complete and accurate report was due but not filed.

1805 DEPARTMENT REPORTS

1805.1 Beginning November 30, 2007, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses, to the Council and the Attorney General by November 30th of each year.

1805.2 Beginning January 1, 2008, and every two (2) years thereafter, the Department shall provide a report to the Council and the Attorney General, 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 cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

1899

DEFINITIONS

1899.1

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

Act- AccessRx Act of 2004, effective May 18, 2004 (D.C. Law 15-164; D.C. Official Code § 48-831.01 et seq.)

Affiliate- any individuals, partnerships, corporations, joint ventures, companies, firms, contractors or other legal entities, if directly or indirectly, either one owns, controls or can control the other, or a third party owns, controls or can control both.

Council- Council of the District of Columbia

Department- Department of Health

Director- Director of the Department

Attorney General- Attorney General for the District of Columbia, formerly known as the Corporation Counsel.

GAAP- Generally Accepted Accounting Principles. A widely accepted set of rules, conventions, standards, and procedures for reporting financial information.

Labeler- An entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs 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 prescription drugs 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 prescription drugs in the District to any person or entity licensed to provide health care in the District.

Trade secret- information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(A) Derives actual or potential independent economic value, from not being generally known to, and not being readily ascertainable by, proper means by another who can obtain economic value from its disclosure or use; and

(B) Is the subject of reasonable efforts to maintain its secrecy.

Wet signature- means a physically generated signature of a person that can be

compared to other physically generated signatures of the person for verification of authenticity.