

DEPARTMENT OF HEALTH

NOTICE OF FINAL RULEMAKING

The Director of the Department of Health ("Department"), pursuant to § 307 of the District of AccessRx Act of 2004, effective May 18, 2004 (D.C. Law 15-164; D.C. Official Code § 48-833.07) (the Act), and Mayor's Order 2006-60, dated June 7, 2006, hereby gives notice of the adoption of the following new chapter 18 of Title 22 of the District of Columbia Municipal Regulations (DCMR), entitled "Prescription Drug Marketing Costs." The adoption of this Chapter 18 is necessary to implement Title III of the Act, which requires manufacturers and labelers of prescription drugs in the District who engage in marketing in the District to report to the Department their prescription drug marketing costs.

The Director of the Department of Health previously caused a Notice of Proposed Rulemaking to be published in the D.C. Register on September 29, 2006 indicating his intent to adopt final rules in not less than thirty (30) days from the date of publication of the September 29, 2006 notice in the D.C. Register at 53 DCR 7879. Pharmaceutical Research and Manufacturers of America thereafter requested a fifteen (15) day extension of the comment period so that more meaningful comments could be submitted. The Director of the Department of Health then caused an Amended Notice of Proposed Rulemaking to be published in the D.C. Register on November 10, 2006 indicating an extension of the comment period through November 14, 2006 and intending no other changes to the proposed rules as indicated in the D.C. Register at 53 DCR 9221. Comments were received by the Department of Health on or before November 14, 2006 from the AARP District of Columbia, Biotechnology Industry Organization, Councilmember David A. Catania, and Pharmaceutical Research and Manufacturers of America. In analyzing the comments, the Director of the Department of Health concluded that substantive changes should be made to the proposed rulemaking to address issues raised by the comments and by analysis of the comments.

The Director of the Department of Health subsequently caused a Notice of Proposed Rulemaking to be published in the D.C. Register on February 23, 2007 at 54 DCR 1678. Comments were received by the Department of Health during the public comment period from Biotechnology Industry Organization and Pharmaceutical Research and Manufacturers of America. In analyzing the comments, the Director of the Department of Health has concluded that no further changes should be made to the proposed rulemaking. No changes have been made to the final rulemaking from the proposed rulemaking notice published on February 23, 2007.

These regulations will become effective upon publication of this notice in the D.C. Register.

Chapter 18 (Prescription Drug Marketing Costs) of Title 22 (Public Health and Medicine) is added as follows:

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 two thousand five hundred dollars (\$2,500), 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 its annual report:

- (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.

**DISTRICT OF COLUMBIA
DEPARTMENT OF INSURANCE, SECURITIES AND BANKING**

NOTICE OF FINAL RULEMAKING

The Commissioner of the Department of Insurance, Securities and Banking, pursuant to the authority set forth in § 4 of the Uniform Consultation Referral Form Act of 2002, effective April 13, 2002 (D.C. Law 14-97, D.C. Official Code § 31-3233) (Supp. 2002)) hereby gives notice of adoption of a new Chapter 43 of Title 26 of the District of Columbia Municipal Regulations (DCMR). The purpose of this new chapter is to provide a uniform referral form to be used when a health insurer requires that an insured have a written referral form to receive consultation services. This is an effort to simplify the referral process. The Notice of Proposed Rulemaking was published in the D.C. Register at 54 DCR 1878 (March 2, 2007). The final rulemaking will be effective when published in the D.C. Register.

26 DCMR is amended by adding a new Chapter 43, Uniform Consultation Referral Form, to read as follows:

CHAPTER 43

UNIFORM CONSULTATION REFERRAL FORM

4300 APPLICABILITY

- 4300.1 Each health insurer that requires an enrollee or subscriber to have a written referral in order to receive services shall use the uniform consultation referral form adopted by the Commissioner.
- 4300.2 Each health insurer must comply with these rules beginning with referrals issued 120 days after the promulgation of the final regulation.

4301 CONSULTATION REFERRAL FORM

- 4301.1 The health insurer may not impose as a condition of coverage a requirement to modify the uniform consultation referral form or to require the submission of additional consultation referral forms.
- 4301.2 The health insurer may provide a separate set of instructions for use by the health care provider regarding the health insurer's specific managed care requirements, and the instructions may be preprinted on the back of the uniform consultation referral form, if the instructions do not result in any modifications in the format of, or information categories directed to be supplied on the front of the uniform consultation referral form.

- 4301.3 The health insurer may provide stamps or preprinted stickers to include additional information to be inserted in the health insurer information block.
- 4301.4 The health insurer may preprint the designated health insurer information in the health insurer information field on the uniform consultation referral form.
- 4301.5 The health care provider shall use the uniform consultation referral form and complete it properly.
- 4301.6 The consultant or facility provider shall accept a properly completed uniform consultation referral form.

4302 ELECTRONIC TRANSFER

- 4302.1 The uniform consultation referral form may be transmitted by facsimile, so long as, the format and the data on the uniform consultation referral form remain unchanged.

4303-4398 RESERVED

4399 DEFINITIONS

- 4399.1 "Health benefits plan" means any accident and health insurance policy or certificate, hospital and medical services corporation contract, health maintenance organization subscriber contract, plan provided by a multiple employer welfare arrangement, or plan provided by another benefit arrangement. The term "health benefit plan" does not mean accident only, credit, or disability insurance; coverage of Medicare services or federal employee health plans, pursuant to contracts with the United States government; Medicare supplemental or long-term care insurance; dental only or vision only insurance; specified disease insurance; hospital confinement indemnity coverage; limited benefit health coverage; coverage issued as a supplement to liability insurance, insurance arising out of a workers' compensation or similar law; automobile medical payment insurance; medical expense and loss of income benefits; or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance.

"Health insurer" means any person that provides one or more health benefit plans or insurance in the District of Columbia, including an insurer, a hospital and medical services corporation, a fraternal benefit society, a health maintenance organization, a multiple employer welfare

arrangement, or any other person providing a plan of health insurance subject to the authority of the Commissioner.

“Commissioner” means the Commissioner of the Department of Insurance, Securities and Banking.

APPENDIX 43-1

**DISTRICT OF COLUMBIA
DEPARTMENT OF INSURANCE,
SECURITIES, AND BANKING**

UNIFORM CONSULTATION REFERRAL FORM

Uniform Consultation Referral Form

1. Patient Information		2. Carrier Information	
Date of Referral:		Name:	
Name (Last, First, MI)		Address:	
Date of Birth: (MM/DD/YY)		Phone:	
Member#:		Fax:	
Site #:		Referral Number:	
3. Primary or Requesting Provider:			
Name: (Last, First, MI)		Specialty:	
Institution / Group Name:		Provider ID:	Provider ID #: 2 (If Required)
Address: (Street #, City, State, Zip)			
Phone Number:		Facsimile / Data Number:	
4. Consultant / Facility Provider:			
Name: (Last, First, MI)		Specialty:	
Institution / Group Name:		Provider ID:	Provider ID #: 2 (If Required)
Address: (Street #, City, State, Zip)			
Phone Number:		Facsimile / Data Number:	
5. Referral Information:			
Reason for Referral:			
Brief History, Diagnosis and Test Results:			
6. Service Desired: Provide Care as indicated:		7. Place of Service:	
<input type="checkbox"/> Initial Consultation Only <input type="checkbox"/> Diagnostic Test: (specify) _____ <input type="checkbox"/> Consultation With Specific Procedures: (specify) _____ <input type="checkbox"/> Early, Periodic Screening, Diagnosis & Treatment <input type="checkbox"/> Standing Referral <input type="checkbox"/> Specific Treatment: _____ <input type="checkbox"/> Global OB Care & Delivery <input type="checkbox"/> Other: (explain) _____		<input type="checkbox"/> Office <input type="checkbox"/> Outpatient Medical/Surgical Center* <input type="checkbox"/> Radiology <input type="checkbox"/> Laboratory <input type="checkbox"/> Inpatient Hospital* _____ <input type="checkbox"/> Extended Care Facility* _____ <input type="checkbox"/> Other: (explain) _____ (Specific Facility Must be Named)	
Number of visits: (If blank, 1 visit is assumed)	Authorization #: (If Required)	Referral is Valid Until: (Date) (See Carrier Instructions)	
Signature: (Individual Completing This Form)		Authorizing Signature: (If Required)	

Referral certification is not a guarantee of payment. Payment of benefits is subject to a member's eligibility on the date that the service is rendered and to any other contractual provisions of the plan / carrier. *This form may not be use electronically.*