GOVERNMENT OF THE DISTRICT OF COLUMBIA
Department of Health

Prescription Drug Marketing Costs
A Guide for Pharmaceutical Manufacturers and Labelers
Published by the District of Columbia Department of Health
Calendar Year 2012

Description of Requirements

Pursuant to the requirements of Chapter 18 of Title 22 of the District of Columbia Municipal Regulations (DCMR), entitled "Prescription Drug Marketing Costs," and Title III of the AccessRx Act of 2004, manufactures and labelers of prescription drugs dispensed in the District of Columbia ("District") who engage in marketing in the District must report to the Department of Health ("Department") their costs for pharmaceutical drug marketing in each calendar year by July 1st of the following year.

Submission Procedures

Fill out the "Company Information," "Gift Expenses," "Advertising Expenses," and "Aggregate Cost" sheets of the spreadsheet titled "2012_Prescription_Drug_Marketing_Costs.xls," and email the "Company Information," "Gift Expenses," and "Advertising Expenses" sheets to **DC.Accessrx@dc.gov**. Although you are required to utilize the "Aggregate Cost" sheet to perform your calculations, you are not required to submit the worksheet itself. You may elect instead to only submit the totals based on your calculations using the "Aggregate Cost" worksheet. The other three worksheets must be submitted. In addition, print out the "Company Information" sheet *only*, provide wet signature certification, and mail it to the Department accompanied by a **$5,000*** check made payable to **"D.C. Treasurer."**
The report must be submitted by July 1st, and the signed statement and check must be received within seven (7) days of the report's submission.

Mail signed "Company Information" sheets and checks to:

Department of Health
Pharmaceutical Control – AccessRx
ATTN: Patricia M. D'Antonio
899 N. Capitol Street, NE
Second Floor
Washington, D.C. 20002

***With passage of the "Fiscal Year 2010 Balanced Budget Support Emergency Act of 2010," the fee for the program is $5,000.**

Spreadsheet Instructions
The "2012_Prescription_Drug_Marketing_Costs.xls" document contains four sheets in which information should be entered: *Company Information*, *Gift Expenses*, *Advertising Expenses,* and *Aggregate Cost*. (The fifth sheet, Instructions, is for reference purposes.) **Please make sure you fill out all four required sheets.**

Sheet 1: Company Information: The Company Information sheet includes fields for the company's contact information and the contact information of the individual responsible for the company's compliance. Pursuant to 22 DCMR 1801.5, the responsible individual "shall be a member of senior management or senior level company official within the manufacturer's or labeler's company or corporate structure."

The "2012 Marketing Expenses" section of this sheet should contain the relevant totals from the Gift Expenses, Advertising Expenses, and Aggregate Cost sheets. **PLEASE DOUBLE CHECK that the totals listed on this sheet match the totals on the three following sheets** (i.e., that the Gift Expense figure on Sheet 1 matches the Gift Expense total on Sheet 2, etc.). Add the Gift Expenses, Advertising Expenses, and Aggregate Cost figures to get the Total Marketing Expenses. **Please confirm that the addition is correct.**

Sheet 2: Gift Expenses: The Gift Expenses sheet collects the following information, as described in §48-833.03 of the AccessRx Act of 2004:

> 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.

The following expenses are not subject to reporting requirements:

> (1) Marketing expenses of twenty-five dollars ($25) or less per day and per health care provider or entity;

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

(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; and

(4) 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.

Using one line per payment, fill in the information required for each of the columns. Please note that for some columns, there is a limited set of accepted values. Detailed instructions about the information required for each column appear in the "Column Instructions: Gift Expenses" section on page 5 of this document.

IMPORTANT: Note that if you enter "Other" in the column for Credentials, Recipient Type, Nature of Payment, Primary Purpose, or Secondary Purpose, **you must enter details in the next column**. For instance, if your company provided lunch to the receptionist at a physician's office, you would enter "Other" in the Recipient Type column and "Receptionist" in the Other Type column.

Sheet 3: Advertising Expenses: §48-833.03 of the AccessRx Act of 2004 describes these expenses as:

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.

22 DCMR 1802.3 provides the following examples:

Advertising, marketing, direct promotion, market research survey, patient education including materials such as disease management information; materials/consulting to promote new uses of drugs.

Using one line per payment, fill in the information required for each of the columns. Please note that for some columns, there is a limited set of accepted values. Detailed instructions about the information required for each column appear in the "Column Instructions: Advertising Expenses" section on page 8 of this document.

Sheet 4: Aggregate Cost: The Aggregate Cost sheet collects the following information, as described in 22 DCMR 1801.1:

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 and

> promotional activities ... 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.

Using one line per employee or contractor, enter the position title for each employee or contractor who directly or indirectly engages in advertising and promotional activities and devotes any time to activities pertaining to the District. If the employer or contractor was a registered detailer in the District of Columbia during the past calendar year, provide that person's license number. In the corresponding columns, enter the salary, benefits, and commission amounts for each of these employees or contractors. Multiply the sum of those figures by the percentage of time that individual spent on activities conducted within the District or directed to recipients who are residents of or are employed in the District. Although you are required to utilize the "Aggregate Cost" sheet to perform your calculations, you are not required to submit the worksheet itself. You may elect instead to only submit the totals based on your calculations using the worksheet.

Detailed instructions about the information required for each column appear in the "Column Instructions: Aggregate Cost" section on page 10 of this document.

Column Instructions

Column Instructions: Gift Expenses

If you have no gift expenses to report, enter "None" in the first available cell.

A. Payment Date
Enter the date on which the payment was made, in MM/DD/YYYY format.

B. Non-Individual Recipient
If the recipient is not an individual – e.g., if the payment was made to an organization, hospital, or department – enter the name of the recipient here. If the recipient is an individual, leave this cell blank.

C. Recipient Last Name
If the recipient of the payment is an individual, enter his or her last name here. If the recipient is not an individual, leave this cell blank.

D. Recipient First Name
If the recipient of the payment is an individual, enter his or her first name here. If the recipient is not an individual, leave this cell blank.

E. Recipient Middle Initial
If the recipient of the payment is an individual, enter his or her middle initial here. If the recipient is not an individual, leave this cell blank.

F. Recipient Credentials
Accepted values: APRN, DDS, DO, DPM, DVM, MD, ND, NP, OD, PA, RN, Other
If the recipient of the payment is an individual, enter his or her credentials here. If the recipient is not an individual, leave this cell blank. Use the above abbreviations (e.g., do not spell out "doctor" or "nurse" if the credentials are MD or RN). If the recipient is not an individual, leave this cell blank.

G. Other Credentials
If "Other" is entered in the "Recipient Credentials" cell, enter the recipient's credentials here. Otherwise, leave this cell blank.

H. Recipient Affiliated Facility
Enter the name of the facility (e.g., George Washington University Medical Center, American Heart Association DC Office) with which the recipient is affiliated.

I. Recipient Type
Accepted values: Clinic, Hospital, Medical Practice, Pharmacist, Physician, University, Other Prescriber, Other Healthcare Provider, Other Organization, Other
Enter the above term that best describes the type of recipient.

J. Other Type
If "Other" is entered in the "Recipient Type" cell, enter the type of recipient here. Otherwise, leave this cell blank.

K. Nature of Payment
Accepted values: Book, Cash or Check, Donation, Entertainment, Food, Grant, Lodging, Product Samples, Transportation, Other
Enter the above term that best describes the nature of payment.

L. Other Nature
If "Other" is entered in the "Nature of Payment" cell, enter the nature of payment here. Otherwise, leave this cell blank.

M. Primary Purpose
Accepted values: Consulting, Education, Marketing, Speaker Fee or Payment, Other
Enter the above term that best describes the primary purpose of the payment.

N. Other Primary Purpose
If "Other" is entered in the "Primary Purpose" cell, enter the primary purpose of the payment here. Otherwise, leave this cell blank.

O. Secondary Purpose
Accepted values: None, Consulting, Education, Marketing, Speaker Fee or Payment, Other
Enter the above term that best describes the secondary purpose of the payment. (If the payment had no secondary purpose, enter "None.")

P. Other Secondary Purpose
If "Other" is entered in the "Secondary Purpose" cell, enter the secondary purpose of the payment here. Otherwise, leave this cell blank.

Q. Value
Enter the dollar value of the payment in $X,XXX.XX format.

R. Trade Secret?
If the company has designated this payment a trade secret, enter "Yes" in this cell; if it has not designated the payment a trade secret, enter "No."

22 DCMR 1899.1 defines a Trade Secret as follows: "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."

S. Trade Secret Explanation

If you answered "Yes" to the question "Is this payment a Trade Secret?" explain the justification for the trade secret designation. Otherwise, leave this cell blank.

T. Resubmission?

If this submission is a resubmission of data (i.e., an addition or correction to an earlier submission), enter "Yes." If this is the first time you are submitting this information, enter "No."

U. Original Submission Date

If you answered "Yes" to the question "Is this a resubmission of data?" enter the date of the original submission that this submission is amending or replacing. Otherwise, leave this cell blank.

V. Resubmission Description

If you answered "Yes" to the question "Is this a resubmission of data?" enter details about how this submission amends or replaces the submission whose date is entered in the "Original Submission Date" field. Otherwise, leave this cell blank.

Column Instructions: Advertising Expenses

If you have no advertising expenses to report, enter "None" in the first available cell.

A. Activity Date

Enter either a single date for the activity, in MM/DD/YYYY format, or a date range, in MM/DD/YYYY – MM/DD/YYYY format.

B. Type of Activity

Accepted values: Direct-to-Consumer Advertisement Production, Direct-to-Consumer Advertisement Placement, Other Advertisement Production, Other Advertisement Placement, Market Research, Other Promotional Activity

Enter the type of activity (e.g., advertising, direct promotion, patient education).

C. Medium Type

Accepted values: Conference or Other Event, Direct Mail, Internet/Email, Medical Journal, Newspaper/Magazine, Patient Materials, Radio, TV/Video, Other Printed Material, Other

Enter the type of medium used in the activity (e.g., radio, television, magazines, newspapers, direct mail, telephone).

D. Medium Name

If applicable, enter the name of the medium used (e.g., newspaper name, name of television or radio station). If no medium name applies, leave this cell blank.

E. Product Marketed

Enter the name of the prescription drug being advertised; if no specific drug was advertised, enter "general."

F. Target Audience

Enter the name of the audience to whom the advertising was directed (e.g., general public, prescribers).

G. Cost of Activity

Enter the cost of the activity, in $X,XXX.XX format.

H. Trade Secret

If the company has designated this payment a trade secret, enter "Yes" in this cell; if it has not designated the payment a trade secret, enter "No."

22 DCMR 1899.1 defines a Trade Secret as follows: "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."

I. Trade Secret Explanation

If you answered "Yes" to the question "Is this payment a Trade Secret?" explain the justification for the trade secret designation. Otherwise, leave this cell blank.

J. Resubmission?

If this submission is a resubmission of data (i.e., an addition or correction to an earlier submission), enter "Yes." If this is the first time you are submitting this information, enter "No."

K. Original Submission Date

If you answered "Yes" to the question "Is this a resubmission of data?" enter the date of the original submission that this submission is amending or replacing. Otherwise, leave this cell blank.

L. Resubmission Description

If you answered "Yes" to the question "Is this a resubmission of data?" enter details about how this submission amends or replaces the submission whose date is entered in the "Original Submission Date" field. Otherwise, leave this cell blank.

Column Instructions: Aggregate Cost

If you have no aggregate cost to report, enter "None" in the first available cell.

A. Position Title

Enter the position title for each employee or contractor who directly or indirectly engages in advertising and promotional activities and devotes any time to activities pertaining to the District.

B. License # (DC Detailers)

If the position was filled by a detailer licensed in the District during the past calendar year, enter the detailer's license number. If it was not filled by a detailer licensed in the District, leave this field blank.

C. Salary

Enter the salary paid to the employee or contractor during the past calendar year, in $XX,XXX.XX format.

D. Benefits

Enter the dollar value of the benefits paid to the employee or contractor during the past calendar year, in $XX,XXX.XX format.

E. Commission

Enter the amount of commission payments made to the employee or contractor during the past calendar year, in $XX,XXX.XX format. If no commissions were paid to the employee or contractor, leave this field blank.

F. Total Compensation

Enter the sum of the Salary, Benefits, and Commission, in $XX,XXX.XX format.

G. Time Percentage

Enter the percentage of the employee or contractor's time spent during the past calendar year on activities conducted within the District or directed to recipients who are residents of or are employed in the District.

H. DC Position Total

Multiply Total Compensation by the Time Percentage and enter the result here, in $XX,XXX.XX format.