

Prescription Drug Marketing Costs A Guide for Pharmaceutical Manufacturers and Labelers Published by the District of Columbia Department of Health Calendar Year 2019

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” worksheets of the workbook titled “2019_Prescription_Drug_Marketing_Costs.xls,” and email the Excel workbook containing the “Company Information,” “Gift Expenses,” and “Advertising Expenses” worksheets to DC.Accessrx@dc.gov. Although you are required to utilize the “Aggregate Cost” worksheet to perform your calculations, you are not required to submit the worksheet itself. You may elect instead to only submit the total based on your calculations using the “Aggregate Cost” worksheet. The other three worksheets must be completed using the accepted values and submitted in **Excel format, not as a PDF**. In addition, print out the “Company Information” worksheet 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” worksheets and checks to:

Department of Health
Pharmaceutical Control – AccessRx
ATTN: Shauna White
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 “2019_Prescription_Drug_Marketing_Costs.xls” document contains four worksheets in which information should be entered: *Company Information*, *Gift Expenses*, *Advertising Expenses*, and *Aggregate Cost*.

(The fifth worksheet, Instructions, is for reference purposes.) **Please make sure you fill out all four required worksheets.**

Worksheet 1: Company Information

The Company Information worksheet 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 “2019 Marketing Expenses” section of this worksheet should contain the relevant totals from the Gift Expenses, Advertising Expenses, and Aggregate Cost worksheets. **PLEASE DOUBLE CHECK that the totals listed on this worksheet match the totals on the three following worksheets** (i.e., that the Gift Expense figure on Worksheet 1 matches the Gift Expense total on Worksheet 2, etc.). Add the Gift Expenses, Advertising Expenses, and Aggregate Cost figures to get the Total Marketing Expenses. **Please confirm that the sum of the three figures is correct.**

Worksheet 2: Gift Expenses

The Gift Expenses worksheet 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. Gifts must be classified as either individual or non-individual. **Individuals** are persons licensed to provide health care in the District who receive gifts or payments, including cash, food, or in-kind items. **Non-individuals** are entities such as hospitals, clinics, nursing facilities, pharmacies, and health organizations.

Gifts given to physicians and teaching hospitals **must be reported** to the Open Payments system. A physician is a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. See, 42 U.S.C.A. § 1395x(r). Additionally, to reduce “double counting” of payments, gifts to physicians or teaching hospitals **should not be included or “rolled up”** in reported payments to practices or other non-individual recipients. **Payments reported to Open Payments should not be reported to the AccessRx.**

IMPORTANT: Gifts to staff of physician offices or medical practices should be attributed to named individuals, whenever possible. If a gift cannot be reasonably allocated to a specific individual or individuals, it may be reported as a non-individual gift but this is not preferred. Any non-individual gifts must not include the physician’s share, as it is reported to Open Payments.

IMPORTANT: Note that if you enter “Other” in the column for Credentials, Recipient Type, Nature of Payment, Form 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 clinic, you would enter “Other” in the Recipient Type column and “Receptionist” in the Other Type column.

IMPORTANT: Columns which have listed Accepted Values **must be filled** with one of the Accepted Values. Do not enter a value that is not listed as an option. Detailed instructions about the information required for each column appear in the “Column Instructions: Gift Expenses” section on page 5 of this document

Worksheet 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.

Worksheet 4: Aggregate Cost

The Aggregate Cost worksheet 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” worksheet to perform your calculations, you are not required to submit the worksheet itself. You may elect instead to only submit the total 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: 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/YY format (the “Short Date” Excel 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 entity 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: *APN/NP, RN/LPN, PharmD, RPH, ND, PA, DDS*, DO*, DPM*, MD*, OD*, DVM, 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 “nurse” if the credentials are NP or RN). If the recipient is not an individual, leave this cell blank. *Note that gifts to physicians given after July 31, 2013 are **not required to be reported to the District**. A physician is a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. See, 42 U.S.C.A. § 1395x(r). Gifts to physicians should only be reported to AccessRx under special circumstances, when a gift is not reported to Open Payments.

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, Dentist*, Hospital*, Medical Education or Communication Company, Medical Staff, Nonprofit Organization, Nurse, Nurse Practitioner/Advanced Practice Nurse, University, Pharmacist, Physician*, Physician Assistant, Psychologist, Social Worker, Technician, Other* Enter the above term that best describes the type of recipient.

*Note that gifts to physicians and teaching hospitals given after July 31, 2013 are not required to be reported to the District. The list of teaching hospitals is available at:

<http://www.cms.gov/OpenPayments/About/Resources.html>. Gifts to physicians should only be reported to AccessRx under special circumstances, when a gift is not reported to Open Payments.

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: *Consulting Fee, Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program, Honoraria, Gift, Entertainment, Food and Beverage, Travel and Lodging, Education, Charitable Contribution, Royalty or License, Current or prospective ownership or investment interest, Compensation for serving as faculty or as a speaker for a non-accredited and noncertified continuing education program, Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program, Grant, Space Rental or Facility Fees, 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. Form of Payment

Accepted values: *Cash or Cash Equivalent, In-kind Items and Services; Stock, stock options, or any other ownership interest; Dividend, profit or other return on investment, Other*
Enter the above term that best describes the form of payment.

N. Other Form

If “Other” is entered in the “Form of Payment” cell, enter the form of payment here. Otherwise, leave this cell blank.

O. Primary Purpose accepted values: *Consulting, Education, Marketing, Donation, Other*

Enter the above term that best describes the primary purpose of the payment.

P. 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.

Q. Secondary Purpose

Accepted values: *None, Consulting, Education, Marketing, Donation, Other*

Enter the above term that best describes the secondary purpose of the payment. (If the payment had no secondary purpose, enter “None.”)

R. 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.

S. Value

Enter the dollar value of the payment in \$X,XXX.XX format (the “Currency” Excel format).

T. 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.”

U. 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.

V. 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.”

W. 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. If applicable, the date should be listed as MM/DD/YY (the “Short Date” Excel format).

X. 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 a single date for the activity, in MM/DD/YY format (the “Short Date” Excel format). If the activity took place over a date range, enter the date when the activity began.

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 (the “Currency” Excel 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. If applicable, the date should be listed as MM/DD/YY (the “Short Date” Excel format).

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 (the "Currency" Excel 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 (the "Currency" Excel 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 (the "Currency" Excel 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 (the "Currency" Excel 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 (the "Currency" Excel format).