

Reporting Prescription Drug Marketing Costs Frequently Asked Questions

1. Who is required to report to Access Rx?

Answer: Title III Sec 301 says “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.”

2. When is the reporting deadline? **Answer:** July 1st

3. Are late submissions accepted?

Answer: Late submissions must be approved by the Program. Please email dc.accessrx@dc.gov

4. What file format should AccessRx reports be submitted in?

Answer: Manufacturers should submit prescription drug marketing expenditure reports as an Excel file to the DC Department of Health. Please do not submit reports as PDFs. Please ensure that the file is not password-encrypted.

5. Who should be listed as the contact on the Company Information tab of the AccessRx Report?

Answer: Up-to-date contact information should be listed each year for the individual who should be contacted if a clarification is required. The listed individual should be able to be reached directly via email and phone for inquiry regarding the company’s submitted report.

6. Should payments to physicians and teaching hospitals reported to Open Payments also be reported to Access Rx?

Answer: No. Do not report physician and teaching hospitals to both Open Payments and AccessRx. Manufacturers are not required to report payments to the District (AccessRx) if they have been reported to Open Payments (CMS). In fact, payments to physicians and teaching hospitals should only be reported to AccessRx in special circumstances when they have not been reported to Open Payments. When reporting non-individual gifts to a physician’s office (i.e. a group meal), please ensure that gift amounts reported to AccessRx do not include gifts or a portion of a gift given to a physician or other individual whose gifts should be reported to Open Payments.

7. How should gifts to medical staff of physician offices or medical practices be reported?

Answer: It is highly preferred that companies should attribute all gifts, including food and beverages, directly to named individuals or entities. Gifts to medical staff of

physician offices or medical practices that cannot be reasonably allocated to named individuals may be reported as a non-individual gift instead of an individual gift. The name of the gift should clarify that the gift is attributed to a count of individuals (e.g., “To the Office of Dr. XXX” or “Medical Staff of GWU Hospital”). If any portion of a nonindividual gift would be reasonably assumed to apply to a physician, that portion of the total gift should be excluded from AccessRx reporting and reported to Open Payments.

8. Can gifts to physicians be “rolled-up” into gifts given to a group?

Answer: No. Gifts to physicians should not be “rolled-up” into gifts to a group. Gifts to physicians reportable to Open Payments should not be reported to AccessRx.

9. For gift expenses, which fields are required fields and which can be left blank?

Answer: In the gift expenses tab, payments should either be reported for a “NonIndividual Recipient” or for an “Individual Recipient.”

For non-individual entities, the “Non-Individual Recipient” column should be filled in. The three columns for reporting the name of an individual should be left blank. For “Non-Individual Recipients,” the columns for “Recipient Credentials” and “Recipient Affiliated Facility” can be left blank.

If the recipient is an Individual Recipient, the columns for the recipient’s last name, first name, and middle initial should be filled in. The column for “Non-Individual Recipient” should be left blank.

The following columns should be filled out for all payments, whether the recipient is an individual or non-individual: “Recipient Type,” “Nature of Payment,” “Form of Payment,” “Primary Purpose,” “Value,” “Trade Secret?,” and “Resubmission.” The columns for “Other Credential,” “Other Type,” “Other Nature,” etc. can be left blank if the preceding column was not reported as “Other.”

Accepted values for columns are listed as a comment in the heading in the submission form as well as in the instructions tab. Only those accepted values should be entered for those columns.

10. For reporting advertising expenses, how should the “Activity Date” be reported: should it be reported when the actual advertisement took place or when the date of payment occurred? For instance, an advertisement may have occurred in 2015, but the payment occurred in 2016. In this case, the data would not have been available for the report until 2016.

Answer: Dates for advertising can be reported in ranges. “Activity Date” refers to when the advertising took place. For television or radio advertisements, the date reported

should correspond to when the activity happened, and the payment amount should correspond to the cost of the activity. For mailings or email promotion, the date could be when the materials were mailed or sent out.

11. Can negative values be submitted?

Answer: No. Negative values cannot be entered into the database.

12. If a pharmaceutical manufacturer has nothing to report in DC for healthcare provider payments, does the manufacturer still have to file a report?

Answer: Yes. If a manufacturer did not make any payments to healthcare providers in the District, the manufacturer is not required to submit gift expenses to AccessRx. However, the manufacturer must still report aggregate and advertising expenditures to AccessRx if the manufacturer utilized detailers or employed or contracted with anyone who was engaged in marketing or advertising in the District.

13. Due to COVID-19 my company is unable to provide a wet signature, can we provide an electronic signature in place of it?

Answer: Yes, please provide the report with an electronic signature. However, the signed report with a wet signature will eventually need to be submitted to the Department of Health, Pharmaceutical Control Division. Please provide the report with a wet signature when possible and note that the initial application was previously submitted with an electronic signature.