Pharmaceutical Marketing Expenditures in the District of Columbia, 2017



Government of the District of Columbia Department of Health Health Regulation and Licensing Administration

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Executive Summary

Overview

This annual report discusses the scope of pharmaceutical marketing expenditures in the District of Columbia in 2017. Title III of the AccessRx Act of 2004 requires any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District" to disclose, in an annual report to the District of Columbia Department of Health (DOH), expenses for marketing prescription drugs in the District. These expenses include costs of direct promotion to District residents; costs of educational and informational sessions, gifts, and other marketing to healthcare professionals and entities licensed to provide care in the District; and costs associated with employees or contractors who directly or indirectly engage in these activities in the District. Data collected by AccessRx complement federally-reported data from the Centers for Medicare and Medicaid Services' (CMS) Open Payments program. Open Payments collects information on gifts from pharmaceutical companies to physicians and teaching hospitals. Appendices A and B provide additional information on reporting requirements for Open Payments and AccessRx.

In 2017, 183 pharmaceutical manufacturer and labelers submitted reports to the AccessRx Program on marketing expenditures in the District of Columbia. Companies reported spending \$103.2 million, which is an increase of \$4 million from the total reported in 2016. This report illustrates pharmaceutical marketing overall and then analyzes subgroups such as physicians, nurses, teaching hospitals, and various organizations. Finally, this report will provide recommendations for reporting and utility of the data for future years.

Key Findings

In 2017, pharmaceutical and device manufacturers reported a total of **\$103.2 million** for marketing expenditures in the District of Columbia. The expenditures are classified and analyzed in three main categories: *Gift Expenses, Advertising Expenses,* and *Aggregate Expenses. Gift Expenses* accounted for \$26.1 million (25.3%), *Advertising Expenses* for \$11.6 million (11.2%), and *Aggregate (Detailing) Expenses* for \$65.5 million (63.5%), of the total expenses.

Between 2016 and 2017:

- Total expenditures increased by \$4 million (4.1%), from \$99.2 million in 2016 to \$103.2 million in 2017.
- *Gift Expenses* increased by \$1.4 million (5.9%), from \$24.7 million in 2016 to \$26.1 million in 2017.
- *Advertising Expenses* decreased by approximately \$55,000, from \$11,658,176 in 2016 to \$11,603,211 in 2017.

- Aggregate Expenses (Detailing) increased by \$2.7 million (4.3%), from \$62.8 million in 2016 to \$65.5 million in 2017.
- *Gifts to Individual Recipients* totaled \$16.6 million.
 - *Physicians* received \$14.2 million in gifts, accounting for 86% of all gifts received by *Individual Recipients*.
 - \$14.0 million was reported to Open Payments and \$209,923 was reported to AccessRx.
 - The 25 physicians who received the highest amount of gift values, received a total of \$6.3 million.
 - 1% of the physicians who received payments from pharmaceutical companies received half of the total value received by physicians in 2017.
 - *Advanced Practice Nurses* (nurses with independent prescribing authority) received a total of \$432,521.
 - *Physician Assistants* received a total of \$81,834.
 - *Dentists* received a total of \$464,857.
 - \$457,186 was reported for Open Payments and \$7,671 was reported to AccessRx.
 - The top two dentists who received the highest amount of gift values received approximately three quarters of the total value.
 - *Registered Nurses* received a total of \$449,514.
 - *Pharmacists* received a total of \$78,692.
 - Other Healthcare Providers received a total of \$45,341.
 - *Clinical Office Staff and Other Individual Recipients* received a total of \$857,347.
- *Gifts to Non-Individual Recipients* totaled \$9.5 million.
 - *Teaching Hospitals* accounted for the largest portion with \$4.4 million in gifts.
 - \$3.8 million was reported to Open Payments and approximately \$600,000 was reported to AccessRx.
 - The 2017 Open Payments List of *Teaching Hospitals* in DC include: Children's Hospital, George Washington University, Howard University Hospital, Georgetown University Hospital, Sibley Memorial Hospital, Providence Hospital, Washington Hospital Center, National Rehabilitation Hospital, and St. Elizabeth's Hospital.
 - Companies did not report *Gifts* to National Rehabilitation Hospital and St. Elizabeth's Hospital to either Open Payments or AccessRx.
 - *Professional Organizations* received \$1,595,082.
 - *Advocacy Organizations* received \$1,061,693.
 - Universities received \$856,919.
 - *Clinical Organizations* received \$684,428.
 - Continuing Medical Education Organizations received \$492,155.
 - Other Non-Individual Recipients received \$374,546.

I. Summary of Pharmaceutical Marketing Expenditures

Pharmaceutical manufacturers and labelers spent \$103.2 million on marketing in the District of Columbia including gift, advertising, and aggregate expenditures, according to the reports submitted to the DC Department of Health.

The total sum includes data from the District of Columbia's AccessRx program and the Centers for Medicare and Medicaid Services' (CMS) Open Payments program. One hundred and eightythree pharmaceutical manufacturers and labelers reported \$85 million in marketing expenditures to the DC AccessRx program, which is approximately a 5% increase from 2016. More pharmaceutical companies reported marketing expenditures to the Open Payments program; 502 pharmaceutical manufacturers and labelers reported spending \$18.3 million on gifts to physicians and teaching hospitals in 2017. This is a slight increase (2%) from 2016 (\$18 million). The number of companies reporting to Open Payments and AccessRx is steadily increasing: 542 companies reported in 2017, 498 companies reported in 2016, and 463 companies reported in 2015.

Total Expenses

The total amount of marketing expenditures in 2017 was \$103.2 million; a 4% increase from 2016. The total amount includes \$26.1 million for *Gift Expenses*, \$11.6 in *Advertising Expenses*, and \$62.8 in *Aggregate Expenses*. *Gift Expenses* and *Aggregate Expenses* increased slightly from 2016, while *Advertising Expenses* remained about the same.

Table 1 displays the total reported amount in each category from 2006 to 2017. *Gift Expenses* reported from 2006 to 2012 represents only data from AccessRx. The Open Payments program began its first data collection in August 2013, and therefore from 2013 to 2017, *Gift Expenses* include AccessRx and Open Payments data.

Reporting Year	Gift Expenses	Advertising Expenses	Aggregate Expenses (Detailing)	Grand Total
2017	\$26,118,323	\$11,603,211	\$65,526,876	\$103,248,410
2016	\$24,672,754	\$11,658,176	\$62,833,677	\$99,164,608
2015	\$24,362,166	\$5,631,108	\$66,225,062	\$96,218,336
2014	\$22,562,396	\$7,903,100	\$60,671,713	\$91,137,209
2013	\$30,686,134	\$5,673,841	\$65,158,392	\$101,518,367
2012	\$30,487,486	\$5,445,732	\$61,537,192	\$97,470,410
2011	\$18,859,946	\$6,879,230	\$57,815,759	\$83,554,935
2010	\$21,010,822	\$6,791,214	\$57,551,911	\$85,353,946
2009	\$22,034,979	\$7,569,036	\$66,483,622	\$96,087,637
2008	\$27,090,335	\$8,108,052	\$101,425,020	\$136,623,408
2007	\$31,337,226	\$10,253,274	\$116,573,964	\$158,164,463
2006	\$34,440,072	\$10,890,983	\$99,889,040	\$145,220,094

Table 1: Pharmaceutical Marketing by Expenditure Type, 2017



Figure 1: Total Pharmaceutical Marketing by Expenditure Type

Figure 2: Summary of Pharmaceutical Marketing Expenditures



*Companies are required by federal law to report payments to physicians and teaching hospitals to Open Payments. However, under special circumstances, companies may report payments to physicians and teaching hospitals to AccessRx that are included in these totals.

Gift Expenses

Gift Expenses are payments accepted by individuals or entities licensed to provide health care in the District of Columbia. Pharmaceutical companies are required to report expenses associated with educational and informational programs and materials, food, entertainment, traveling, products, and other activities. Appendices A and B provide further details reporting requirements for AccessRx and Open Payments, respectively.

The total value of *Gift Expenses* reported in 2017 is \$26.1 million. This is a 6% increase from the value reported in 2016 (\$24.7 million). Five hundred and twenty-four pharmaceutical companies reported costs to Open Payments and AccessRx, which is an 11% increase from 474 companies in 2016; an additional 18 companies submitted reports indicating that they had no gift expenses for District-based providers in 2017.

Approximately 40,000 gifts totaling \$18.3 million were reported by 502 companies to Open Payments. These gifts ranged from less than \$1 to \$995,526, with a median value of \$22. Around 13,000 gifts totaling \$7.8 million were reported by 119 companies to AccessRx. These gifts ranged from less than \$1 to \$280,000, with a median value of \$54. These amounts reflect the general pattern that most gifts are reported to be of modest values.

Table 2 displays the distribution of companies based on their reported gift expenses. More than 50 companies reported expenses totaling over \$100,000 while most companies (68%) reported spending less than \$10,000. Section II of this report further discusses *Gift Expenses*, specifically, with sub-sections IIa and IIb describing the various recipients of gift payments.

Total Reported Value	Number of Companies	Percent of Total Number	Total Value	Percent of Total Value
More than \$1,000,000	3	0.55%	\$4,614,232	17.67%
\$500,001 - \$100,000	7	1.29%	\$4,881,697	18.69%
\$250,001 - \$500,000	20	3.69%	\$6,921,392	26.50%
\$100,001 - \$250,000	26	4.80%	\$4,359,548	16.69%
\$50,001 - \$100,000	41	7.56%	\$2,874,657	11.01%
\$25,001 - \$50,000	32	5.90%	\$1,183,629	4.53%
\$10,001 - \$25,000	46	8.49%	\$756,879	2.90%
\$1,001 - \$10,000	127	23.43%	\$469 <i>,</i> 470	1.80%
\$1 - \$1,000	222	40.96%	\$56,819	0.22%
No Reported Costs	18	3.32%	-	-
Total	542	100.00%	\$26,118,323	100.00%

Table 2: Distribution of Gift Expenses in DC, 2017

Advertising Expenses

Advertising Expenses include costs associated with advertising and promotional activities for prescription drugs, specific to the District of Columbia.

In 2017, 84 companies (46% of the companies that submitted data to AccessRx) reported a total of \$11.6 million in *Advertising Expenses*. This amount is approximately \$50,000 less than the total amount reported in 2016. As in past reports, *Advertising Expenses* remains the category with lowest value of expenditures, accounting for 11% of the total marketing costs. Of the companies that reported marketing expenses, 99 did not report *Advertising Expenses*.

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	3	1.6%	\$7,209,350	62.1%
\$250,001 - \$1,000,000	4	2.2%	\$1,802,950	15.5%
\$100,001 - \$250,000	11	6.0%	\$1,828,046	15.8%
\$25,001 - \$100,000	8	4.4%	\$427,356	3.7%
\$10,001 - \$25,000	14	7.7%	\$233,831	2.0%
\$1,001 - \$10,000	26	14.2%	\$94,857	0.8%
\$1 - \$1,000	18	9.8%	\$6,823	0.1%
No Reported Costs	99	54.1%	-	-
Total	183	100.0%	\$11,603,211	100.0%

Table 3: Distribution of Advertising Expenses in DC, 2017

Aggregate Expenses (Detailing)

Aggregate Expenses are payments made to employees or contractors engaged in District of Columbia marketing and promotional activities, including salaries. The District is the only jurisdiction in the United States that requires reporting of these costs.

In 2017, 166 pharmaceutical companies reported spending a total of \$65.5 million in *Aggregate Expenses*, accounting for 63% of all reported marketing expenses. This total is an increase of 4% over the 2016 total. Seventeen companies reported no *Aggregate Expenses* in 2017.

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	16	8.7%	\$42,577,064	65.0%
\$500,001 - \$1,000,000	15	8.2%	\$11,089,338	16.9%
\$250,001 - \$500,000	13	7.1%	\$4,555,543	7.0%
\$100,001 - \$250,000	29	15.8%	\$4,537,031	6.9%
\$25,001 - \$100,000	45	24.6%	\$2,299,811	3.5%
\$1 - \$25,000	48	26.2%	\$468,088	0.7%
No Reported Costs	17	9.3%	-	-
Total	183	100.0%	\$65,526,876	100.0%

Table 4: Distribution of Aggregate Expenses in DC, 2017

The following are examples of position titles for aggregate personnel:

- Sales Representative/Specialist
- Territory Manager
- Regional Sales Director

- Medical Science Liaison
- Account Manager
- District Manager

II. Gift Expenses Analysis

In 2017, pharmaceutical and device manufacturers reported spending a total of \$26.1 million for gifts in the District of Columbia. We separate *Gifts Expenses* into two primary categories for analysis: *Individual Recipients* and *Non-Individual Recipients*.

Individual Recipients are persons who received gifts or payments including cash, food, or in-kind items. Examples include health care providers and medical and administrative staff. In 2017, this group received more than 50,000 gifts, totaling \$16.6 million. *Physicians* accepted approximately 54% of all *Gift Expenses* and 86% of gifts to *Individual Recipients*, with a total of \$14.2 million. Consistent with previous years, *Physicians* have the highest number of accepted gifts, highest value for an individual payment, and the lowest median value among all *Individuals Recipients* and among all *Gift Expenses* overall. More details for *Individual Recipients* are in section IIa of this report.

Non-Individual Recipients include entities such as teaching hospitals, clinics, and health organizations. This group received \$9.5 million from a total of 863 gifts. More details for *Non-Individual Recipients* are in section IIb of this report.

2017 Gifts to Individual Recipients						
Individual Recipient	Total Value	Frequency	Highest Value	Median Value		
Physicians	\$14,200,257	36,735	\$995,526	\$22		
Physician Assistants	\$81,834	1,022	\$1,950	\$53		
Advanced Practice Nurses	\$432,521	2,220	\$34,250	\$70		
Dentists	\$464,857	1,629	\$16,700	\$23		
Nurses	\$449,514	1,819	\$37,595	\$71		
Pharmacists	\$78,692	647	\$9 <i>,</i> 073	\$90		
Other Healthcare Providers	\$45,341	58	\$10,800	\$110		
Clinical Office Staff and Other Individual Recipients	\$857,347	6,222	\$5,130	\$48		
Total	\$16,610,363	50,352				
2017 Gifts to Non-I	ndividual Reci	pients				
Non-Individual Recipient	Total Value	Frequency	Highest Value	Median		
Teaching Hospital			• chic	Value		
	\$4,443,138	488	\$408,250	\$2,500		
Professional Organizations	\$4,443,138 \$1,595,082	488 69				
			\$408,250	\$2,500		
Professional Organizations	\$1,595,082	69	\$408,250 \$259,590	\$2,500 \$7,500		
Professional Organizations Advocacy Organizations	\$1,595,082 \$1,061,693	69 45	\$408,250 \$259,590 \$116,000	\$2,500 \$7,500 \$15,000		
Professional Organizations Advocacy Organizations Universities	\$1,595,082 \$1,061,693 \$856,919	69 45 58	\$408,250 \$259,590 \$116,000 \$224,317	\$2,500 \$7,500 \$15,000 \$2,500		
Professional Organizations Advocacy Organizations Universities Clinical Organizations	\$1,595,082 \$1,061,693 \$856,919 \$684,428	69 45 58 37	\$408,250 \$259,590 \$116,000 \$224,317 \$175,000	\$2,500 \$7,500 \$15,000 \$2,500 \$2,500		
Professional Organizations Advocacy Organizations Universities Clinical Organizations Continuing Medical Education Organizations	\$1,595,082 \$1,061,693 \$856,919 \$684,428 \$492,155	69 45 58 37 89	\$408,250 \$259,590 \$116,000 \$224,317 \$175,000 \$280,000	\$2,500 \$7,500 \$15,000 \$2,500 \$2,500 \$139		

Table 5: Distribution of Gift Expenses by Type of Recipient, 2017

IIa. Payments to Individual Recipients

This section presents more detailed data on gift payments to *Individual Recipients*, including *Physicians, Advanced Practice Nurses, Physician Assistants, Dentists, Nurses, Pharmacists, Other Healthcare Providers, and Clinical Office Staff and Other Individual Recipients*. Total gifts received by *Individual Recipients* in 2017 were \$16.6 million.

The Centers of Medicare and Medicaid's Open Payments program requires the reporting of payments to physicians. The AccessRx program supplements Open Payments by requiring companies to report payments to other healthcare providers. Under certain circumstances, payments to physicians also do not have to be reported to Open Payments. For example, reporting to Open Payments is not required if the physician is a resident at the time of gift receipt, or the payment was made by a manufacturer with only one approved product during the 180-day grace period following FDA approval of that product. These exceptions do not apply to AccessRx, so these payments are reported to AccessRx.

Starting on the next page, we present results for each category of *Individual Recipients*.

Physicians (Open Payments and AccessRx Data)

Physicians in the District of Columbia received a total of \$14.2 million in gifts in 2017, which was 86% of the total amount of gifts reported across all *Individual Recipients*. Of this total, \$13,990,334 was reported to Open Payments and \$209,923 was reported to AccessRx.

Companies reported payments to 3,159 different *Physicians* practicing in the District of Columbia in 2017. This total is about 9% lower than the number of *Physicians* who received gifts in 2016. According to the American Association of American Medical Colleges' 2017 State Physician Workforce Data Report, there are 5,901 active *Physicians* in the District.¹ These figures indicate that more than half of District *Physicians* received at least one gift in 2017.

Table 6 shows the distribution of gifts to *Physicians* according to the total value received in 2017. Over half (52%) of the total gift value went to just 1% of *Physicians* who received gifts.

Total Reported Value	Number of Physicians	Percent of Total Number	Total Value	Percent of Total Value
More than \$250,000	5	0.2%	\$2,622,682	18.5%
\$100,001 - \$250,000	29	0.9%	\$4,725,964	33.3%
\$50,001 - \$100,000	38	1.2%	\$2,633,487	18.5%
\$25,001 - \$50,000	43	1.4%	\$1,596,202	11.2%
\$10,001 - \$25,000	73	2.3%	\$1,176,816	8.3%
\$1,001 - \$10,000	333	10.5%	\$1,024,147	7.2%
\$251 - \$1,000	502	15.9%	\$256,101	1.8%
\$1 - \$250	2,136	67.6%	\$164,857	1.2%
Total	3,159	100.0%	\$14,200,257	100.0%

Table 6: Distribution of Gifts to Physicians in DC, 2017

Consistent with past years, *Speaking* remains the category with the highest proportion of gift values, with \$5.8 million or 41% of the total gift value. The subset category, "services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program" accounted for approximately 90% of speaking fees.

Consulting is the second largest category representing gift value, with \$4.3 million or 30% of the total value. *Other* and *Travel and Lodging* both accounted for 11% of the total value, with values of \$1.6 million and \$1.5 million, respectively. *Food and Beverage* was the smallest share of the total gift value at \$962,914 (7%), but represented three quarters of the total frequency (number) of gifts. The frequencies for the remaining categories were: *Travel and Lodging* (12%), *Speaking* (6%), *Consulting* (4%), and *Other* (3%).

¹ 2017 State Physician Workforce Data Report.

https://www.aamc.org/download/484526/data/districtofcolumbiaprofile.pdf.

Figure 3: Gifts to Physicians By Nature of Payment



*Speaking consists of gifts reported as honoraria; compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program; and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

**Other consists of gifts reported as education, charitable contribution, ownership or investment interest, entertainment, gift, grant, and royalty of license.

Top 25 Physicians

Open Payments provides publicly available data at <u>https://openpaymentsdata.cms.gov</u>, which allows the reporting of the names of *Physicians* who received payments. Table 7 shows the 25 *Physicians* in the District of Columbia with the highest gift values, summing to \$6.3 million. Seven of these physicians were not among the top 25 *Physicians* in 2016.

2017 is the first year in which Open Payments reported a physician receiving over \$1 million in payments in DC. Dr. Kavita Patel moved up from #2 in 2016 to #1 in 2017, with total earnings of \$1,106,421 from 47 separate payments. Her highest accepted payment was a stock payment from Tesaro valued at \$995,526. Dr. Patel's accepted total value is more than twice as much as the value accepted by Dr. Jesse Goodman (\$534,265), who is ranked #2 among *Physicians*.

Ranking in 2016	Physician Name	Specialty	Affiliation	Payments in DC	Number of Payments
1 (2)	Kavita K. Patel, MD	Internal Medicine	Sibley Primary Care	\$1,106,421	47
2 (1)	Jesse Goodman, MD	Infectious Disease	MedStar Georgetown University Hospital	\$534,265	21
3*	James A. D'orta	Emergency Medicine	MedStar Georgetown University Hospital	\$383,993	9
4 (15)	Fahd S. Amjad, MD	Neurology	MedStar Georgetown University Hospital	\$321,942	477
5 (7)	Robert K. Shin, MD	Neurology	MedStar Georgetown University Hospital	\$276,062	265
6 (11)	Warren Yu, MD	Orthpaedic Surgery	The GW Medical Faculty Associates	\$246,187	130
7 (3)	Maurice Nahabedian, MD	Reconstructive Surgery	MedStar Georgetown University Hospital	\$243,760	311
8 (12)	Joseph R. O'Brien, MD, MPH	Orthopaedic Surgery	The Orthopaedic Center Care Center	\$235,240	110
9 (16)	Paul J. Kim, DPM	Podiatry	MedStar Georgetown University Hospital	\$228,165	295
10 (9)	James A. Simon, MD	Gynecology	Sibley Memorial Hospital	\$219,760	284
11 (17)	Paul S. Cooper, MD	Orthpaedic Surgery	MedStar Georgetown University Hospital	\$217,861	83
12 (13)	Laxman Bahroo, DO	Neurology	MedStar Georgetown University Hospital	\$217,223	394
13 (5)	Ron Waksman, MD	Interventional Cardiology	MedStar Washington Hospital Center	\$204,195	81
14 (20)	Richard A. Elion, MD	Family Medicine	Whitmen-Walker Health	\$189,148	222
15 (19)	Autumn Burnette, MD	Allergy & Immunology	Howard University Hospital	\$185,960	314
16 (8)	Imadeddine Tabbara, MD	Hematology & Oncology	The George Washington University Hospital	\$182,501	147
17 (18)	Andrea J. Singer, MD	Internal Medicine	MedStar Georgetown University Hospital	\$174,028	212
18*	Andrew Shorr, MD, MPH	Pulmonary	MedStar Washington Hospital Center	\$167,857	98
19*	Fernando L. Pagan, MD	Neurology	MedStar Georgetown University Hospital	\$162,175	239
20 (10)	John Marshall, MD	Hematology & Oncology	MedStar Georgetown University Hospital	\$157,130	141
21*	Natasa Janicic-Kahric, MD	Endocrinology	MedStar Georgetown University Hospital	\$155,138	297
22 (24)	Scott I. Kahan, MD, MPH	Preventive Medicine	National Center for Weight and Wellness	\$143,175	142
23*	Douglas Vannostrand, MD	Radiology	MedStar Washington Hospital Center	\$138,511	94
24*	Guillermo Gutierrez, MD, PhD	Internal Medicine	The George Washington University Hospital	\$128,583	176
25*	Aline C. Pishvaian, MD	Gastroenterology	MedStar Georgetown University Hospital	\$127,938	118

Table 7: Top 25 Physician Gift Recipients in Washington, DC

* Did not appear in list of "Top 25 Physician Gift Recipients" in 2016

Advanced Practice Nurses (AccessRx Data)

Advanced Practice Nurses (APNs) include nurse practitioners, nurse-midwives, and nurse anesthetists; all have independent prescribing authority in the District of Columbia. In 2017, APNs received a total of \$432,521 in gifts, a 28% increase from 2016 (\$339,254).

Speaking and *Food and Beverage* were the two categories with the highest gift values for *APNs*, accounting for \$127,357 (30%) and \$120,882 (28%) of the total, respectively. Gifts categorized under *Other* were 17% of the total gift value, and *Travel and Lodging* made up 15% of the total. The category with the lowest value is *Consulting*, at 10% of the total gift value.

Food and Beverage accounted for the highest gift frequency for *APNs*, adding up to 1,809 gifts (81%) out of the total 2,220 reported gifts. The remaining categories were each less than 10% of the total frequency of gifts received by *APNs*: *Travel and Lodging* (8%), *Speaking* (5%), *Other* (4%), and *Consulting* (2%).



Figure 4: Gifts to Advanced Practice Nurses By Nature of Payment

*Speaking consists of gifts reported as honoraria; compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program; and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

**Other consists of gifts reported as education and charitable contribution.

Physician Assistants (AccessRx Data)

Physician Assistants (PAs) are independent prescribers and received a total of \$81,834 in 2017. This total value is about 30% lower than the total in 2016 (\$116,293).

Most gifts to *PAs* were *Food and Beverage*, which totaled \$61,475 (75%). *Consulting* is the second largest share at 10% of the total gift value. Gifts for *Travel and Lodging* and *Speaking* were each 7% of the gift value, and *Other* gifts made up the remaining 1% of the gift value.

Food and Beverage gifts also accounted for the highest frequency of gifts to *PAs*, adding up to 94% of the total number of gifts accepted by *PAs*. The other four categories each made up of 2% or less of the total gift frequency: *Travel and Lodging* (2%), *Other* (2%), *Speaking* (1%), and *Consulting* (1%).



Figure 5: Gifts to Physician Assistants By Nature of Payment

*Speaking consists of gifts reported as, honoraria; compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program.

**Other consists of gifts reported as education and other.

Dentists (Open Payments and AccessRx Data)

In 2017, there were 1,629 unique gift payments to *Dentists*. The total value of gifts reported to *Dentists* through Open Payments was \$457,186 and another \$7,671 was reported to AccessRx, for a grand total of \$464,857. The total value of gifts to *Dentists* in 2017 was triple the total amount reported in 2016 (\$153,578).

Top 10 Dentists

Table 8 presents the top 10 *Dentists* who accepted the highest total value of gifts in 2017, provided by Open Payments. This is the first year that we are reporting the top 10 *Dentists*, particularly because the two highest ranked *Dentists*, Wayne Hickory (DMD) and Brian Gray (DDS), account for nearly three quarters (\$343,603 or 74%) of the total value accepted by *Dentists* in the District and are more in line with payments received by the top 25 *Physicians* (see page 10).

Ranking in 2017	Dentist Name	Specialty	Affiliation	Payments in DC	Number of Payments
1	Wayne Hickory, DMD	Orthodontics	Embassy Row Orthodontics	\$205,169	33
2	Brian Gray, DDS	General Practice	Giannini & Gray Dental Partners	\$138,434	84
3	Steven Guttenberg, DDS, MD	Oral & Maxillofacial Surgery	The Washington Institute for Mouth, Face, and Jaw Surgery	\$15,543	7
4	Hamid Shafie, DDS	Prosthodontics	MedStar Washington Hospital Center	\$10,764	15
5	Raha Yousefi, DDS	Periodontics	District Perio	\$3,301	15
6	Thomas Sokoly, DDS	General Practice	Sokoly Dental	\$3,012	2
7	Thanos Kristallis, DDS	Prosthodontics	Washington Metro Center Dental	\$2,893	13
8	Faisal Mir, DDS	General Practice	Smile Dental	\$2,798	21
9	Scott Hetz, DMD	Endodontics	Advanced Endodontic Associates	\$2,791	13
10	Paula Russo, DDS	Endodontics	Paula Russo, DDS	\$2,730	5

Table 8: Top 10 Dentists Gift Recipients in Washington, DC

Consulting was the category with the highest portion of the total gift values for *Dentists*, with a total of \$191,016 (41%). *Speaking* is the next highest category with a value of \$146,600 (32%). *Travel and Lodging* totaled \$54,948 (12%). *Other* gifts accounted for \$30,377 (6%), which includes numerous small in-kind donations such as sterile gloves and presents such as gift cards. Companies categorized these particular items as "gifts" – which was unique to *Dentists* in the 2017 *Individual Recipients* data.

Food and Beverage represented more than half (51%) of the total number of gifts given to *Dentists. Other* gifts accounted for 38% of the total number, followed by *Travel and Lodging* (8%), *Speaking* (2%), and *Consulting* (1%).



Figure 6: Gifts to Dentists By Nature of Payment

*Speaking consists of gifts reported as, honoraria; compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program; and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

**Other consists of gifts reported as gifts, education, donation, and entertainment.

Nurses (AccessRx Data)

In 2017, companies reported making 1,819 gifts to *Nurses* valued at a total of \$449,514, which is approximately three times as much as the total value reported in 2016 (\$151,383).

Consulting gifts made up the largest proportion of the total gift value, at \$284,648 (63%). *Food and Beverage* gifts were the next largest category at \$99,499 (22%), followed by *Speaking* at \$49,271 (11%). *Travel and Lodging* made up of 3% of the total value of gifts to *Nurses* with \$12,837, and *Other* made up of 1% total with \$3,258.

Food and Beverage represented 81% of the total number of gifts, followed by *Speaking* (6%), *Consulting* (5%), *Travel and Lodging* (5%), and *Other* (3%).



Figure 7: Gifts to Nurses By Nature of Payment

*Speaking consists of gifts reported as compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program; and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program.

**Other consists of gifts reported as education, grant, and other.

Pharmacists (AccessRx Data)

Pharmacists received a total of \$78,692 in gifts in 2017. Pharmaceutical companies reported 647 unique gifts to *Pharmacists*. This was a 57% increase in gift value compared to 2016.

Food and Beverage gifts accounted for most gifts, both in terms of total value and frequency. *Pharmacists* received 545 *Food and Beverage* gifts totaling \$47,598 (60% of the total). The next highest category is *Travel and Lodging*, which represented \$13,114 (17%). *Consulting* gifts totaled \$7,625 (10%), *Speaking* gifts totaled \$6,213 (8%), and *Other* gifts totaled \$4,142 (5%).

In terms of frequency, more than 8 in 10 reported gifts to *Pharmacists* (84%) were *Food and Beverage*. *Other* gifts were 10% of the total number of gifts, followed by *Travel and Lodging* (3%), *Speaking* (2%), and *Consulting* (1%).



Figure 8: Gifts to Pharmacists By Nature of Payment

*Speaking consists of gifts reported as compensation for services other than consulting, including serving as a faculty or as a speaker at a venue other than a continuing education program.

**Other consists of gifts reported as education and other.

Other Healthcare Providers (AccessRx Data)

Other Healthcare Providers include healthcare professionals not previously discussed under specific categories. These healthcare providers include, but are not limited to, social workers, psychologists, and speech-language pathologists. In 2017, 58 gifts were reported to *Other Healthcare Providers*, totaling \$45,341. This is a decrease of less than \$4,000 from 2016.

Consulting gifts made up the majority of the total gift value at \$30,600 (67%), but this amount was comprised of only 4 unique gifts. *Speaking* gifts totaled \$7,650 (17%). *Travel and Lodging* and *Food and Beverage* both made up 8% of the total gift value, with totals of \$3,618 and \$3,473, respectively.

In terms of total numbers, *Food and Beverage* made up a majority of the gifts at 69% of the total. *Travel and Lodging* represented 19% of the total, followed by *Consulting* at 7% of the total. *Speaking* had the least number of gifts, accounting for 5% of total gifts.



Figure 9: Gifts to Other Healthcare Providers By Nature of Payment

*Speaking consists of gifts reported as honoraria.

Clinical Office Staff and Other Individual Recipients (AccessRx Data)

Clinical Office Staff and Other Individual Recipients include medical and administrative staff and persons who do not fall into any of the other subcategories discussed. These individuals received 6,222 gifts totaling \$857,347 in 2017. From 2016 to 2017, the total reported value of gifts to these recipients increased by 50%.

Food and Beverage accounted for the largest proportion of the value, accounting for \$424,029 (49%) of the total. *Other* gifts represented \$372,765 (44%) of the total value. The remaining categories include *Consulting* (4%), *Travel and Lodging* (2%), and *Speaking* (1%).

Food and Beverage also accounted for the largest share of total gift frequency, representing 94% of the total. *Other* gifts were 5% of the total number of gifts, *Travel and Lodging* accounted for 1% of the total volume, and *Consulting and Speaking* accounted for less than 1%.





*Speaking consists of gifts reported as honoraria and compensation for services other than consulting, including serving as faculty or as a guest speaker at a venue other than a continuing education program.

** Other consists of gifts reported as education, grant, and other.

IIb. Payments to Non-Individual Recipients

Companies report payments to *Teaching Hospitals* through Open Payments. The AccessRx program collects information on gifts to various additional organizations, such as *Professional Organizations, Advocacy Organizations, Clinical Organizations, Continuing Medical Education Organizations,* and *Other Non-Individual Recipients*. These *Non-Individual Recipients* received a total of \$9.5 million in 2017.

As with *Physicians*, if a company did not report a payment to a *Teaching Hospital* through Open Payments due to a special circumstance, the payment is supposed to be reported to AccessRx.

Starting on the next page, we present results for each type of *Non-Individual Recipient*.

Teaching Hospitals (Open Payments and AccessRx Data)

The 2017 Open Payments List of Teaching Hospitals includes nine DC teaching hospitals:

- 1. Children's Hospital
- 2. George Washington University
- 3. Howard University Hospital
- 4. Georgetown University Hospital
- 5. Sibley Memorial Hospital

- 6. Providence Hospital
- 7. Washington Hospital Center
- 8. National Rehabilitation Hospital
- 9. St. Elizabeth's Hospital

Pharmaceutical companies did not report gift payments to National Rehabilitation Hospital and St. Elizabeth's Hospital in 2017. The other seven *Teaching Hospitals* received 488 gifts totaling \$4.4 million, with \$3,834,905 reported to Open Payments and \$608,233 reported to AccessRx. Compared to 2016, *Teaching Hospitals* received approximately 17% less in gifts in 2017.

Washington Hospital Center received more than half (53%) of the total value, with \$2.4 million from 116 gifts. Georgetown University Hospital received the second largest value and the highest amount of gifts, with \$1.5 million from 187 gifts. George Washington University received \$195,210, Children's Hospital received \$186,031, and Howard University Hospital received \$145,440. Gifts to Providence Hospital and Sibley Memorial Hospital make up less than 1% of the total value, with \$25,968 and \$1,102, respectively.

Teaching Hospital	Total Value	Frequency	Median Gift Value
Washington Hospital Center	\$2,360,831	116	\$5,000
Georgetown University Hospital	\$1,528,556	187	\$3,000
George Washington University Hospital	\$195,210	87	\$1,000
Children's Hospital	\$186,031	44	\$347
Howard University Hospital	\$145,440	42	\$1,937
Providence Hospital	\$25 <i>,</i> 968	10	\$2,250
Sibley Memorial Hospital	\$1,102	2	\$551
Total	\$4,443,138	488	-

Table 9: Gifts to Teaching Hospitals in Washington, DC

A majority of *Teaching Hospital* gifts were received in the form of *Grant* (\$1.9 million or 43%). This was followed by *Space Rental* (\$1.2 million or 28%) and *Education* (\$809,193 or 18%). The remaining categories comprise much smaller proportions of the total value, these include *Gift* (\$173,151 or 4%), *Other* (164,664 or 4%), and *Speaking* (\$152,344 or 3%).

In terms of the frequency of gifts, *Space Rental* is the most common type of payment (33%). *Grant* is the next largest category at 25% of the total, followed by *Speaking* (14%), *Education* (13%), *Gift* (10%), and *Other* (5%).



Figure 11: Gifts to Teaching Hospitals By Nature of Payment

*Speaking consists of gifts reported as honoraria and compensation for services other than consulting, including serving as faculty or as a guest speaker at a venue other than a continuing education program, compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.

**Other consists of gifts reported as charitable contribution, food and beverage, consulting, travel and lodging, and royalty or license.

Professional Organizations (AccessRx Data)

Professional Organizations include healthcare provider professional organizations, medical specialty organizations, national organizations, and local chapters.

In 2017, 69 gifts to *Professional Organizations* totaled \$1.6 million, about 26% less than the total reported in 2016 (\$2.1 million). Half of the total value of gifts were in the form of *Grants* (\$790,197 or 49%). *Other* gifts represented \$236,900 or 15% of the total value, followed by *Education* at \$221,500 or 14% of the total. *Charitable Contribution* were \$164,500 or 10% of the total value. *Space Rental* and *Sponsorship* each accounted for 6% of the total, with values of \$93,615 and \$88,370, respectively. Reporting for *Sponsorship* began in 2016; there was a 26% increase in spending in this category in 2017 compared to 2016 value (\$70,100).



Figure 12: Gifts to Professional Organizations By Nature of Payment

*Other consists of gifts reported as compensation for services other than consulting and other.

Advocacy Organizations (AccessRx Data)

Advocacy Organizations include disease-specific advocacy organizations, community based organizations, and research organizations.

In 2017, *Advocacy Organizations* received \$1.1 million from a total of 45 gift payments, about 12% higher than the total in 2016. Approximately one-third (34%) of the total gift value to *Advocacy Organizations* fell into the category *Other*, making it the category with the highest total gift value for the second consecutive year.

Education represented \$276,167 (26%) of the total gift value, followed by *Sponsorship* with \$230,000 (22%), and *Charitable Contribution* with \$182,500 (17%). *Space Rental* was \$9,910 (1%) and *Grants* accounted for \$2,641 (less than 1%).

The proportions in terms of number of payments are relatively similarly to those for value, with the exception of *Grants*. While *Grants* were less than 1% of the total value of gifts to *Advocacy Organizations* in 2017, they accounted for 18% of the total frequency.



Figure 13: Gifts to Advocacy Organizations By Nature of Payment

*Other consists of gifts reported as compensation for services other than consulting and other.

Universities (AccessRx Data)

Universities accepted 58 gift payments totaling \$856,919 in 2017. From 2016 to 2017, total gift value increased by approximately 11%, but the number of payments decreased by 42%.

Grant accounted for the largest proportion of the total gift value and total gift frequency to *Universities*, with companies reporting 27 gifts totaling \$723,419. *Charitable Contribution* is the second-highest category at \$57,500 (7%), but accounts for the lowest gift frequency (9%). *Space Rental* and *Other* each accounted for \$38,000 (4%) of the total gift value but 28% and 17% of the total gift frequency, respectively.



Figure 14: Gifts to Universities By Nature of Payment

*Other consists of gifts reported as other, travel and lodging, and consulting fees.

Clinical Organizations (AccessRx Data)

Clinical Organizations include establishments that provide medical treatment, such as non-teaching hospitals, clinics, and private practices.

In 2017, gifts to *Clinical Organizations* totaled \$684,428, which is approximately \$7,000 less than the value reported in 2016. Most gifts were in the form of *Grants*, which accounted for \$583,578 (85%) of the total gift value. *Space Rental* accounted for \$85,498 (13%) of the total, *Other* accounted for \$13,900 (2%) of the total, and *Food and Beverage* accounted for \$1,452 (less than 1%).



Figure 15: Gifts to Clinical Organizations Nature of Payment

*Other consists of gifts reported as other, education, and charitable contributions.

Continuing Medical Education Organizations (AccessRx Data)

Continuing Medical Education Organizations received a total of \$492,155 in 89 gift payments in 2017. This value is approximately 3.5 times greater than the total value reported for these organizations in 2016 (\$142,774).

Education accounted for the largest proportion of the total gift value (\$466,720 or 95%) but the smallest proportion of frequency (5%). *Grant* represented \$12,809 or 3% of the total, followed by *Space Rental*, which accounted for \$12,625 or 2% of the total.

By number of gifts, *Grant* were the majority of the total number of gifts (88%). *Space Rental* and *Education* accounted for 7% and 5% of the total frequency of gifts, respectively.



Figure 16: Gifts to Continuing Medical Education Organizations Nature of Payment

Education

5%

Other Non-Individual Recipients (AccessRx Data)

In 2017, *Other Non-Individual Recipients* received 77 gifts, totaling \$374,546, a little more than six times greater than \$60,258, the value reported in 2016. *Grants* accounted for the majority (81%) of the gift value with a total of \$303,109, followed by *Other* with \$61,992 or 17% of the total value. *Space Rental* and *Consulting Fees* both represented 1% of the total value with \$5,500 and \$3,945, respectively. Out of the 77 gifts to *Other Non-Individual Recipients*, 62 (81%) of the gifts were accepted by "Meeting Event Planners", but only totaled \$16,992.



III. Advertising Expenses Analysis

Pharmaceutical companies are required to report their *Advertising Expenses* specific to the District of Columbia. However, reporting instructions do not clarify how companies should calculate the expenses. It is unknown whether companies reported the actual cost of advertising in DC or calculated a percentage based on national advertising spending.

Activity Type

Of the 183 companies that reported marketing expenditures to AccessRx in 2017, 84 reported *Advertising Expenses* totaling \$11.6 million. Companies reported expenses based on *Activity Type* with the majority of expenses classified into five categories: *Direct-to-Consumer Advertising, Other Advertising Production and Placement, Other Promotional Activity, Market Research,* and *Other*.

As shown in Figure 18, *Direct-to-Consumer Advertising* was the category with the highest value, representing 73% of all advertising in 2017. *Other Advertising Production and Placement* accounted for 19% of the total value or \$2.3 million, an increase of more than six times the amount reported in 2016 (\$364,962). The remaining categories, *Other Promotional Activity, Market Research* and *Other*, made up less than 10% of the total.



Figure 18: Advertising Expenses by Activity Type

Total Value

Media Type

Advertising Expenses were classified into nine media type categories: Television, Internet, Patient and Other Printed Materials, Newspaper and Magazine, Conference and Other Event, Radio, Medical Journal, Direct Mail, and Other.

Nearly half (49%) of the payments for *Advertising Expenses* fell under *Television*, which accounted for \$5.7 million. *Newspaper and Magazine*, *Internet*, and *Patient and Other Printed Materials*, each accounted for 12% or approximately \$1.4 million of the total *Advertising Expenses*. *Other* gifts accounted for 7% of the total value (\$758,353) and *Conference and Other Event* payments represented 4% of the total value (\$509,576). The *Medical Journal* category accounted for \$64,138 or 1% of the total value and *Direct Mail* accounted for \$37,287 or less than 1% of the total value.



Figure 19: Advertising Expenses by Media Type

IV. Recommendations for AccessRx

Based on the analysis on the 2017 data, we ask the Health Regulation and Licensing Administration to consider the following recommended changes to AccessRx policies and practices. The goals of these recommendations are to reinforce the original objectives of the AccessRx program and to make AccessRx data more consistent with federal Open Payments data.

1. Improve data reporting instructions to improve the quality of data collected by AccessRx from pharmaceutical companies.

Pharmaceutical companies are given detailed reporting instructions and a list of Frequently Asked Questions (FAQs) when filing marketing expenditures reports. Yet, each year we encounter gaps and inconsistencies in reporting, which lead to limitations in data analyses. Some common errors include: reporting gifts that were reported to Open Payments, reporting gifts to medical/office staff as gifts to individual physicians, including the physician share in the total value allocated to the physician's office, reporting categories inconsistently, etc.

Reporting instructions should improve to ensure that we are capturing accurate and reliable data. As recommended in previous years, transitioning AccessRx to an online platform would facilitate data collection, cleaning, and analysis processes. The online system would limit and standardize responses. Furthermore, it will make it easier for companies to deliver complete and comprehensive reports, reducing errors and lessening the need for the AccessRx team to contact companies.

2. Improve compliance and communication among pharmaceutical companies.

If errors or inconsistencies are encountered during the data collection and cleaning process, we must contact the company to gain clarification and resolve issues. The AccessRx Act requires companies to provide contact information for a single individual who is considered responsible for the submission and must be a member of senior management or other high-level official within the pharmaceutical company. We run into a number of issues when contacting companies such as late responses or non-responsiveness, incorrect point of contact, and multiple referrals within the company or to external consultants. Delays in obtaining correct information may result in delays in data analysis. Communication protocols or standards should be put in place to ensure that accurate and complete data are collected and analyzed in an efficient manner.

3. Make reports submitted to the AccessRx Act publicly available, consistent with the Open Payments System.

Open Payments provides publicly-available data on gifts to physicians and teaching hospitals. AccessRx data is confidential and only the reports produced using the data are available to the public. Only the District of Columbia Department of Health and the individuals analyzing the data have access to the information, as required by the AccessRx Act of 2004. Making AccessRx data public would allow patients to make better informed decisions and understand the marketing efforts that affect their healthcare providers, clinics, and organizations.

4. Require "product marketed" information for gift expenses reported to AccessRx, consistent with Open Payments requirement.

Open Payments requires pharmaceutical companies to report the marketed name of the drug, device, biological, or medical supply that is associated with the payment listed. This information is beneficial because it allows patients, policymakers, researchers, and the general public to gain insight into how much pharmaceutical companies are spending on marketing for specific drugs or products within the District of Columbia and across the United States. AccessRx currently does not require this level of detail for the information it collects. By requiring companies to report the marketed product or products associated with payments to AccessRx, the District of Columbia Department of Health can provide DC residents, policymakers, and other stakeholders noted above with more information about the relationships between pharmaceutical companies and healthcare providers.

5. Require device manufacturers to report to AccessRx, consistent with Open Payments requirements.

Open Payments, but not AccessRx, requires reporting by device manufacturers. AccessRx requires reporting by any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District" and a total of 183 companies submitted to AccessRx in 2017. Comparatively, Open Payments requires the reporting by "manufacturers of drugs, devices, biologicals, or medical supplies" and a total of 542 companies reported to Open Payments in 2017. Data collected on devices will allow for a greater understanding of marketing expenditures trends in DC. Moreover, this implementation would enable AccessRx to be more consistent with Open Payments, which strengthens the conclusions gathered by both systems.

Appendix A: AccessRx Requirements

Title III of the AccessRx Act of 2004² requires that any "manufacturer or labeler of prescription drugs dispensed in the District that employs, directs, or utilizes marketing representatives in the District" annually report marketing costs for prescription drugs in the District. §48-833.03 describes the content of the annual report:

(a) Except as provided in subsection (b) of this section, the annual report filed pursuant to §48-853.02 shall include the following information as it pertains to marketing activities conducted within the District in a form that provides the value, nature, purpose, and recipient of the expense:

(1) 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;

(2) 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; and

(3) The aggregate cost of all employees or contractors of the manufacturer or labeler who directly or indirectly engage in the advertising or promotional activities listed in paragraphs (1) and (2) of this subsection, including all forms of payment to those employees. The cost reported under this paragraph shall reflect only that portion of payment to employees or contractors that pertains to activities within the District or to

² District of Columbia Official Code. AccessRx Act of 2004.

http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/AccessRx-Act-of-2004.pdf.

recipients of the advertising or promotional activities who are residents of or are employed in the District.

(b) The following marketing expenses are not subject to the requirements of this subchapter:

(1) Expenses of \$25 or less;

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

(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.

The manufacturer or labeler must file the report by July 1st of each year, in the form and manner provided by the Department of Health. §48-833.04 describes the report that the Department must then provide to the City Council:

By November 30th of each year, the Department shall provide an annual report, providing information in aggregate form, on prescription drug marketing expenses to the Council and the Corporation Counsel. By January 1, 2005, and every 2 years thereafter, the Department shall provide a report to the Council and the Corporation Counsel, 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 the cost, utilization, and delivery of health care services, and any recommendations with regard to marketing activities of prescription drug manufacturers and labelers.

§48-833.04 addresses confidentiality:

Notwithstanding any provision of law to the contrary, information submitted to the Department pursuant to this subchapter is confidential and is not a public record. Data compiled in aggregate form by the Department for the purposes of reporting required by this subchapter is a public record as long as it does not reveal trade information that is protected by District, state, or federal law.

Chapter 18 of Title 22 of the District of Columbia Municipal Regulation specifies which information must be included in annual reports in each of the three categories (advertising expenses, marketing expenses, aggregate costs).

Appendix B: Open Payments Requirements

The Patient Protection and Affordable Care Act of 2010 established the Open Payments system through the Centers for Medicare and Medicaid Services. The regulation was promulgated on February 8, 2013, requiring data collection beginning on August 1, 2013. 42 CFR Parts 402 and 403 requires³ "applicable manufacturers of drugs, devices, biologicals, or medical supplies covered by Medicare Medicaid or the Children's Health Insurance Program (CHIP) to report annually to the Secretary [of the Department of Health and Human Services] certain payments or transfers of value provided to physicians or teaching hospitals..."

(a) General rule:

(1) Direct and indirect payments or other transfers of value provided by a manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the applicable manufacturer to CMS on an annual basis.

(b) Covered Products:

(1) Any drug, device, biological, or medical supply that is eligible for payment by Medicare, Medicaid, or CHIP either individually or as a part of a bundled payment (such as the inpatient prospective payment system), and requires a prescription to be dispensed (for drugs and biologicals) or requires premarket approval by, or premarket notification to, the U.S. Food and Drug Administration (for devices, including medical supplies that are devices).

(c) Recipients for whom gifts must be reported:

(1) Physicians, which include those with credentials of Doctor of Medicine, Doctor of Osteopathy, Doctor of Dentistry, Doctor of Dental Surgery, Doctor of Podiatry, Doctor of Optometry, or Doctor of Chiropractic Medicine.

(2) Teaching Hospitals that received payment for Medicare direct graduate medical education (GME), inpatient hospital prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospitals IME programs during the last calendar year.

(c) Limitations. Certain limitations on reporting apply in the following circumstances:

(1) \$10, indexed to inflation, provided total payments to a recipient less than \$100 a year.

(2) Applicable manufacturers that had less than 10 percent gross revenue during the fiscal year preceding the reporting year from covered products are only required to report payments or other transfers of value related to covered products, not all products.

(3) Drug samples intended exclusively for distribution to patients are excluded from the reporting requirements (see rule for more)

³Federal Register. 42 CFR Parts 402 and 403. https://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf.