

Pharmaceutical Marketing Expenditures in the District of Columbia, 2014



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

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This report was submitted to the District of Columbia Department of Health on January 29, 2016.

I. Executive Summary

Overview

This report discusses 2014 pharmaceutical marketing expenditures in the District of Columbia reported to the District of Columbia Department of Health (DOH), as required by the AccessRx Act of 2004. The report is supplemented with data reported to the federal government through the Centers for Medicare and Medicaid Services (CMS) Open Payments system, which collects information on gifts from pharmaceutical and medical device manufacturers to physicians and teaching hospitals.

Pharmaceutical marketing totaled **\$91.2 million** for all gift, advertising, and aggregate employee expenses reported in the District of Columbia in 2014. Expenditures were analyzed from 153 pharmaceutical manufacturers reporting to AccessRx, and 486 pharmaceutical and medical device manufacturers reporting to Open Payments; totaling 516 individual companies. This report discusses pharmaceutical marketing as a whole and then analyzes subgroups – including physicians, nurses, teaching hospitals, and organizations. This report also provides information on the quality of company submissions and recommendations for the reporting and utility of data in future years.

Key Findings

In 2014, pharmaceutical and device manufacturers reported a total of \$91.2 million for gift, advertising, and aggregate expenses in the District of Columbia. *Gift Expenses* accounted for \$22.6 million (24.7% of the total), *Advertising Expenses* for \$7.9 million (8.7%), and *Aggregate Expenses*¹ for \$60.7 million (66.6%).

Between 2013 and 2014:

- Total expenditures decreased by \$10.4 million (10.2%), from \$101.5 million in 2013 to \$91.1 million in 2014.
- *Gift Expenses* decreased by \$8.1 million (26.5 %), from \$30.7 million in 2013 to \$22.6 million in 2014.
- *Advertising Expenses* increased by \$2.2 million (39.3%), from \$5.7 million in 2013 to \$7.9 million in 2014. This represents an increase in advertising to a level not seen since 2009 when *Advertising Expenses* were \$7.2 million.
- *Aggregate Expenses* decreased by \$4.5 million (6.9%), from \$65.2 million in 2013 to \$60.7 million in 2014.

¹ “Aggregate expenses” comprised the amount spent on salaries and other expenses for employees and contractors conducting marketing activities in the District.

Analysis of gifts found that:

- Pharmaceutical companies and device manufacturers reported \$22.6 million in gifts in 2014, including \$7.6 million reported to AccessRx for gifts to organizations, healthcare facilities, and other healthcare providers and \$14.9 million reported to Open Payments as gifts to physicians and teaching hospitals.
- Gifts to Individual Recipients totaled \$11.8 million.
 - *Physicians* received 40,957 gifts totaling \$11.2 million, which represented the greatest frequency (90.1%) and value (94.1%) of gifts to Individual Recipients. Consistent with previous years, the greatest number of gifts (76.9%) to *Physicians* took the form of *Food or Beverage*, but *Speaking and Related Fees* accounted for the most value given (\$5.3 million, or 48.0% of the total value).
 - The 25 physicians receiving the greatest gift values received \$5.3 million, which represents almost half (47.7%) of all gifts to Individual Recipients. Most gifts (79.5%) were in the form of *Monetary Payment* (79.5%). About 85% were payments for *Speaking* (\$3.1 million, or 58.1%) and *Consulting* (\$1.4 million, or 26.7%).
 - *Advanced Practice Nurses* (nurse-practitioners, nurse-midwives, and nurse-anesthetists, all of whom can prescribe drugs) received \$298,809 (2.5% of gift value to Individual Recipients), and *Registered Nurses* received \$108,082 (0.9%). *Physician Assistants* (who can prescribe drugs) received \$73,377 (<1.0%), and *Pharmacists* received \$52,812 (<1.0%). *Other Healthcare Providers* received \$60,920 or <1.0%, and *Other Recipients* received \$100,296 or 0.8%. Gifts to Non-Individual Recipients totaled \$10.7 million.
 - *Professional Organizations* accounted for the greatest value of gifts to Non-Individual Recipients, receiving a total of \$4.4 million (40.9% of gift value).
 - Teaching Hospitals received \$3.8 million (35.4% of gift value), and also received the greatest number of gifts – 628 (45.4% of all gifts) – to Non-Individual Recipients.
 - The Washington Hospital Center received the greatest value in gifts (\$2.6 million), followed by Georgetown University Hospital (\$876,316), Howard University Hospital (\$105,178), George Washington University Hospital (\$81,364), Children’s Hospital (\$80,247), and Sibley Hospital (\$65,340).
 - The remaining Non-Individual Recipients accounted for ten percent or less of the total value. These included *Advocacy Organizations* (\$1.1 million), *Universities* (\$453,562), *Continuing Medical Education Organizations* (\$343,164), *Clinical Organizations* (\$263,550), *Pharmacies* (\$3,789), and *Other Organizations* (\$398,949).

Recommendations

The following recommendations are intended to strengthen the implementation of the original goals of AccessRx, and to make the statute more consistent with the federal Open Payments reporting system. Recommendations are described in more detail on page 33.

1. Improve compliance with instructions.

Gaps and inconsistencies in reporting among pharmaceutical manufacturers are prevalent and lead to limitations in the analyses.

2. Continue to collect AccessRx information, while utilizing Open Payments data to complement analysis of pharmaceutical marketing in the District.

AccessRx provides the District with unique information to explore pharmaceutical marketing practices, including millions in expenses not exposed by the federal Open Payments system. By analyzing AccessRx data and Open Payments together, the DC DOH maintains the most comprehensive understanding on pharmaceutical marketing activity of any jurisdiction in the United States, and enables analysis of gift trends that cannot be performed by any state. Maintaining reporting requirements allows the DC DOH to analyze changing trends, and assess the impact pharmaceutical marketing has on healthcare in the District.

3. Make all reports submitted pursuant to the AccessRx Act publicly available, consistent with the Federal Open Payments system.

Although data in the Open Payments system is publicly available, the information collected in the AccessRx system is not publicly available and can only be analyzed in aggregate. Patients, regulators, and policymakers in the District should have access to specific information about gifts to non-physicians, non-teaching hospitals, organizations, and other entities for which information is not collected by Open Payments. This would also facilitate comparative analyses of the two databases.

4. Require “product marketed” information for gift expenses, consistent with Federal Open Payments requirements.

Unlike Open Payments, the District does not require reports to specify which product is being marketed. Requesting “product marketed” information for gift expenses reported to the AccessRx system would help researchers calculate how much companies spend on marketing specific drugs, and help patients make more informed decisions about their healthcare.

5. Require reporting by device manufacturers, consistent with Federal Open Payments requirements.

Currently, Open Payments, but not AccessRx, requires reporting by medical device manufacturers. AccessRx requirements should be expanded to provide a more complete picture of marketing practices in the District and to remain consistent with the Open Payments system.

II. Introduction

In this report we discuss 2014 pharmaceutical marketing expenditures in the District of Columbia reported to the District of Columbia Department of Health (DOH) and to the Federal government. The District requires pharmaceutical companies to report marketing costs for prescription drugs in the District.² The Centers for Medicare and Medicaid Services established the Open Payments system, required by the Patient Protection and Affordable Care Act of 2010, which collects information on gifts from pharmaceutical and device manufacturers to physicians and teaching hospitals. After Open Payments went into effect in August 2013, the DC DOH instructed companies to report physician and teaching-hospital gifts to Open Payments, and all other gifts to DOH.

This report uses data reported to Open Payments and AccessRx to discuss pharmaceutical marketing expenses as a whole and then analyzes organizations, teaching hospitals, physicians, nurses, and other subgroups. This report also provides information on the quality of company submissions and makes recommendations for the reporting of data in future years.

² Title III of the AccessRx Act of 2004 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 advertising in the District; gifts valued at more than \$25 given to District health professionals; and costs associated with employees or contractors who directly or indirectly engage in advertising and promotional activities in the District.

III. Summary of Pharmaceutical Marketing Expenditures

In 2014, \$91.2 million was spent on pharmaceutical marketing (including gifts, advertising, and aggregate expenses) in the District of Columbia. One hundred fifty-three pharmaceutical manufacturers and labelers reported spending \$76.2 million to the DC DOH. Four hundred eighty-six pharmaceutical and device manufacturers reported spending \$14.9 million on gifts to physicians and teaching hospitals in the District to Open Payments.

Total Expenses

Table 1 shows the total reported amount in each category from 2006 through 2014; Figure 2 shows the percentage spent in each category. The apparent increase in expenditures from 2006 to 2007 is most likely due to improvements in the reporting process rather than an actual increase.³ Expenditures decreased steadily between 2007 and 2011 and then increased substantially in 2012. Expenditures in 2013 and 2014 are affected by the introduction of the federal Open Payments system in August of 2013. An increase in spending was recorded from 2012 to 2013.⁴ A significant drop in gift expenses occurred in 2014, despite the inclusion of gifts from device manufacturers reported to Open Payments.⁵

Table 1
Total Pharmaceutical Marketing Expenditures in DC by Type of Expenditures in Dollars

Reporting Year	Gift Expenses	Advertising Expenses	Aggregate Expenses	Grand Total
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

³ *** The 2006 data may be unreliable as a standardized Excel spreadsheet was first provided to manufacturers in 2007.

⁴ ** The 2013 data includes gifts reported by pharmaceutical companies to AccessRx. From August to December, gifts to physicians and teaching hospitals were derived from Open Payments, not AccessRx.

⁵ * The 2014 data includes gifts reported by pharmaceutical companies to AccessRx. Gifts from pharmaceutical and device manufacturers to physicians and teaching hospitals were derived from Open Payments, not AccessRx.

Figure 1

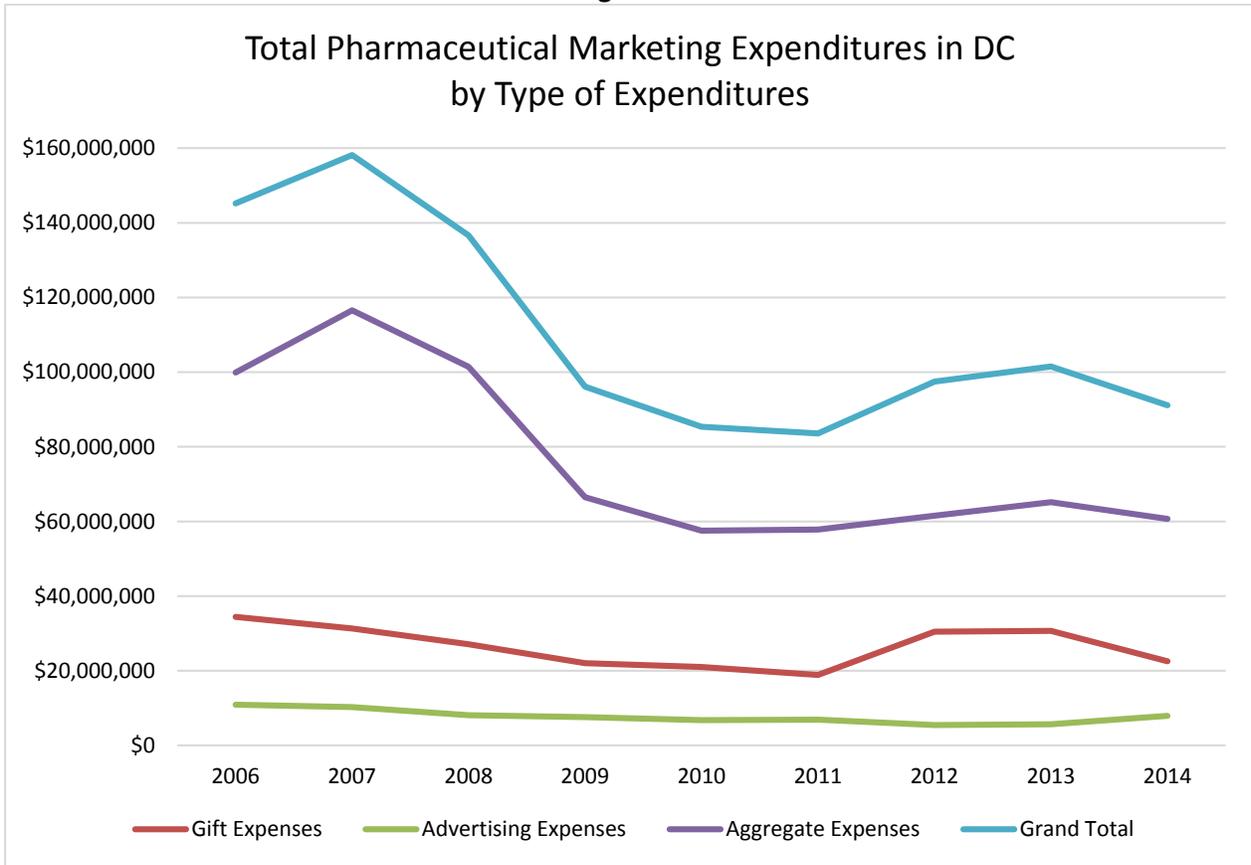
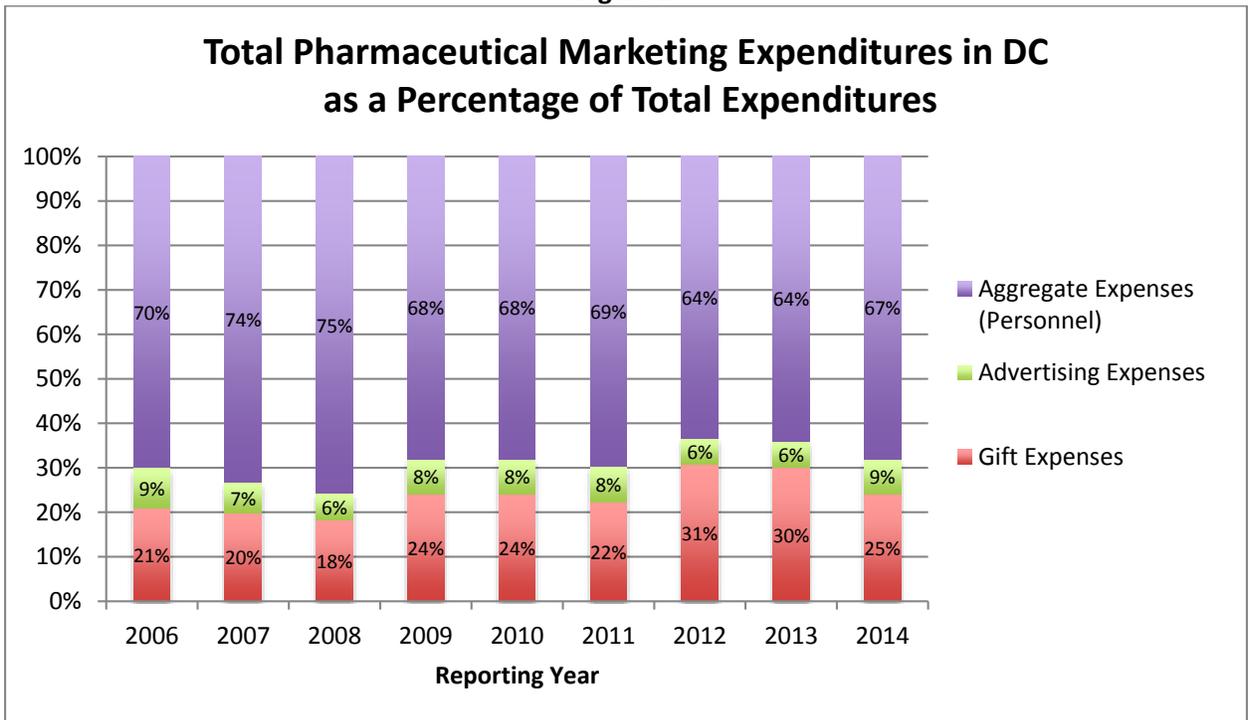


Figure 2



Gift Expenses

Five hundred sixteen pharmaceutical and device manufacturers reported *Gift Expenses* totaling \$22.6 million in value in 2014.

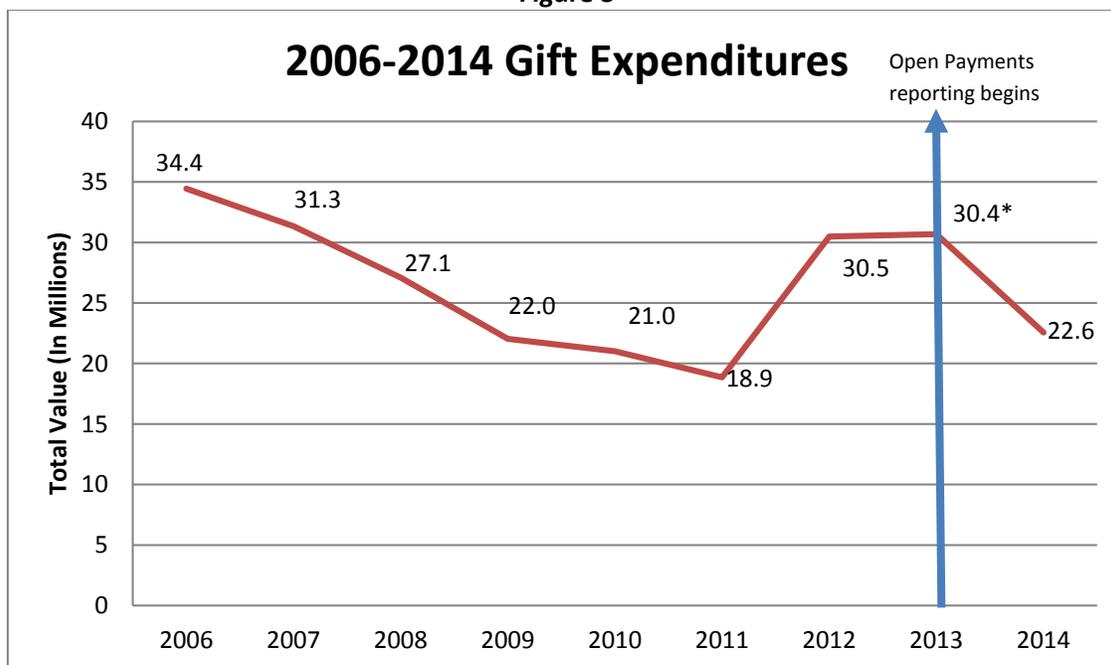
Almost 5,000 gifts totaling \$7.6 million were reported under *Gift Expenses* to AccessRx in 2014. *Gift Expenses* ranged from \$38 to \$1.7 million, with a median value of \$5,284. In 2014, 41,585 additional gifts were reported to Open Payments, accounting for \$14.9 million in value. *Gift Expenses* from the 486 pharmaceutical companies and device manufacturers ranged from \$3 to \$793,701, with a median value of \$1,601. Reported expenditures in 2013 and 2014 are not comparable to previous reporting years due to the introduction of Open Payments.

Table 2
Distribution of 2014 Gift Expenses in DC

Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	2	0.4%	\$2,959,616	13.1%
\$500,001 - 1,000,000	9	1.7%	\$6,740,232	29.9%
\$250,001 - 500,000	14	2.7%	\$4,600,392	20.4%
\$100,001 - 250,000	30	5.8%	\$4,756,082	21.1%
\$25,001 - 100,000	45	8.7%	\$2,222,356	9.8%
\$1 - 25,000	396	76.7%	\$1,283,718	5.7%
No reportable costs	20	3.9%	-	-
Total	516	100.0%	\$22,562,396	100.0%

*Total may not add up to 100% due to rounding.

Figure 3



** The 2013 data includes gifts reported by pharmaceutical companies to AccessRx. From August to December, gifts to physicians and teaching hospitals were derived from Open Payments, not AccessRx.

* The 2014 data includes gifts reported by pharmaceutical companies to AccessRx. Gifts from pharmaceutical and device manufacturers to physicians and teaching hospitals were derived from Open Payments, not AccessRx.

Advertising Expenses

Pharmaceutical companies reported District advertising expenses totaling \$7.9 million in 2014, significantly higher than the \$5.7 million reported in 2013. Advertising expenses include only local – not national – advertising expenditures. Companies that reported advertising expenses had totals ranging from \$18 to \$2.5 million; the median value for expenses was \$9,565.

Of the 68 companies that reported advertising expenses, 66.2% (45 companies) spent \$25,000 or less. Four companies spent over \$500,000 each, accounting for more than two-thirds (69.0%) of all advertising expenses. Table 3 shows the distribution of total *Advertising Expenses* in 2014.

Table 3
Distribution of 2014 Pharmaceutical Advertising Expenses in D.C.

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	3	2.0%	\$4,491,549	56.8%
\$500,001 - 1,000,000	1	<1%	\$957,961	12.1%
\$250,001 - 500,000	2	1.3%	\$710,684	9.0%
\$100,001 - 250,000	4	2.6%	\$791,357	10.0%
\$50,001 - 100,000	6	3.9%	\$438,316	5.5%
\$25,001 - 50,000	7	4.6%	\$242,859	3.1%
\$10,001 - 25,000	11	7.2%	\$172,871	2.2%
\$1,001 - 10,000	21	13.7%	\$91,906	1.2%
\$1 - 1,000	13	8.5%	\$5,597	<1%
No reportable costs	85	55.6%	\$0	0%
Total	153	100%	\$7,903,100	100%*

*Total may not add up to 100% due to rounding.

Aggregate Expenses

In 2014, pharmaceutical companies reported \$60.7 million in *Aggregate Expenses*,⁶ the amount spent on salaries and other expenses for employees and contractors engaged in District marketing activities. *Aggregate Expenses* accounted for two-thirds (66.6%) of total marketing expenses. The 133 companies that reported any spending in this category reported expenses ranging from \$887 to \$5.2 million, with a median value of \$74,943. Twenty companies reported no *Aggregate Expenses*.

“ ... the amount spent on salaries and other expenses for employees and contractors engaged in District marketing activities ... accounted for two-thirds (66.6%) of total marketing. ”

⁶ Pharmaceutical companies are provided with an optional spreadsheet to calculate and report *Aggregate Expenses*. The spreadsheet includes a line for each employee (or contractor) engaged in promotional activities, with salary, benefits, and commission. The amount of employee time devoted to District marketing activities is multiplied by total compensation to yield the District total for that employee.

Of companies that reported any *Aggregate Expenses*, 103 of 133 (77.4 %) spent more than \$25,000. Thirty-one companies (23.3% of the 133 reporting *Aggregate Expenses*) spent more than \$500,000 in 2014. Twenty-one had totals exceeding \$1 million.

Table 4
Distribution of 2014 Pharmaceutical Aggregate Expenses in DC

Total Reported Value	Number of Companies	% of Total Number	Total Value	% of Total Value
More than \$1,000,000	21	13.7%	\$43,786,838	72.2%
\$500,001 - \$1,000,000	10	6.5%	\$7,223,171	11.9%
\$250,001 - \$500,000	11	7.2%	\$4,126,274	6.8%
\$100,001 - \$250,000	19	12.4%	\$3,056,529	5.0%
\$25,001 - \$100,000	42	27.5%	\$2,164,467	3.6%
\$1 - \$25,000	30	19.6%	\$314,443	0.5%
No reportable costs	20	13.1%	-	-
Total	153	100.0%	\$60,671,721	100.0%*

*Total may not add up to 100% due to rounding.

Unique Employee or Contractor Titles

- Area Business Manager
- Clinical Sales Specialist
- District Manager (DM)
- Hospital Sales Specialist
- Imaging Sales Representative
- Medical Science Liaison (MSL)
- National Account Manager
- National Sales Director
- Pharmaceutical Detailer
- Pharmaceutical Sales Rep.
- Professional Urology Sales Specialist
- Regional Account Manager
- Regional Sales Director
- Regional Sales Manager
- Sales Representative
- Sales Specialist, Hepatology
- Sales Specialist
- Sr. District Sales Manager
- Sr. Specialty Account Manager
- Sr. Territory Manager
- Specialty Sales Consultant
- Specialty Sales Representative
- Territory Manager

IV. Gift Expense Analysis

Pharmaceutical companies and device manufacturers reported \$22.6 million in gifts in 2014, including \$7.6 million reported to AccessRx and \$14.9 million reported to Open Payments.

AccessRx requires pharmaceutical companies to report gifts above \$25 to any person or entity licensed to provide healthcare within the District of Columbia. After Open Payments went into effect in August 2013, companies were no longer required to report gifts given to physicians and teaching hospitals to AccessRx, as these expenses were reportable to Open Payments.⁷ After excluding incorrectly reported data, \$7.6 million in gifts to AccessRx was included in the dataset.

Open Payments requires pharmaceutical and device manufacturers to report gifts above \$10 to physicians and teaching hospitals. A total of \$14.9 million was reported in the District in 2014. The data included in this report was published on June 30, 2015 on the CMS Open Payments website.⁸ Supplementing the AccessRx data with Open Payments data enabled the inclusion of device manufacturers; AccessRx does not require device manufacturers to report marketing expenses.

Gift Recipients

AccessRx and Open Payments data were analyzed by recipient type and credentials. Gift recipients fell into two major categories: Non-Individual and Individual Recipients.⁹

There were \$11.8 million in gifts given to Individual Recipients, including *Physicians, Advanced Practice Nurses, Registered Nurses, Physician Assistants, Pharmacists, Other Healthcare Providers, and Other Recipients*. Gifts to *Physicians* accounted for \$11.2 million, or 49.4% of the total \$22.6 million in gifts reported to AccessRx and Open Payments. Consistent with all previous years, *Physicians* also received the greatest number of gifts; in 2014, 88.0% of gifts were given to *Physicians*. For all *Individual Recipients*, *Cash or Check* made up the greatest proportion of gift value, while *Food* made up the greatest frequency of gifts; this finding is consistent with previous years. The *Primary Purpose* of gifts to Individual Recipients was split across *Speaker Fee, Marketing, Education and Consulting*.

“ Gifts to *Physicians* accounted for \$11.2 million, or 49.4% of the total \$22.6 million in gifts reported to AccessRx and Open Payments. ”

There were \$10.7 million in gifts given to Non-Individual Recipients, including *Professional Organizations, Teaching Hospitals, Advocacy Organizations, Universities, Continuing Medical Education (CME) Organizations, Clinical Organizations, Pharmacies, and Other Organizations*. These recipients generally had a higher total value and median gift value compared to *Individual Recipients*. In addition,

⁷ A total of \$9.9 million in gifts was reported in 2014 to AccessRx. However, \$2.3 million in gifts were excluded from the dataset because the date fell outside of 2014 or the recipients were reported as physicians or teaching hospitals.

⁸ CMS Open Payments accessible at: <https://www.cms.gov/openpayments/>

⁹To characterize *Gift Recipients*, AccessRx data queried by *Recipient Type* was further analyzed by *Recipient Credentials*. Open Payments data was queried by *Covered Recipient Type*.

there is a greater range in the value of gifts. The greatest value and frequency of gifts to Non-Individual Recipients were in the form of *Cash or Check* and *Grant*. The reported *Primary Purpose* of gifts to Non-Individual Recipients was split between *Education, Grant, Other, Consulting, and Marketing*.

Table 5

2014 Gifts to Individual and Non-Individual Recipients					
Individual Recipient	Total Value	Frequency	Range of Gift Values (Median)	Nature of Payment Highest Value	Nature of Payment Most Frequent
Physicians	\$11,151,269	40,957	<\$1 – 477,258 (\$20)	Cash or Cash Equivalent	In-kind Items and Services
Advanced Practice Nurses	\$298,809	1,006	<\$1 – 4,500 (\$96)	Cash or Check	Food
Registered Nurses	\$108,082	844	<\$1 – 5,000 (\$96)	Food	Food
Physician Assistants	\$73,377	675	<\$1 – 1,609 (\$78)	Food	Food
Pharmacists	\$52,812	434	<\$1 – 28,000 (\$98)	Food	Food
Other Healthcare Providers	\$60,920	702	<\$1 – 3,000 (\$47)	Food	Food
Other Recipients	\$100,296	547	<\$1 – 12,000 (\$53)	Cash or Check	Food
Total	\$11,845,565	45,165			
Non-Individual Recipient	Total Value	Frequency	Range of Gift Values (Median)	Nature of Payment Highest Value	Nature of Payment Most Frequent
Professional Organizations	\$4,383,732	150	\$32 – 450,000 (\$7,500)	Cash or Check	Cash or Check
Teaching Hospitals	\$3,797,711	628	\$2 – 350,000 (\$1,000)	Cash or Cash Equivalent	Cash or Cash Equivalent
Advocacy Organizations	\$1,072,373	79	\$30 – 250,000 (\$5,000)	Cash or Check	Cash or Check
Universities	\$453,562	43	\$32 – 149,066 (\$2,400)	Grant	Cash or Check
Continuing Medical Education Organizations	\$343,164	65	\$39 – 81,022 (\$210)	Grant	Grant
Clinical Organizations	\$263,550	36	\$53 – 134,589 (\$414)	Grant	Food
Pharmacies	\$3,789	22	\$13 – 981 (\$104)	Food	Food
Other Organizations	\$398,949	361	<\$1 – 150,000 (\$12)	Cash or Check	Cash or Check
Total	\$10,716,831	1,384			
Grand Total	\$22,562,396	46,549			

V. Payments to Individual Recipients

Gifts to Individual Recipients totaled \$11.8 million in 2014. Individual Recipients include *Physicians, Advanced Practice Nurses, Registered Nurses, Physician Assistants, Pharmacists, Other Healthcare Providers, and Other Recipients*.

Physicians received \$11.2 million in 2014, which accounted for the greatest value and frequency of all gifts to Individual Recipients (94.1% and 90.7%, respectively). *Advanced Practice Nurses* received \$298,809 (2.5% of the total value and 2.2% of the total frequency) and *Registered Nurses* received \$108,082 (0.9% of the total value and 1.8% of the total frequency). *Other Recipients* (recipients who fell outside of the defined categories or were undisclosed) totaled \$100,296 or 0.8% of the total value and 1.2% of the total frequency. *Physician Assistants, Other Healthcare Providers* and *Pharmacists* each received less than \$100,000 (<1.0% of the total value and <2.0% of the total frequency). Most gifts to *Physicians* and *Advanced Practice Nurses* were in the form of *Monetary Payments*. Most gifts to *Nurses, Physician Assistants, and Pharmacists* were in the form of *Food and Beverage*.

Each Individual Recipient category is described and analyzed in more detail in the following sections.

“ Most gifts to *Physicians* and *Advanced Practice Nurses* were in the form of *Monetary Payments*. Most gifts to *Nurses, Physician Assistants, and Pharmacists* were in the form of *Food and Beverage*. ”

Physicians

Physicians in the District received \$11.2 million in 2014, a 39.4% increase over the \$8.0 million reported in 2013. 2014 information on physician payments is from Open Payments.¹⁰ The term *Nature of Payment* in Open Payments is similar to the term *Primary Purpose* in AccessRx. The term *Form of Payment* in Open Payments is similar to the term *Nature of Payment* in AccessRx.

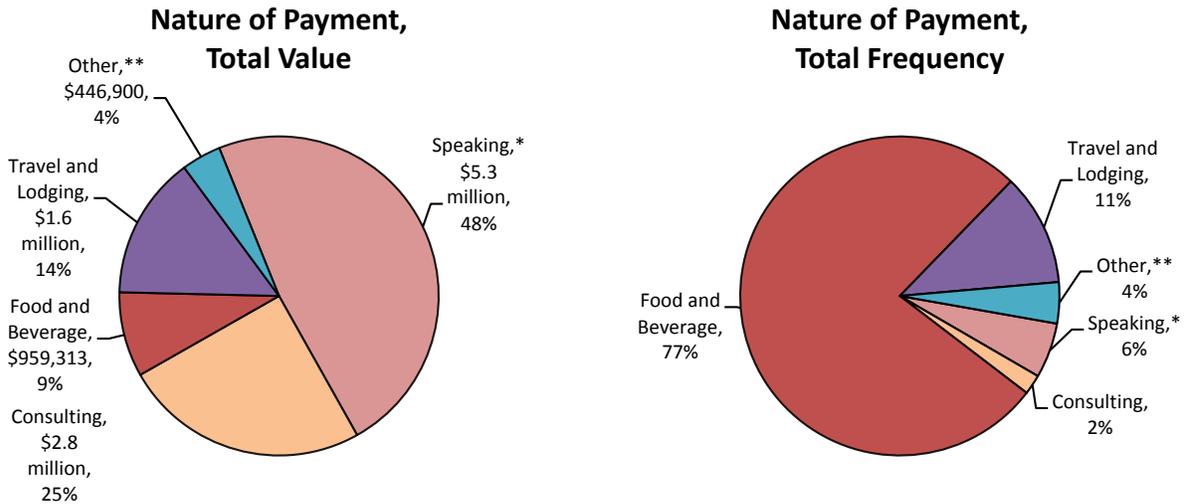
Speaking accounted for the vast majority of physician gifts, accounting for \$5.3 million or 48.0%. *Consulting* made up another quarter of the total value with \$2.8 million (24.9%) followed by *Travel and Lodging* with \$1.6 million (14.5%) and *Food and Beverage* with \$959,313 (8.6%). The remaining value was accounted for by *Other* (\$446,900 or 4.0%), which includes *Royalty or License* (\$136,627), *Education* (\$130,966), *Gift* (\$61,096), *Grant* (\$59,913), *Ownership or Investment Interest* (\$56,888), and *Entertainment* (\$1,409).

When looking at physician gifts by frequency, *Food and Beverage* was the most frequent type of gift, constituting 76.9% of the gifts, a substantial increase from 2013 when *Food and Beverage* made up

¹⁰ An Access database was created using the Open Payments data on physician gifts published on June 30, 2015. The *Nature of Payment* of physician gifts was divided into 10 categories: *Consulting, Education, Entertainment, Food and Beverage, Gift, Grant, Ownership or Investment Interest, Royalty or License, Speaking and Related Fees, and Travel and Lodging*. This database was then queried and analyzed by *Nature of Payment* and by *Form of Payment*. (Open Payments uses the term *Nature of Payment*, which is similar to the AccessRx term *Primary Purpose*. Open Payments uses the term *Form of Payment*, which is similar to the AccessRx term *Nature of Payment*.)

58.7% of gifts. This was followed by *Travel and Lodging* (11.4%) and *Speaking* (5.6%). The remaining gifts each represented less than 5%, including *Other* (4.2%) and *Consulting* (2.0%).

Figure 4
2014 Gifts to Physicians

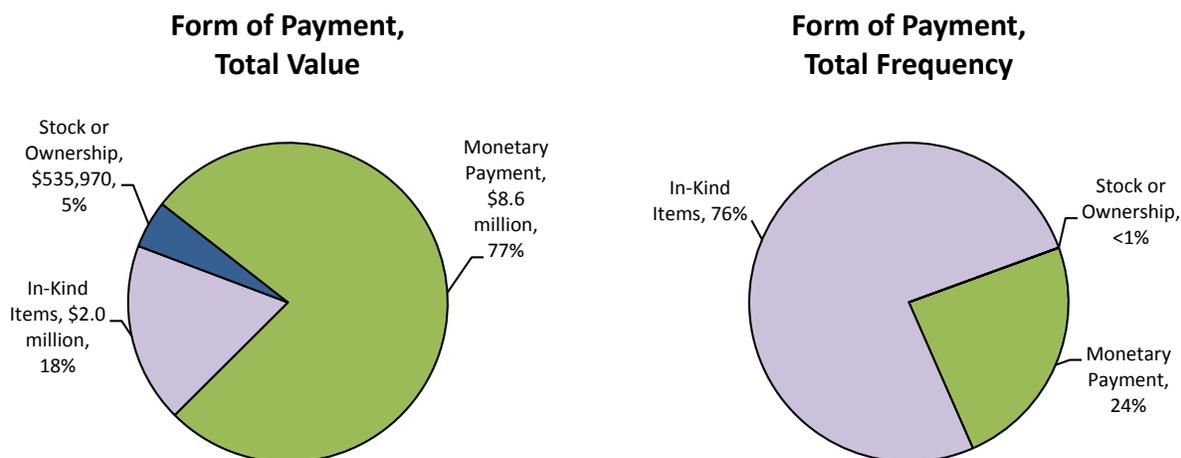


**Speaking* consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing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

** "*Other*" includes gifts reported as *Ownership or Investment Interest, Education, Entertainment, Gift, Grant, and Royalty or License*.

Physician gifts were then classified by the form of payment, including *Monetary Payment, In-kind Items, or Stock or Ownership*. *Monetary Payment* made up the greatest value of gifts (\$8.6 million, or 77.0%) although it represented only 24.0% of the frequency of gifts. This was followed by *In-kind Items*, which accounted for \$2.0 million of the gifts or 18.2% of the total value, and the greatest frequency of gifts, at 76.0%. *Stock or Ownership* accounted for \$535,970, or 4.8% of the total value, accounting for less than 0.1% of the total frequency of gifts.

Figure 5
2014 Gifts to Physicians



Top 25 Physicians

The 25 physicians who received the highest gift values received a total of \$5.3 million, accounting for 47.7% of the total value and 12.5% of the total frequency of gifts to all Individual Recipients. Information on individual physicians is publicly available through Open Payments.

“ The 25 physicians who received the highest gift values received a total of \$5.3 million, accounting for 47.7% of the total value and 12.5% of the total frequency of gifts to Individual Recipients. ”

Among the top 25 physicians, the majority of gifts were attributed to *Speaking* (\$3.1 million, or 58.1%) and *Consulting* (\$1.4 million, or 26.7%). The remaining gifts were accounted for by *Travel and Lodging* (\$680,661, or 12.8%), *Food and Beverage* (\$97,886, or 1.8%), and *Other* (\$30,834, or 0.6%).

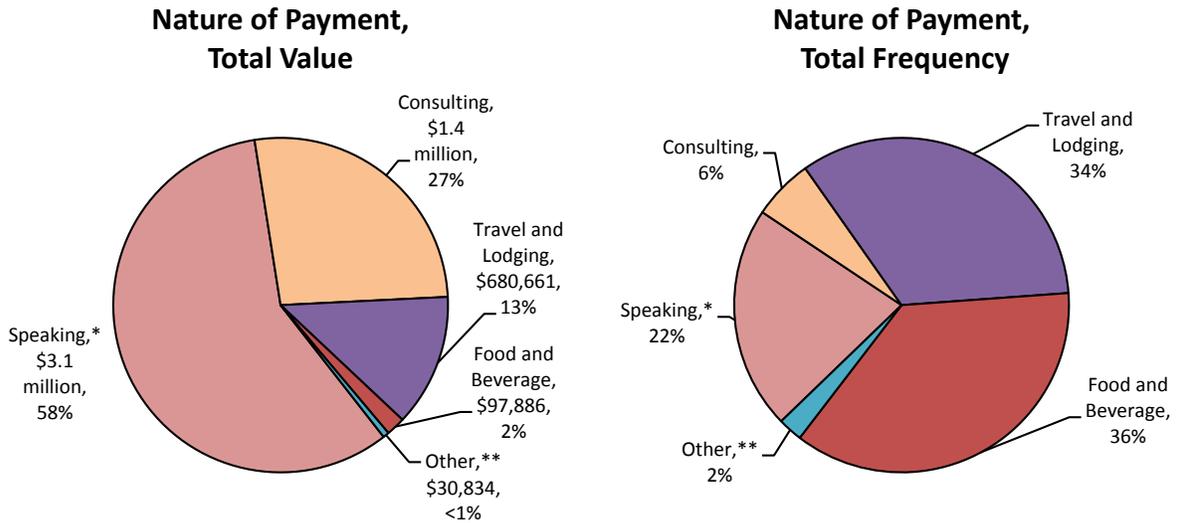
The most frequent gifts among this group included *Food and Beverage* (36.6%), *Travel and Lodging* (33.6%), *Speaking* (21.6%), *Consulting* (5.9%), and *Other* (2.4%).

**Table 6
Physicians Receiving the Highest Gift Values in Washington DC, 2014***

Name	Specialty	Affiliation	Value	Frequency
Helen Barold, MD, MPH	Cardiology	Comprehensive Cardiac Care	\$477,428	17
Imadeddine Tabbara, MD	Hematology/Oncology	The George Washington (GW) Medical Faculty Associates, George Washington University (GWU) School of Medicine and Health Sciences	\$428,214	466
Wayne Olan, MD	Radiology	The GW Medical Faculty Associates, GWU School of Medicine and Health Sciences	\$417,154	222
James Simon, MD	Gynecology	Healthcare for Women	\$330,689	433
Andrea Leonard-Segal, MD	Internal Medicine and Rheumatology	Center for Integrative Medicine	\$269,761	55
Rachel Brem, MD	Radiology, Diagnostic	The GW Medical Faculty Associates, GWU School of Medicine and Health Sciences	\$257,898	45
Ron Waksman, MD	Cardiology	MedStar Washington Hospital Center, Georgetown University Medical Center	\$254,979	169
Laxman Bahroo, DO	Neurology	Georgetown University Medical Center	\$243,788	417
Fernando Pagan, MD	Neurology	Georgetown University Medical Center	\$225,756	327
John Marshall, MD	Hematology/Oncology	MedStar Georgetown University Hospital, Georgetown University Medical Center	\$208,753	206
Natasa Janicic-Kahric, MD	Endocrinology	MedStar Georgetown University Hospital	\$197,118	361
Vasilios Papademetriou, MD	Cardiology	Georgetown University Medical Center	\$187,031	177
Hamid Shafie, DDS	Prosthodontics	Integrated Dental Arts	\$167,297	43
Heidi Jolson, MD, MPH	Infectious Disease	3D Communications	\$161,371	80
Scott Kahan, MD MPH	Preventative Medicine, Obesity Medicine	National Center for Weight and Wellness, Johns Hopkins University, GWU School of Medicine and Health Services	\$159,332	248
Nancy Dawson, MD	Internal Medicine, Hematology/Oncology	Georgetown University Medical Center	\$155,948	144
Guillermo Gutierrez, MD PhD	Pulmonology	The GW Medical Faculty Associates, GWU School of Medicine and Health Sciences	\$147,267	214
Allen Solomon, MD	Cardiology	The GW Medical Faculty Associates, GWU School of Medicine and Health Sciences	\$140,827	193
Vincent Obias, MD	Surgery	The GW Medical Faculty Associates, MedStar George Washington University Hospital	\$139,168	154
John Hogan, MD	Infectious Disease, Hepatology	Unity Health Care	\$135,177	240
Joseph Verbalis, MD	Endocrinology	Georgetown University Medical Center	\$126,469	76
James Lewis, MD	Gastroenterology	Georgetown University Medical Center	\$123,576	166
Richard Elion, MD	Family Medicine	Whitman Walker Health	\$120,768	162
Adelaide Robb, MD	Psychology	Children's National Medical Center, GWU School of Medicine and Health Sciences	\$119,654	145
Theo Hodge, MD	Internal Medicine and Infectious Disease	Capital Medical Associates	\$119,298	351

*Information on gift values and frequency is from Open Payments. Information on affiliations, degrees, and specialties was gathered from online searches and may not be complete.

Figure 6
2014 Top 25 Physician Recipients

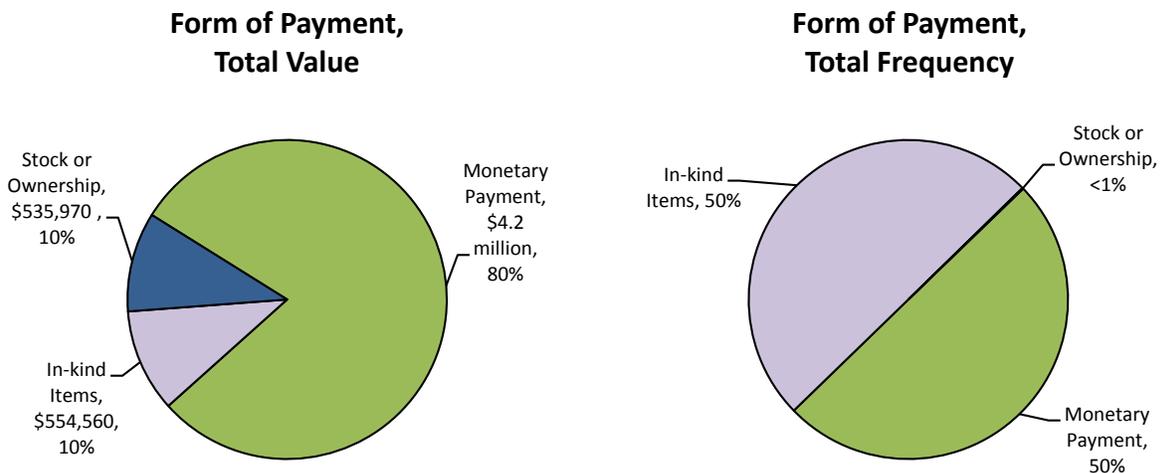


*Speaking consists of gifts reported as honoraria, compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program and compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing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

** "Other" includes gifts reported as Education, Entertainment, or Gift.

When looking at the *Form of Payment*, \$4.2 million in gifts (79.5%) was in the form of *Monetary Payment*, and more than \$500,000 each was in the form of *In-kind Items* and *Stock or Other Ownership Interest* (about 10% each). The frequency of gifts was split between *Monetary Payments* and *In-kind Items*, each making up 50% of the total frequency of gifts. Less than 0.1% of gifts were given in the form of *Stock or Ownership*.

Figure 7
2014 Top 25 Physician Recipients

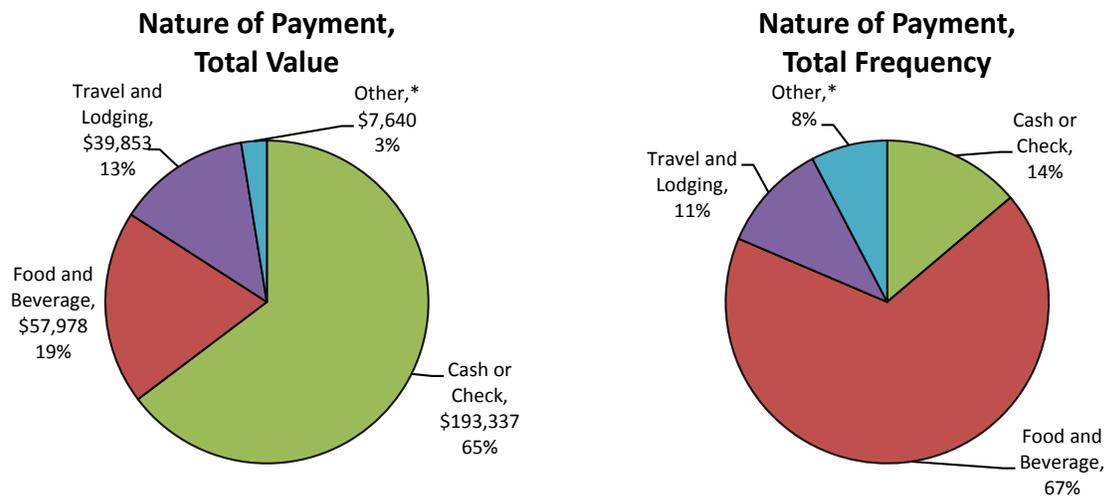


Advanced Practice Nurses

Advanced Practice Nurses include nurse practitioners, nurse-midwives, and nurse-anesthetists; all have independent prescribing authority. Gifts to Advanced Practice Nurses totaled \$298,809 in 2014.

Cash or Check made up the greatest proportion of total gift value, with \$193,337 or 64.7% of gift value and 13.8% of frequency. This was followed by *Food and Beverage*, with \$57,978 or 19.4% of gift value and 67.6% of frequency. The remaining gifts came in the form of *Travel and Lodging* (\$39,853 or 13.3% of value and 10.9% of frequency) and *Other* (\$7,640 or 2.6% of value and 7.7% of frequency).

Figure 8
2014 Gifts to Advanced Practice Nurses



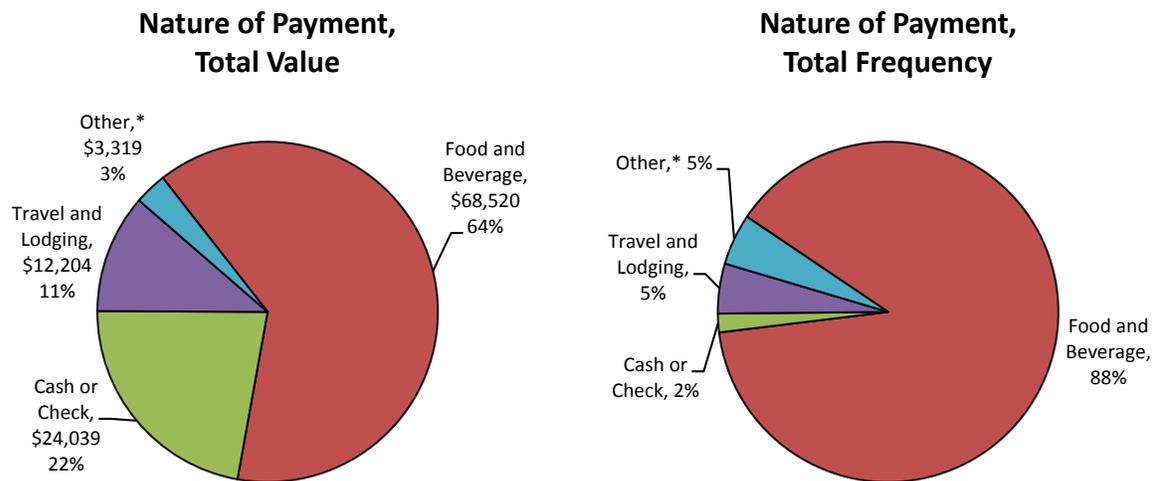
* "Other" includes gifts reported as *Book* or *Other*.

Nurses

Gifts to Nurses totaled \$108,082 in 2014.¹¹

Nurses primarily received gifts in the form of *Food and Beverage* (\$68,520 or 63.4% of total value, and 88.6% of the total frequency). *Cash or Check* accounted for nearly one-quarter of the total gift value (\$24,039 or 22.2%), but only 1.8% of the total gift frequency. *Travel and Lodging* accounted for \$12,204 or 11.3% of total gift value, and 4.7% of the total gift frequency. *Other* gifts accounted for the remaining gift value (\$3,319 or 3.1%) and 4.9% of frequency, which included gifts reported as *Books* and *Other*.

Figure 9
2014 Gifts to Registered Nurses



* "Other" includes gifts reported as *Book* or *Other*.

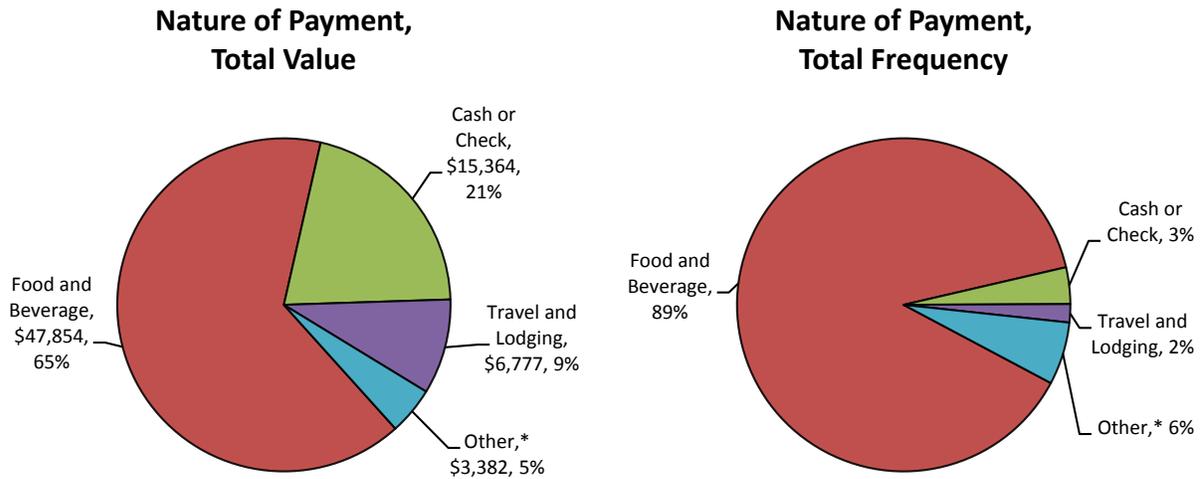
¹¹To generate the data for this section, AccessRx data was queried by the *Recipient Credentials of Registered Nurse, Nurse, LPN, and LVN*.

Physician Assistants

Gifts to Physician Assistants totaled \$73,377 in 2014.¹²

Physician Assistants primarily received gifts in the form of *Food and Beverage*, with \$47,854 or 65.2% of total value and 88.6% of the total frequency. *Cash or Check* accounted for \$15,364 or 20.9% of total value and 3.6% of total frequency. *Travel and Lodging* and *Other* each accounted for less than 10% of the total gift value and frequency.

Figure 10
2014 Gifts to Physician Assistants



* "Other" includes gifts reported as *Book* or *Other*.

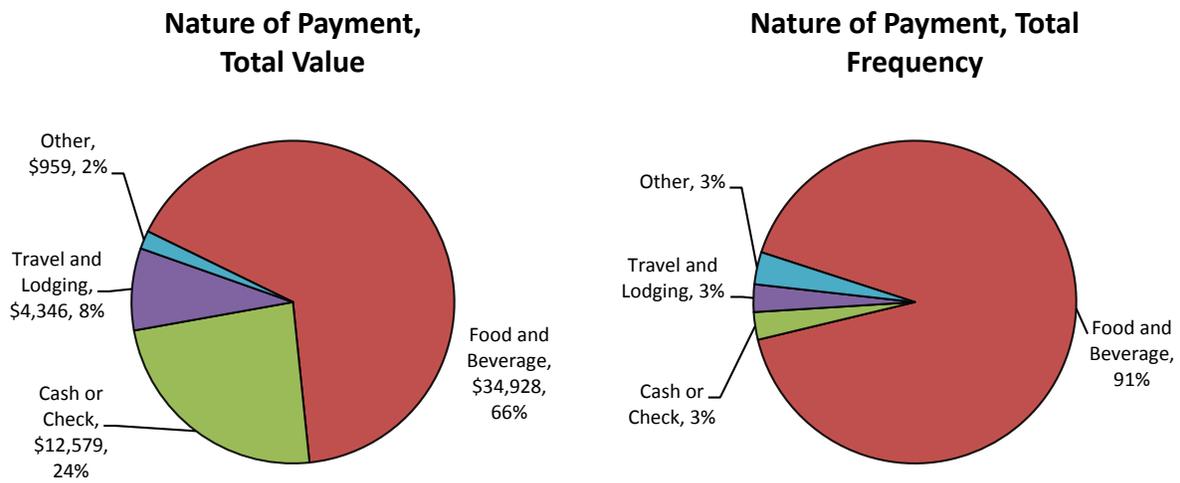
¹² This section reflects data associated with records queried in the AccessRx database by the *Recipient Credential* of Physician Assistant.

Pharmacists

Gifts to pharmacists totaled \$52,812 in 2014.¹³

Pharmacists primarily received gifts in the form of *Food and Beverage*, which accounted for the greatest amount and greatest frequency of gifts (\$34,928 or 66.1% of value and 91.2% of frequency). This was followed by *Cash or Check* (\$12,579 or 23.8% of value and 2.8% of frequency) and *Travel and Lodging* (\$4,346 or 8.2% of value and 2.8% of frequency). *Other* gifts accounted for the remaining gift value (\$959 or 1.8%) and 3.2% of frequency, which included gifts reported as *Books* and *Other*.

Figure 11
2014 Gifts to Pharmacists



* "Other" includes gifts reported as *Book* or *Other*.

¹³ This section includes records reported with Recipient *Credentials* of Physician Assistant.

Other Healthcare Providers

Gifts to Other Healthcare Providers totaled \$60,920 in 2014.¹⁴ The majority of gifts to Other Healthcare Providers were reported as *Food and Beverage*, with \$40,733 or 66.9% of gift value and 92.5% of gift frequency. This was followed by *Cash or Check* (\$10,676 or 17.5% of value or 4.1% of frequency), *Speaking* (\$3,000 or 4.9% of value and 0.1% of frequency), *Travel and Lodging* (\$3,603 or 5.9% of value and 1.6% of frequency), and *Other* (\$2,908 or 4.8% of value or 1.7% of frequency).

Other Recipients

Gifts to Other Recipients totaled \$100,296 in 2014. This group of Other Recipients included those with designations such as *Chief Executive Officer, Director, Office Staff, Administrator, None, Unknown, and Other*.

Cash or Check accounted for the greatest proportion of value making up nearly half of the gifts reported to *Other Recipients* (\$47,016 or 46.7% of value and 3.1% of frequency). This is followed by *Food* (\$35,712 or 35.6% of value and 85.6% of frequency), *Travel and Lodging* (\$16,068 or 16.0% and 11.2% of frequency), and *Other* (\$1,500 or 1.5% of value and 0.2% of frequency).

¹⁴ Records were queried in the AccessRx database by the *Recipient Type* of *Other Healthcare Provider, Other Prescriber* and *Other* after the more precise groupings (physician assistants, pharmacists, advanced practice nurses and registered nurses) were excluded. Examples of *Recipient Credentials* in the dataset include *Certified Diabetic Educator, Resident, Rapid Response Team* and *Other*.

VI. Payments to Non-Individual Recipients

Gifts to Non-Individual Recipients totaled \$10.7 million in 2014. This analysis includes gifts reported to recipients and organizations based in the District of Columbia. The DC Department of Health is unique, nationwide, in its ability to capture gifts to national organizations. These organizations affect healthcare in many ways, including creating medical guidelines, affecting policies, and creating and disseminating continuing medical education. Non-Individual Recipients were divided into the following categories:

- *Professional Organizations* received \$4.4 million (40.9%)
- *Teaching Hospitals* received \$3.8 million (35.4%)
- *Advocacy Organizations* received \$1.1 million (10.0%)
- *Universities* received \$453,562 (4.2%)
- *Continuing Medical Education (CME) Organizations* received \$343,164 (3.2%)
- *Clinical Organizations* received \$263,550 (2.5%)
- *Pharmacies* received \$3,789 (<0.1%)
- *Other Organizations* received \$398,949 (3.7%)

Teaching Hospitals received the greatest frequency of gifts (45.4%), followed by *Other Organizations*, (26.1%). Although *Professional Organizations* received a small proportion of gift frequency (10.8%), gifts were of significant monetary value (on average, \$29,225).¹⁵ Groups with the lowest frequency of gifts included *Advocacy Organizations* (5.7%), *CME Organizations* (4.7%), *Universities* (3.1%), *Clinical Organizations* (2.6%) and *Pharmacies* (1.6%).

Professional Organizations

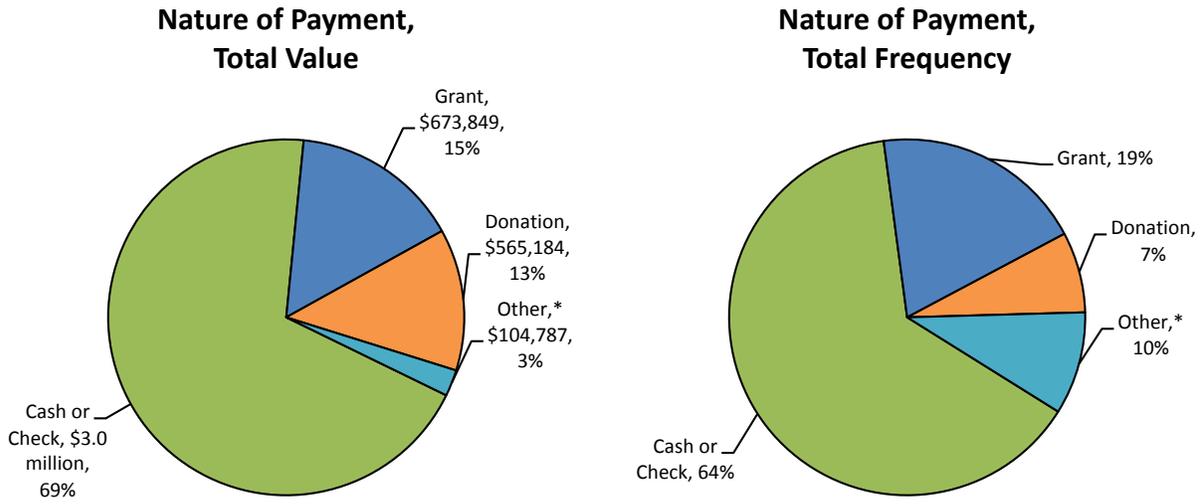
Gifts to *Professional Organizations*, including societies and associations, totaled \$4.4 million in 2014.

Gifts to *Professional Organizations* primarily took the form of *Cash or Check* (\$3.0 million, or 69.3%), which also accounted for the greatest frequency of gifts (64.0%). *Grants* accounted for \$673,849, or 15.4% of the total value and 19.3% of the total frequency. *Donations* accounted for \$565,184, or 12.9% of the total value and 7.3% of the total frequency. Gifts categorized as *Other* accounted for \$104,787 or 2.4% of the total value and 9.3% of the total frequency.

It is unclear whether there is any substantive distinction between *Cash or Check*, *Grants*, or *Donations* to *Professional Organizations*. In total, gifts in the form of these *Monetary Payments* totaled \$4.3 million.

¹⁵ Gifts to foundations affiliated with organizations were combined with their respective organizations.

Figure 12
2014 Gifts to Professional Organizations



*"Other" includes gifts reported as *Book, Food, or Other*.

Teaching Hospitals

Gifts to *Teaching Hospitals* totaled \$3.8 million in 2014. This information is publicly available in Open Payments, with *Teaching Hospitals* in the District that received gifts listed below.

Two-thirds (67.8%) of all gifts to *Teaching Hospitals* in the District went to the Washington Hospital Center (\$2.6 million). This hospital also received the greatest number of gifts, accounting for 42.7% of the total gift frequency. The District's academic medical centers received substantial gifts. Georgetown University Hospital accounted for one-quarter (23.1%) of the total gift value, receiving \$876,316. Howard University Hospital received \$105,178 and George Washington University Hospital received \$81,364. Children's Hospital and Sibley Memorial Hospital also received substantial amounts; \$80,247 and \$65,340, respectively.

Table 7
2014 Gifts to Teaching Hospitals in Washington, DC

Teaching Hospital	Total Value	Frequency	Median Gift Value
Washington Hospital Center	\$2,574,142	268	\$2,500
Georgetown University Hospital	\$876,316	143	\$1,500
Howard University Hospital	\$105,178	40	\$1,812
George Washington University Hospital	\$81,364	119	\$218
Children's Hospital	\$80,247	27	\$1,000
Sibley Memorial Hospital	\$65,340	15	\$266
National Rehabilitation Hospital	\$8,786	7	\$500
Providence Hospital	\$6,338	9	\$544
Total	\$3,797,711	628	

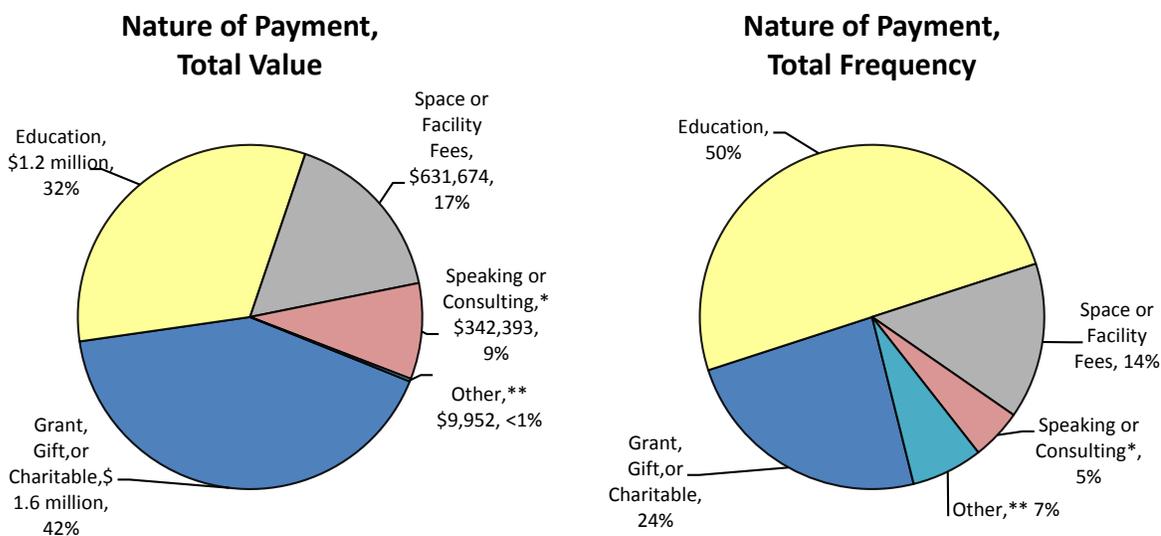
Of the \$3.8 million in gifts to *Teaching Hospitals*, 41.6% of the total value was in the form of *Grant, Gift, or Charitable* (\$1.6 million). This was followed by *Education* (\$1.2 million or 32.5%) and *Space Rental and Facility Fees* (\$631,674 or 16.6%). The remaining categories included *Speaking or Consulting* (\$342,393 or 9.0%) and *Other* (\$9,952 or 0.3%), each accounting for less than 10% of the total value. Companies could choose which categories to report in, and may have chosen different categories; for example, funding for a CME conference may have been categorized as a grant, education, or space rental fee.

“ The District’s academic medical centers received substantial gifts. ”

The frequency of gifts differs slightly, with *Education* accounting for half of the total number of gifts (50.0%) to *Teaching Hospitals*. This is followed by *Grant, Gift, or Charitable* with 23.9% of the total gift frequency and *Space or Facility Fees* with 14.6%. The remaining categories included *Speaking or Consulting* (4.8%) and *Other* (6.7%), each accounting for less than 10% of the total gift frequency.

The vast majority of gifts to *Teaching Hospitals* were *Cash or Cash Equivalent*. Of the \$3.8 million in gifts to *Teaching Hospitals*, \$3.3 million (87.7% of the total) were *Cash or Cash Equivalent*. The remaining \$465,895 (12.3%) in gifts were *In-kind Items and Services*.

Figure 13
2014 Gifts to Teaching Hospitals¹⁶



**Speaking or Consulting* consists of gifts reported as honoraria, consulting, serving as 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”* includes gifts reported as *Travel and Lodging, Royalty or License, Food and Beverage, or Other*.

¹⁶ The term *Nature of Payment* in Open Payments is similar to the term *Primary Purpose* in AccessRx. The term *Form of Payment* in Open Payments is similar to the term *Nature of Payment* in AccessRx.

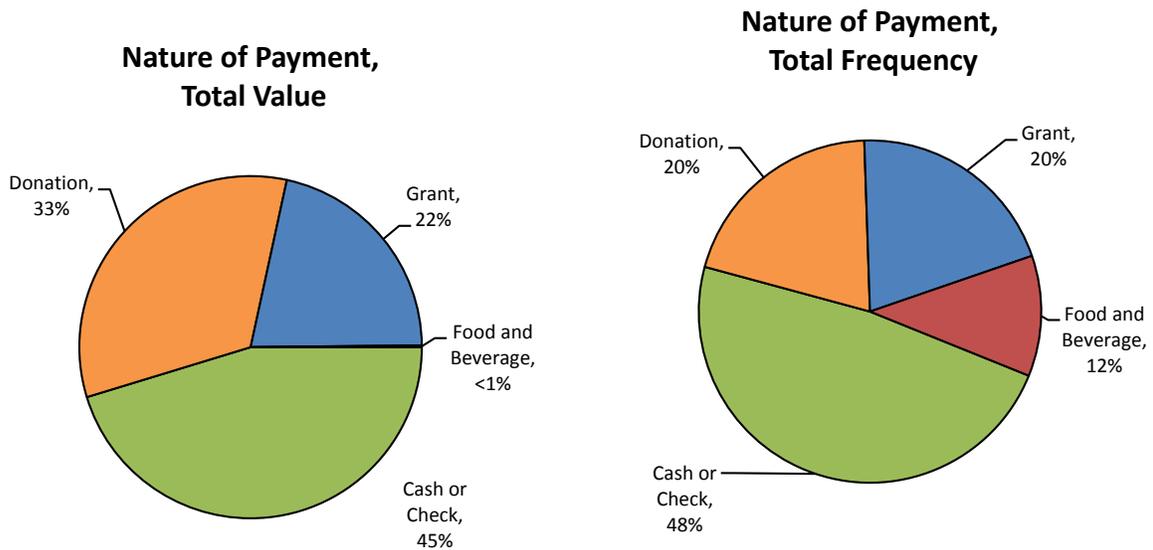
Advocacy Organizations

Gifts to *Advocacy Organizations* totaled \$1.1 million in 2014. This included advocacy and research organizations that often focus on certain diseases or topics.

“ Gifts to *Advocacy Organizations* totaled \$1.1 million in 2014. ”

Gifts in the form of *Cash or Check* made up nearly half of the total value (\$485,614 or 45.3%) and frequency (48.1%) of gifts. This was followed by *Donations* (\$355,125 or 33.1% of value) and 20.3% of the total frequency. *Grants* accounted for another \$229,840 (21.4%) and 20.3% of the total frequency. *Food and Beverage* made up 0.2% of the total value and 11.4% of the frequency. The majority of gifts had a *Primary Purpose* of “*Other*” (\$773,950 or 72.2%), making it difficult to determine what these gifts were for.

Figure 14
2014 Gifts to Advocacy Organizations



Universities

Gifts to Universities totaled \$453,562 in 2014. *Grants* accounted for the greatest value of gifts with \$367,138 or 80.9% of the total value and 37.2% of the total frequency of gifts. *Cash and Checks* accounted for \$51,424 or 11.3% of the total value and 58.1% of the total frequency. *Donations* accounted for the least value (\$35,000 or 7.7%) and frequency (4.7%).

Continuing Medical Education Organizations

Gifts to *Continuing Medical Education Organizations* totaled \$343,164 in 2014. The Nature of Payment of all 65 gifts was reported as a *Grant* with the *Primary Purpose as Education*.

Clinical Organizations

Gifts to *Clinical Organizations* (non-teaching hospitals, clinics, and medical center) totaled \$263,550 in 2014. *Grants* accounted for the greatest value of gifts (\$208,388 or 79.1%) and 22.2% of frequency. *Cash or Check* and *Donation* each accounted for \$25,000 or 9.5% of the total gift value (5.6% and 13.9% of frequency, respectively). *Food* accounted for only \$4,663 or 1.8% of total value, but 55.6% of gift frequency. The remaining one gift was designated as *Other* (0.2% of value and 2.8% of frequency).

Pharmacies

Pharmacies in the District received 22 gifts totaling \$3,789 in 2014. All of the gifts were in the form of *Food or Beverage* with a *Primary Purpose of Marketing*.

Other Non-Individual Recipients

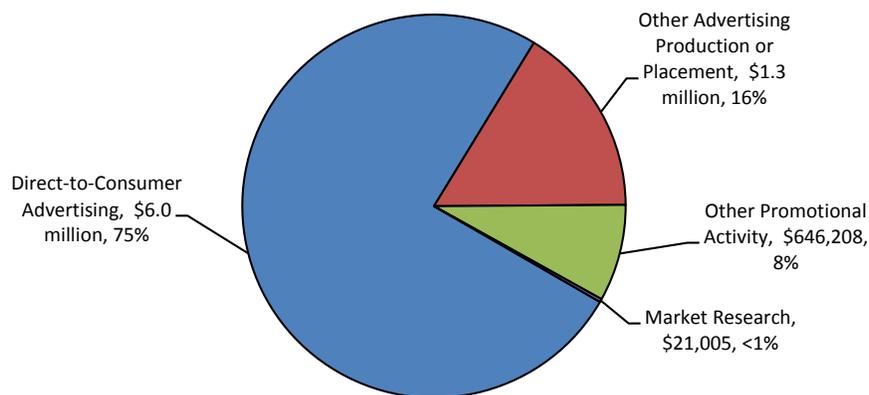
Other Non-Individual Recipients received a total of \$398,949; this group included consulting firms and government agencies. The vast majority of gifts to this group were in the form of *Cash or Checks* (\$376,635 or 94.4% of the total value and 97.8% of the total frequency). This was followed by *Grants*, accounting for \$22,009 or 5.5% of value, and 1.1% frequency. *Food and Beverage* and *Donations* accounted for less than 1% of the total gift value and frequency.

VI. Advertising Expenses

Of the companies reporting marketing expenditures in 2014, 68 reported Advertising expenditures totaling \$7.9 million. An analysis of Advertising by *Activity Type* found that the majority of expenditures fell into the following categories: *Direct-to-Consumer Advertising*, *Other Advertisement Production or Placement*, *Other Promotional Activity*, and *Market Research*.

Direct-to-Consumer Advertising Placement accounted for \$6.0 million or 75.4% of all *Advertising Expenses*, a significant increase from the \$3.8 million reported spending in 2013. Expenditures classified as *Other Advertising Production or Placement* totaled \$1.3 million, or 16.2% of advertising expenditures; *Other Promotional Activities* totaled \$646,208, or 8.2% of advertising expenses. The remaining fell under *Market Research*, totaling \$21,005, or 0.3% of expenditures.

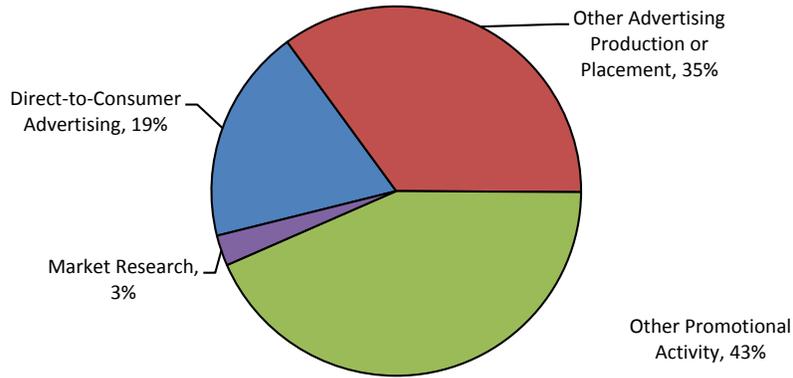
Figure 15
2014 Advertising Expenses
Advertising Expenses by Type of Activity,
Total Value



The picture is somewhat different when considering the frequency of different types of *Advertising Expenses*. Expenditures classified as *Other Promotional Activity* accounted for the greatest number of reported expenditures (43.3%). *Other Advertising Production or Placement* accounted for slightly more than one-third of the expenditures (35.1%). The remaining went to *Direct-to-Consumer Advertising* (18.8%) and *Market Research* (2.7%).

Figure 16
2014 Advertising Expenses

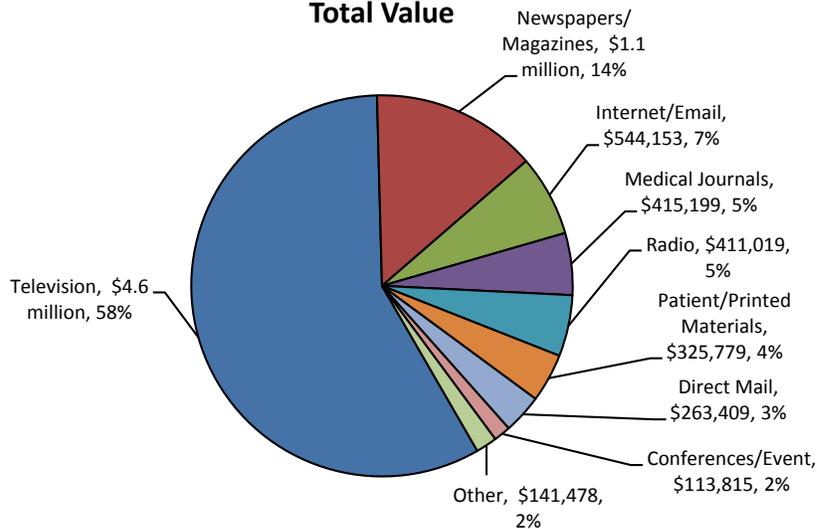
**Advertising Expenses by Type of Activity,
 Total Frequency**



Advertising responses were grouped into eight media categories: *Television*, *Newspapers/Magazines*, *Internet/Email*, *Medical Journals*, *Radio*, *Patient/Printed Materials*, *Direct Mail*, *Conferences/Events*, and *Other*. The majority of expenditures fell under *Television*, which accounted for \$4.6 million, or 57.9% of the total value. Other significant contributors include *Newspapers/Magazines* (\$1.1 million or 14.1%) and *Internet/Email* (\$544,153 or 6.9%). *Medical Journals* (\$415,199 or 5.3%), *Radio* (\$411,019 or 5.2%), *Patient/Printed Material* (\$325,779 or 4.1%), *Direct Mail* (\$263,409 or 3.3%), *Conferences/Events* (\$113,815 or 1.4%), and *Other* (\$141,478 or 1.8%) each account for 5% or less of the total value.

Figure 17
2014 Advertising Expenses

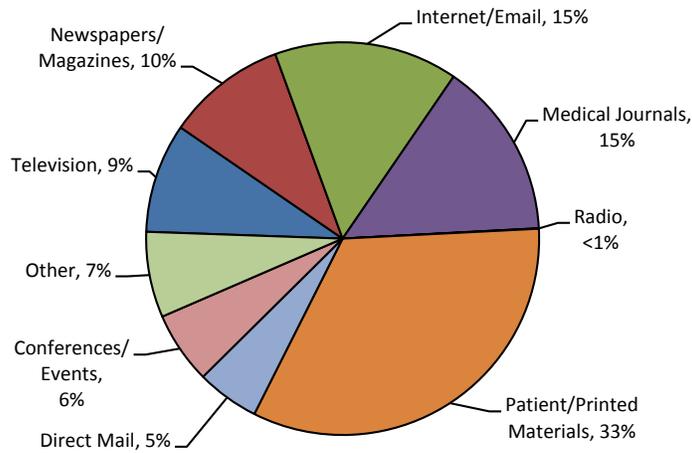
**Advertising Expenses by Medium Type,
 Total Value**



*"Other" includes Advertising reported as *Personal*, *Telephone*, and *Other*.

When considering the frequency of expenditures, the picture changes. *Patient/Printed Materials* accounted for the greatest share of advertising frequency, accounting for 33.2% of the total frequency. The next highest frequencies included *Internet/Email* (15.1%) and *Medical Journals* (14.6%). Other *Media Types* that each account for 10% or less of the total count include *Newspapers/Magazines* (9.9%), *Television* (9.0%), *Conferences/Events* (5.9%), *Direct Mail* (5.2%), and *Other* (7.1%).

Figure 18
2014 Advertising Expenses
Total Advertising by Medium Type,
Total Frequency



*"Other" includes Advertising reported as *Personal*, *Telephone*, and *Other*.

VII. Recommendations

Based on this analysis of 2014 data from AccessRx and Open Payments, we make the following recommendations. These changes would strengthen the implementation of the original goals of AccessRx, and would make the statute more consistent with the federal Open Payments reporting system. Some of the suggested changes would require amending the AccessRx Act.

1. Improve compliance with instructions.

As described in the 2015 AccessRx Impacts report, gaps and inconsistencies in reporting among pharmaceutical manufacturers are prevalent and lead to limitations in the analyses. To ensure that the District receives reports that conform to the requirements of AccessRx and accurately reflect spending patterns, strategies to improve reporting accuracy could be put in place. Prompt responses from the District of Columbia Department of Health to companies that submit incomplete or incorrect information should include a request that corrected information be sent. Ideally, companies that submit incomplete or inaccurate information would receive follow-up communication within 30 days of their initial submission. To support and encourage the most consistent reporting, we recommend the AccessRx reporting system be configured to limit responses in select columns to options detailed in the instructions, with only acceptable responses used in each category and all required fields completed.

2. Continue to collect AccessRx information, while utilizing Open Payments data to complement analysis of pharmaceutical marketing in the District.

AccessRx provides the District unique information to explore pharmaceutical marketing practices, including millions in spending from aggregate, advertising, and gift expenses not exposed by the federal Open Payments system. By adding gifts to physicians and teaching hospitals reportable to Open Payments to the AccessRx data, the DC DOH maintains the most comprehensive understanding on pharmaceutical marketing activity of any state in the United States. With a growing national focus on healthcare transparency, the District's analysis of gift trends to physicians, physician assistants, nurses and other healthcare prescribers provides information that cannot currently be analyzed by any other state. Maintaining reporting requirements allows the DC DOH to continue to analyze changing trends, and assess the impact on healthcare.

3. Make all reports submitted pursuant to the AccessRx Act publicly available, consistent with the Federal Open Payments system.

With data on gifts to physicians and teaching hospitals now publicly available by the Open Payments system, it would be appropriate to also make the information collected in the AccessRx system publicly available. Currently, the database containing AccessRx data is developed each year for use solely by the Department of Health, but the AccessRx Act requires that it remain confidential. In the interest of informed healthcare decision making, patients should have access to information about marketing efforts that may be related to their health conditions. This would also facilitate comparative analyses of the two databases.

4. Require “product marketed” information for gift expenses, consistent with Federal Open Payments requirements.

Unlike Open Payments, the District does not require reports to specify which product is being marketed. Requesting “product marketed” information for gift expenses reported to the AccessRx system would help researchers calculate how much companies spend on marketing specific drugs, and reports of this information could also help patients make more informed decisions about their healthcare, such as selecting a generic version of a drug or asking questions of a provider who suggests a new medication.

5. Require reporting by device manufacturers, consistent with Federal Open Payments requirements.

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,” resulting in the reporting of 153 companies in 2014. Comparatively, Open Payments requires manufacturers of “drugs, devices, biologicals, or medical supplies” to report expenses, which included 486 companies in 2014. AccessRx requirements should be expanded to provide a more complete picture of marketing practices in the District and to remain consistent with the Open Payment system.

VIII. Quality of Submissions

The quality of company submission was evaluated based on overall completeness and compliance with disclosure requirements. Submissions were classified as follows:

- *Complete*: All required information was provided
- *Almost Complete*: Most required information was provided
- *Incomplete*: Required information was missing
- *N/A*: No marketing expenses were reported

Using this general categorization, 93.5% of all companies provided complete submissions, a higher percentage than 2013 (86.3%). Complete submissions included all required information (e.g., date of payment, full names and credential of recipient, type of recipient, nature of payment, primary purpose of payment, and value of payment). This rating does not account for the appropriateness of responses (i.e., whether the company used the accepted terms for each category), but merely for whether the required fields are completed.

Another 3.9% of companies provided almost-complete submissions. These reports contained most of the information required, but were missing information, such as recipient details or dates. The number of submissions in this category was similar to 2013, when 5.0% of companies had almost-complete submissions.

Lastly, 2.6% of companies provided incomplete submissions; this was a slightly lower percentage from 2013, when it was 3.7%. Some important required information was absent from these company submissions, the most common being only providing a total of all gifts without a detailed breakdown of individual gifts.

Of note, eight companies provided complete submissions despite indicating having \$0 in reported marketing expenditure in the District in 2014.

As in previous years, submissions did not contain sufficient information to fully determine whether companies were using Generally Accepted Accounting Principles, but we found no indications that companies were failing to use them.

Appendix A: AccessRx Requirements

Title III of the AccessRx Act of 2004¹⁷ 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 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;

¹⁷ 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>, accessed January 27, 2016.

(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 requires¹⁸ “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...” Specific reporting requirements outlined by §403.904 include:

(a) General rule:

(1) Direct and indirect payments or other transfers of value provided by an applicable 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 (FDA) (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 total 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)

¹⁸Federal Register. 42 CFR Parts 402 and 403. <https://www.gpo.gov/fdsys/pkg/FR-2013-02-08/pdf/2013-02572.pdf>, accessed January 27, 2016.