



# Life Science Compliance *Update*

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Feature Article

## 'Tis The Season - 2015 Open Payments Highlights and Risk Management Considerations

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**Abstract:** On June 30th, 2016 CMS published the third year of Open Payments data. With more than two full years of transaction level spend data publicly available, an opportunity exists for Life Sciences companies to utilize Open Payments data as an additional tool in their technology-enabled risk management strategies.

On June 30th, 2016, CMS published the third year (second full-year) of Open Payments data for Transfers of Value (ToVs) for the period between January and December 2015 (2015 data). The 2015 data set provides details for twelve full months containing approximately 11.9 million records, attributed to over 619,000 HCPs and Teaching Hospitals, and totaling over \$7.5 Billion in ToVs to HCPs and Teaching Hospitals.

Over the past two years Life Sciences companies have used this data to identify potential compliance risks, as well as potentially gain insights into commercial business functions such as:

- Identifying activity outliers, both to internal policies and to the broader industry
- Updating Key Opinion Leader (KOL) utilization strategies to ensure engagements are executed in accordance with established or planned needs (e.g., in line with a needs-assessment or similar plan)
- Developing an understanding of peer speaker bureau composition and geographic coverage
- Identifying KOLs or Principal Investigators (PI) experienced with certain products or therapeutic areas

With this third year of data, Life Sciences companies can expand their analysis of the data to include year over year trend analysis. As the data set increases with each year of published data, the opportunity to conduct more extensive and possibly predictive analyses, based on historical performance, becomes possible.

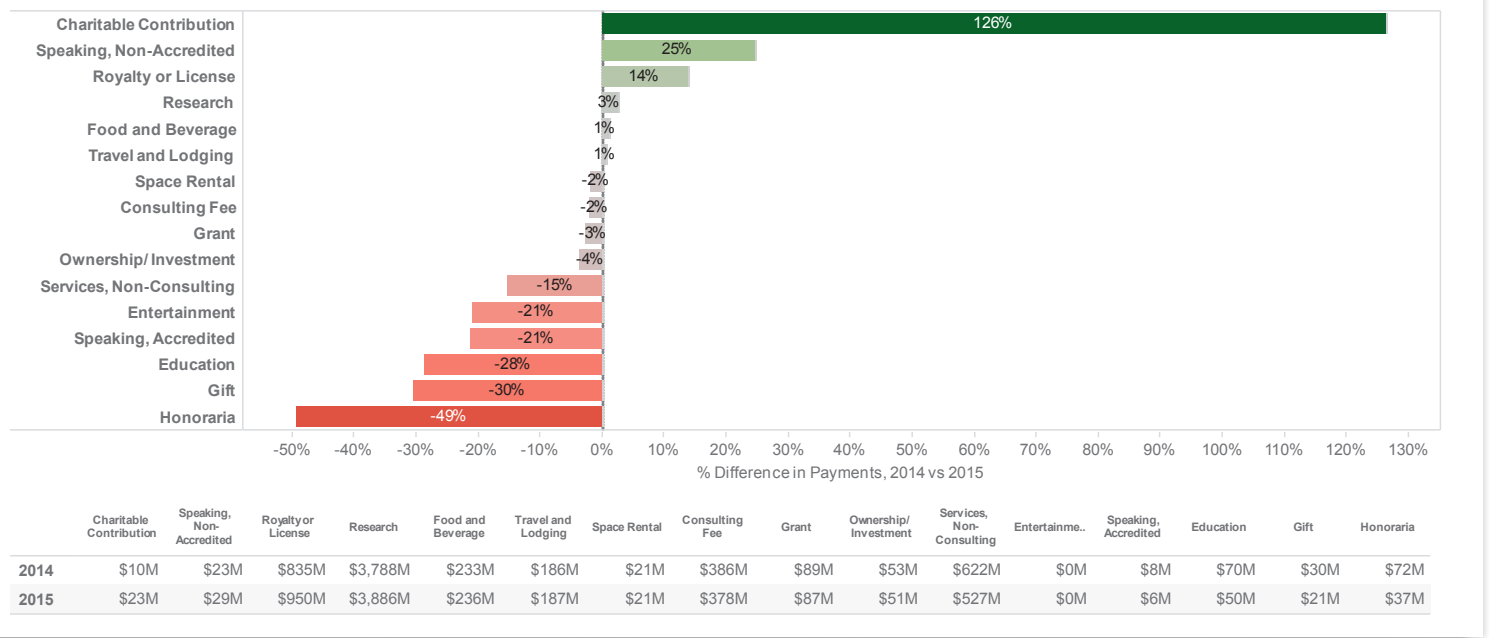
However, Life Sciences companies are not the only entities utilizing the spend data. The federal government has announced in various public settings its intention to utilize Open Payment information to cross reference activities with data from other organizations in order to manage compliance.

As stated by CMS, effective July 2014, the new system of record allows CMS to share Sunshine data with other agencies when disclosure is deemed “reasonably

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The authors of this article are consultants with Huron Life Sciences, which serves the continuum of Life Sciences organizations to deliver unique solutions that bridge the process of scientific discovery and sustainable business model creation with strategies that reduce the risks associated with regulatory and government scrutiny. If you have questions about Global Transparency, Data Analytics or any other considerations, please feel free to contact Mark Linver at 312-515-1677 or [milver@huronconsultinggroup.com](mailto:milver@huronconsultinggroup.com).

**Figure 1: 2014 vs 2015 Open Payment Trends**



necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.”<sup>2</sup> Combined with other data publications (Medicare Part-D, -B, etc.), regulators have ever increasing opportunities and avenues for investigative inquiries of providers and drug and device companies. Not only has the federal government compared and analyzed data across data sets, the press and industry watchdog groups are already cross-referencing Open Payments data with available Medicare Part D data to identify and publish payment trends, identify prescribing patterns and draw conclusions.

Further, as HHS-OIG Senior Counsel Mary Riordan stated at the recent PCC, “Companies have spent a lot of time, effort, and resources to comply with open payments reporting requirements, and I would recommend that [they] capitalize on those investments.” By analyzing Open Payments transactions, Life Sciences companies can help identify spending patterns, trends, and possible anomalies.

The following sections provide a high-level analytic view of the 2015 data and an initial trend analysis of year over year spend for the periods 2013 through 2015.

## Year over Year Trends

During the 2015 program year, there were several shifts in the types of spend reported by Life Sciences companies from the previous years. As illustrated in Figure 1 above, Life Sciences companies spending that is usually attributed to direct interactions with HCPs decreased between 2014 and 2015. For example, there was an almost 50% decrease in spend dollars categorized as Gift or Honoraria. This may represent a decrease in compensation of this type, or may be a result of Life Sciences companies choosing to classify these payments as Consulting or Speaking fees. If this represents a decrease, the following question should be asked or explored: was the decrease a result of Life Sciences companies changing their approach for engaging HCPs or was there a behavioral shift by HCPs choosing not to participate in activities resulting in honoraria?

Conversely, spend not related to direct HCP interaction increased or remained constant over the past two years. For example, ToVs for Charitable Contributions increased over 120% and ToVs for speaking for non-accredited educational programs also increased by 25%.

<sup>2</sup> 79 Fed. Reg. 32547 (Jun. 5, 2014).

| Entity Name               | Nature                  | Program Year |           |
|---------------------------|-------------------------|--------------|-----------|
|                           |                         | 2014         | 2015      |
| HCOs (Teaching Hospitals) | Honoraria               | \$617K       | \$296K    |
|                           | Gift                    | \$17,658K    | \$11,758K |
|                           | Charitable Contribution | \$9,371K     | \$18,204K |
|                           | Gift                    | \$591K       |           |
|                           | Gift                    | \$400K       |           |
|                           | Charitable Contribution | \$162K       | \$202K    |
|                           | Honoraria               | \$265K       | \$94K     |
|                           | Honoraria               | \$225K       | \$102K    |
|                           | Honoraria               | \$144K       | \$179K    |
|                           | Gift                    |              | \$0K      |
|                           | Honoraria               | \$216K       | \$78K     |
|                           | Charitable Contribution |              | \$288K    |
|                           | Honoraria               | \$81K        | \$180K    |

HCP Names  
Anonymized

It is also interesting to note that Research increased from 2014 to 2015, reversing the trend seen between Aug-Dec 2013 and Aug-Dec 2014 which showed a decrease in these types of payments.

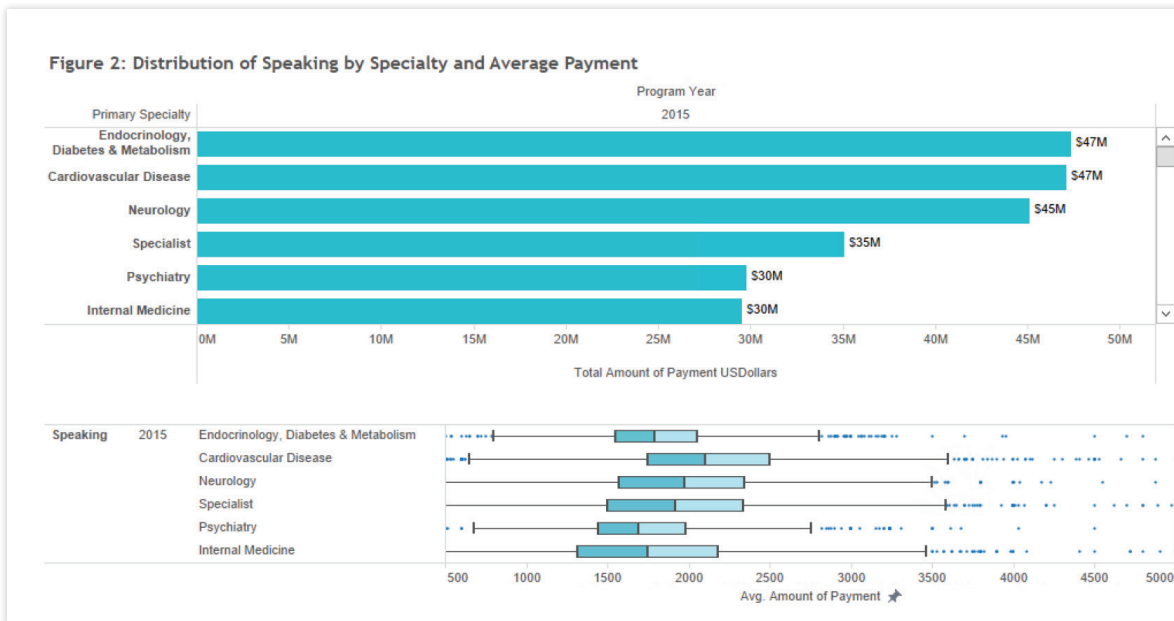
To further investigate the shift in spend, an analytic view illustrating the top ten recipients of gifts, honoraria and charitable contributions for the years 2014 and 2015 was created and is provided below. As the analytic view below illustrates, at an HCP detail level, amounts paid to HCPs classified as Honoraria decreased (for the majority) while payments to HCPs classified as Charitable Contributions, most normally associated with spend to Teaching Hospitals, increased. For example, reported spend of gifts to HCOs, decreased by ~\$6M while Charitable Contributions increased by ~\$9M. A one-year observation doesn't indicate a trend but helps identify activity or shifts in spend patterns that could indicate a need for further investigation or analysis.

## Analyzing 2015 Open Payments Data to Manage Risk

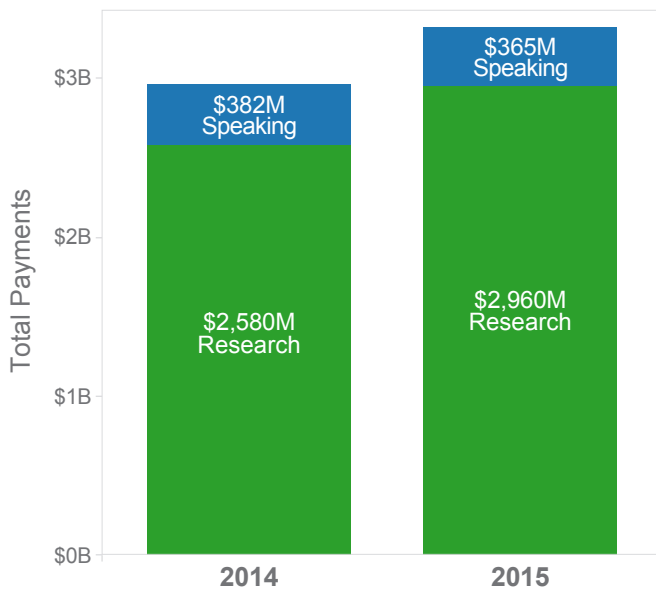
As datasets become more robust, organizational stakeholders beyond the compliance department, may request interpretations of the spend data to gain insights into areas such as speaker bureau monitoring, consulting and research composition. While general statistics on Open Payments can show trends in the data, additional analysis is usually required to explain trends or anomalies.

For example, from a compliance perspective, analysis views can be constructed to illustrate how payments are distributed over time and can be reviewed for the frequency of payment in order to help identify outlier events that could impose risk or violate policy, and may require additional root cause analysis. The analysis view shown in Figure 2 below illustrates those speaking payments made to HCPs that were greater than \$500 and less than or equal to \$5,000. By reviewing data by specialist (type), payment amount and payment frequency, Life Sciences companies have been able to conduct the following analyses:

- Review speaking and consulting data in order to identify outliers in payments to HCPs which may be indicative of violations of internal policies and broader industry guidelines. For the diagram below, outliers may be identified by the payment amounts



**Figure 3:** Total Payments to HCPs Engaged to Speak and to serve as Principal Investigator for the same Product



and a number of payments that were greater than the median payment identified in the “Average Amounts/Payments” chart.

- Benchmark HCP fees and confirm Fair Market Value (FMV) ranges. As illustrated in the figure above, endocrinology and cardiovascular specialists received the highest compensation in 2015. The average speaker payment for cardiovascular specialists was approximately \$1,600. Utilizing this information, Life Sciences companies are able to compare internal payments to internal policies, budgets and established FMV ranges.

In addition to identifying average payment and analyzing policy/FMV compliance, spend data is used by life sciences companies to help identify possible relationships that HCPs may have with Life Sciences companies and determine appropriateness to engage with those HCPs. For example, Figure 3 above illustrates the fees paid to HCPs that provided speaking and research services to Life Sciences companies for the same product. Although an overlap exists, this certainly does not prove a conflict of interest exists, as it is possible for Principal Investigators to speak after conducting research given their familiarity with a compound. It does represent a potential area of scrutiny particularly in the context of

public perception. Identifying an overlap is one variable that should be considered in selection HCPs in the Needs Assessment process.

## Creating an Analysis Platform

The risk-management insights that can be found in Open Payments data are significant, and the focus towards utilizing the data for internal analysis is only the beginning. With more than two full years of transaction level spend data publicly available, an opportunity exists for Life Sciences companies to utilize Open Payments data as an additional tool in their technology-enabled risk management strategies.

However, creating an analysis platform is easier said than done. It usually requires more than simply reviewing online data provided on the public website. The effort to access and load data into an analysis model is complex and should be approached as a major project undertaking. Actionable goals and measures of success should be established from the onset. Careful consideration must also be paid to organizational dynamics.

Finally, as Open Payments touches multiple business units (Sales, Research, Compliance, Marketing, Medical, etc.), having a broad range of stakeholders involved in reviews of this information can often generate significant insights that can result in improvements across the business while continuing to maintain an effective compliance program.

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