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Open Payments Driving Adjustments in HCP Engagement Practices

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The Open Payments (aka “Sunshine”) Act requires pharmaceutical and medical device manufacturers to annually report their direct and indirect payments or other transfers of value (“ToV”) to healthcare professionals (“HCP”) and teaching hospitals to the Centers for Medicare and Medicaid Services (“CMS”). The first data set, for August - December 2013 spend, was submitted to CMS in March 2014 and published in September 2014. During this first submission, manufacturers encountered many issues with submitting the data, which led to a published data set that was incomplete. Over a third of the data was either “de-identified” at the physician level or removed from the database entirely due to data integrity issues.

On June 30th, 2015 CMS published the second year of program data containing transactions for the period between January and December 2014 (“2014 data”). The 2014 data set provides details for twelve full months containing approximately 11.4 Million transactions, attributed to over 600,000 HCPs and Teaching Hospitals, and totaling \$6.4 Billion in ToV to HCPs and Teaching Hospitals. On June 30th, CMS also published the missing and/or de-identified data from the initial 2013 reporting period.

With more than a full year of transaction level spend data publicly available, an opportunity exists for Life Sciences companies to utilize the Open Payments data in order to identify potential compliance risks, as well as potentially gain insights into commercial business functions. For example, data analysis can assist with:

- 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 Key Opinion Leaders (“KOLs”) or Principal Investigators (“PI”) experienced with certain products or therapeutic areas

The following examples demonstrate how manufacturers and GPOs are utilizing spend data to enforce compliance, minimize risk and optimize operations.

Analyzing Open Payments for Compliance and Commercial Insight

As datasets become more robust, stakeholders of organizations may request interpretations of the spend data to gain insights into speaker bureau monitoring, consulting and research composition as well as geographic coverage.

For example, from a compliance perspective, analysis views can be constructed to illustrate the distribution of payments over time and reviewed for frequency of payment. Analyzing payments over time can help identify outlier events that may require additional root cause analysis. This payment analysis can be expanded to compare payments made in order to:

- Identify the risk of exceeding yearly caps on meals
- Compare the number and cost of executed speaking and consulting engagements with the planned budget and expectations
- Benchmark HCP fees and confirm Fair Market Value (“FMV”) ranges by comparing payments to HCPs
- Optimize the use of HCPs by comparing the overlap of HCP utilization across products or companies

The following figure illustrates the potential utility of Open Payments data in comparing spending practices between two manufacturers during 2014.

Specifically, this graph contrasts how manufacturers differ in the frequency and amount of physician speaker fees associated with two competing products. The manufacturer of Alephtru,¹ for example, not only utilized speaker programs to a greater extent than the manufacturer of Destex, but has fees over a much wider range of value and pays certain speakers far more. One doctor for the Alephtru manufacturer earned \$110,000 for 30 separate engagements; another spoke at 47 engagements for a total of \$89,000.² On the other hand, the highest paid physician on the Destex list earned \$50,000 for 22 arrangements, while the vast majority spoke at eight or fewer engagements for less than \$20,000 on the year.

¹ The actual drug names here have been replaced and retitled with two pseudonyms, “Destex” and “Alephtru.”
² While we use the term “engagements” here, CMS gives manufacturers flexibility in how they report payments made over multiple dates in the same Nature of Payment category. (See FAQ10086). Thus, one limitation to the Open Payments analysis is that it may be hard to decipher whether a manufacturer is simply combining numerous engagements into one single lump sum for purposes of Open Payments reporting.

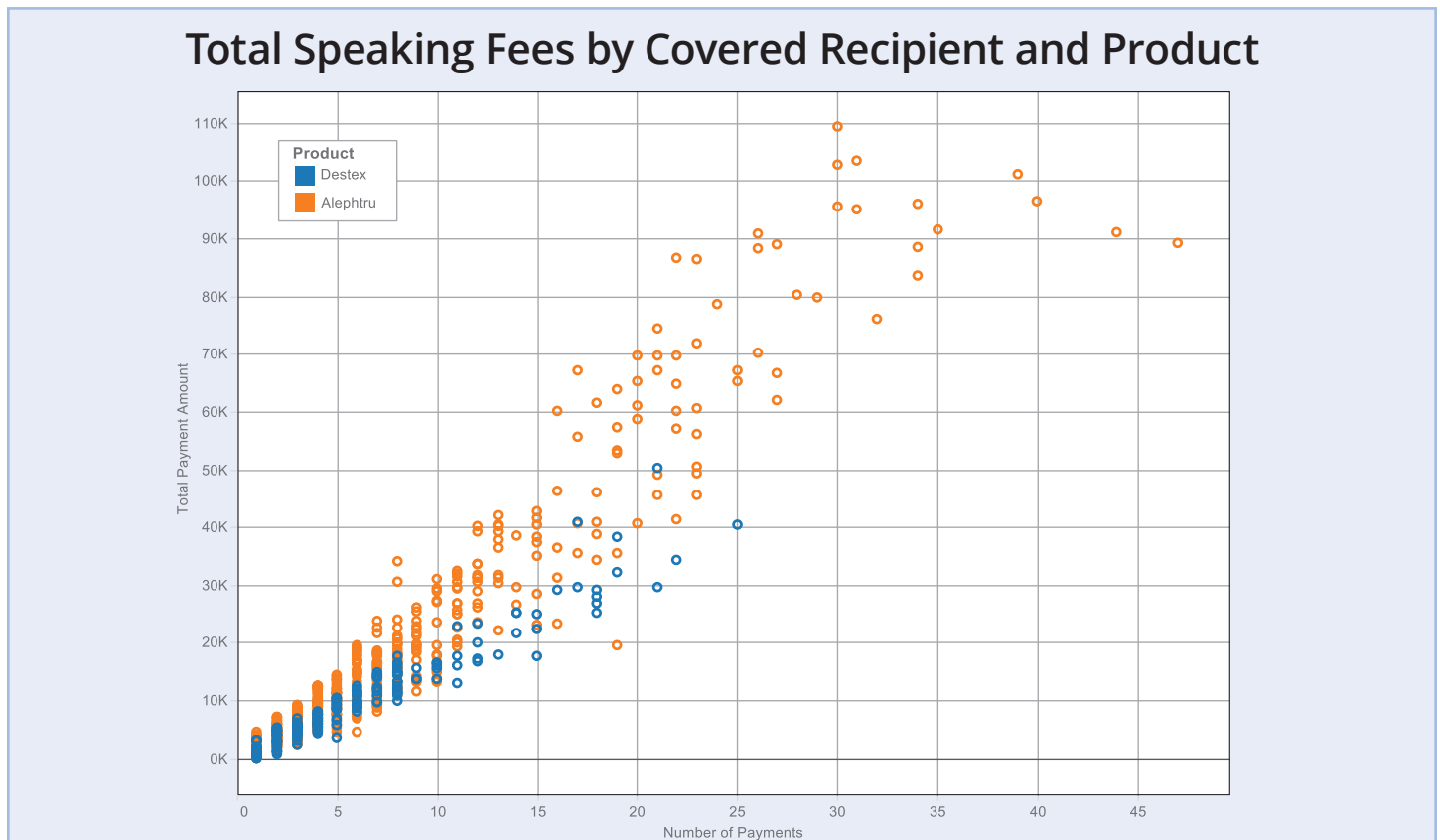


FIGURE 1: Comparison of spend practices for two competing products, which highlights the differences between amounts paid for speaker bureau engagements.

In addition to revealing potential outliers, the Open Payments data can be viewed to optimize resource allocation. For example, by analyzing travel patterns for HCPs performing Fee for Service engagements opportunities may exist to:

- Optimize the use of local or nearby resources
- Plan cost effective travel
- Maximize HCP utilization and geographic coverage for planning speaker bureaus

The figure below provides an example of how speakers might be employed across geographic areas. The figure illustrates the number of speakers residing in each state that normally are engaged for the listed product. For example, Alephtru has a greater focus in Texas than Destex, with 57 and 15 speakers respectively.

Speaker Program Sizing by Product

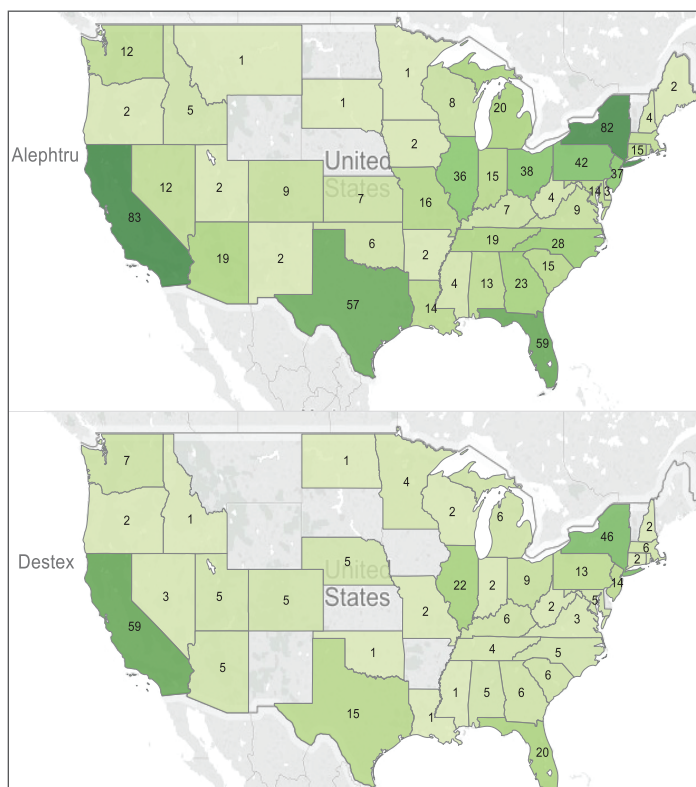


FIGURE 2: Illustrative view of speakers residing in geographic areas for two competing products across the U.S.

Creating an Analysis Platform

Analyzing Open Payments data can be useful; however, creating an analysis platform usually requires more than simply reviewing online data provided in the public website. The effort to access and load data into an analysis model is complex and should be approached as a well-planned effort. Actionable goals and measures of success should be established from the onset. Careful consideration must also be paid to organizational dynamics. As Open Payments touches multiple business units (Sales, Research, Compliance, Marketing, Medical, etc.), all stakeholders should have a seat at the table. Instead of undertaking these efforts in a siloed fashion, a cross-functional team can often generate significant insight. This integrated approach, however, must be balanced with the need to adhere to applicable regulations and policies which is where the compliance functions role comes into play.

For example, when creating an analysis platform, consideration of the types and purposes of the data visualizations should drive the design of the underlying data views used to create the visualizations.

Factors that should be considered for viewing the data include:

- Comparisons should be made between companies with similar portfolios and/or products in similar stages of their lifecycle.
- Consideration should be made to the corporate structure of the reporting entity (multi-national corporation, domestic subsidiary, join-venture, etc.).
- Attention should be paid to the points of view of various stakeholders who have an interest in the desired outcomes, and a fine balance must be drawn to how the information will be communicated and used (Compliance, Sales / Marketing, and Research). Promotional strategies derived without consideration for regulatory controls can result in compliance risk.

- Compliance teams should be actively involved in all phases of these projects, not only for their own desired insights, but to also guide commercial stakeholders through the legal issues surrounding Open Payments and engagement of healthcare professionals.
- Approach for consolidating and grouping data elements for “roll-up” and “drill-down” visualizations needs to be determined prior to designing and implementing the data analysis platform. Key issues that should be addressed include the allocation of expenses to multiple products, the rollup of subsidiaries to a single parent company, aggregate vs. detailed reporting, and how the reporting categories are typically used by peer companies being evaluated.

Analysis Best Practices and Growing Trends in Transparency

The 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. From a regulatory perspective, the government may 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 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.”³ 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.

In addition to utilizing United States spend data, opportunities will exist to capture and utilize spend data to address compliance and operational issues in Europe and eventually on a global scale. For example, many manufactures are working toward complying with the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) disclosure requirements, which are often times more onerous than U.S. Open Payments requirements. While considering privacy and consent requirements, data analysis can be conducted on reported data to help manufacturers integrate compliance controls while optimizing budgets and operations.

Although the global regulatory requirements around transparency and disclosure are rapidly growing for pharmaceutical and device manufacturers, these same data sets provide a rich environment for benchmarking and insight—provided these analyses are conducted in a carefully planned, methodical approach. In future publications we will explore case studies and best-practices when conducting these analyses, and revisit in detail the ever-growing set of publically available data and its potential applications.

³ 79 Fed. Reg. 32547 (Jun. 5, 2014)

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