

Aggregate Spend: Mitigating Compliance Risks with Compliance-Grade Data

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The Transparency Landscape

The United States is leading the way toward increased transparency by life sciences companies and healthcare organizations. In recent years, six states have enacted legislation that requires certain life sciences companies to report details related to financial interactions with healthcare professionals and healthcare organizations. Some states have also imposed spend limits, constraints around such activities as in-office meals, and detailer registration and education requirements.

Then, in March 2010, President Obama signed the Patient Protection and Affordable Care Act ("PPACA"). Section 6002 of the PPACA embodies the Physician Payments Sunshine Act ("Sunshine Act"). This legislation, co-sponsored by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI), requires drug, device, biological, and medical supply companies to report a wide range of payments to physicians and teaching hospitals in all states.¹ The first report is due March 31, 2013; it will cover data for the fiscal year 2012.

¹ Senator Grassley's office has indicated that the legislation may be revisited to determine whether the scope of the reporting requirements is broad enough to meet Congress' goals.

Plaintiff attorneys link to Dollars for Docs: “Call your local MedMal attorney to find out if you have a claim resulting from your physician’s conflicts of interest.”

With this federal legislation, the trend toward greater transparency has taken on a new urgency. Reporting Companies that had previously made do with cumbersome *ad hoc* manual reporting processes are reconsidering that approach. As in-house professionals learn more about the complexity of implementing a viable enterprise-wide Aggregate Spend database

solution, there is a dawning realization that preparation for the 2013 federal report has to start now.²

In this article, the third in Life & Moran’s Transparency and Disclosure White Paper Series, we look at the importance of compliance-grade data as the backbone to your Aggregate Spend solution.

Increased Scrutiny

Until recently, Reporting Companies could only speculate about the impact of releasing healthcare professional spend data on the broad scale required under Sunshine. Then along came ProPublica.org and the Massachusetts Department of Health and Human Services.

ProPublica: A Preview of Sunshine

ProPublica, a non-profit news organization, is out for another Pulitzer Prize.³ Their recent series, “[Dollars for Docs](#),” went viral starting October 21, 2010, when they published data and related analyses of cash payments made to more than 17,700 doctors by seven currently reporting companies.⁴ The project was carried out in partnership with other media outlets, including NPR, PBS, the Chicago Tribune, and the Boston Globe. Other newspapers and blogs around the country have fanned

With such revelations, the breadth and vehemence of the on-line response is sobering. Government investigators are salivating, and the Plaintiff’s Bar is shopping for a new boat—a big one.⁵

The companies profiled in the series responded to questions from ProPublica about their healthcare professional vetting practices. Five of the seven confirmed that they rely on self-reporting and federal databases, and do not regularly look at state Medical Board websites for disciplinary actions. That is now changing, and companies are rapidly re-assessing their consultant vetting processes.

Some of the doctors profiled in the series helped spur the viral response

- In 2004, Dr. Donald Ray Taylor admitted that he had given young female patients rectal and vaginal exams without documenting why, and exposed women’s breasts during medical procedures. When asked by a hospital official to explain his actions, he allegedly responded, “Maybe I am a pervert, I honestly don’t know.” Dr. Taylor was the third highest-paid speaker for one of the companies, earning \$142,050 in 2009 and \$52,400 through June 2010.⁵
- Dr. William D. Leak, a pain physician, was found by the Ohio medical board to have performed “unnecessary” nerve tests on 20 patients, and subjected some patients to “an excessive number of invasive procedures, including injections of agents that destroy nerve tissue.” Dr. Leak was paid \$85,450 by one Reporting Company in 2009 as a promotional speaker and advisor.⁶
- A Duke University assistant professor, Anil Potti, has been on paid leave since the summer of 2010 for allegedly padding his resume and falsely claiming to have been a Rhodes Scholar. He received \$86,950 in 2009 and 2010.⁷

² For more information about what companies can do now to prepare for the Sunshine Act, see “[Disclosure and Transparency White Paper Series, Aggregate Spend: Preparing for Sunshine](#).” This paper also includes a helpful summary of the Sunshine Act.

³ ProPublica is a non-profit corporation which describes itself as a newsroom that produces investigative journalism in the public interest. In 2010, it became the first online news source to win a Pulitzer Prize for its coverage of Hurricane Katrina

⁴ Eli Lilly, GlaxoSmithKline, AstraZeneca, Pfizer, Merck, Johnson & Johnson, and Cephalon.

⁵ “[Drug Companies Hire Troubled Doctors As Experts](#)” National Public Radio, (visited November 30, 2010).

⁶ “[Doctors Push Drugs for Dollars](#),” AARP website, (visited November 30, 2010).

⁷ “[Dollars for Docs hits home](#),” Durham, NC Herald Sun, (visited November 30, 2010).

⁸ A quick Google search of Plaintiff attorney medical malpractice websites and blogs revealed numerous posts mentioning the federal Sunshine provisions as helpful to building and winning cases. Plaintiffs’ attorneys are urging potential clients to question their trust in physicians and to question the therapy they received.

The publication of spend data in 2013 under the Sunshine Act will only increase public and governmental scrutiny. In light of the furor created by the ProPublica disclosure, Massachusetts data, and revitalized and energetic government investigation, life sciences companies are re-evaluating their technical and information requirements. With this education, comes the realization that an Aggregate Spend solution, designed to meet the reporting requirements of the various state disclosure and the Sunshine Act reports, has applications and considerations beyond merely getting the report out. It requires a careful consideration of the data that drives the reports, including accurate “compliance-grade” data.

Massachusetts: Too Much Information

Massachusetts, adding to the furor created by ProPublica’s “Dollars for Docs,” [released spend data submitted by over 400 Reporting Companies for the period July 1 to December 31, 2009](#). Included on the Massachusetts website is an Excel spreadsheet containing the names and email addresses of more than 450 individuals at Reporting Companies who submitted the data, including administrative staff. Massachusetts suggested that Reportable Recipients could contact these individuals if they “believe the data reported ... is incorrect.”

Government scrutiny

On October 26, 2010, during a speech to industry about fraud, waste, and abuse, Tony West, Assistant Attorney General (Civil Division, Department of Justice), reaffirmed that healthcare fraud is a top priority for the Attorney General’s office, noting that future efforts would include more fraud investigation, higher fines, larger judgments, and longer sentences.

Eric Blumberg, FDA deputy chief for litigation, reiterated FDA’s intent to target pharmaceutical executives for misdemeanor prosecutions. “It’s clear we’re not getting the job done with large, monetary settlements,” said Mr. Blumberg. “Unless the government shows more resolve to criminally charge individuals at all levels in the company, we cannot expect to make progress in deterring off-label promotion.... If you’re a corporate executive

or are advising a corporate executive, now is the time to comply. That conduct may already be under the criminal microscope.”

These pronouncements were followed by the [indictment, on November 8, 2010, of a former attorney for GlaxoSmithKline](#) on charges of obstructing justice and making false claims to federal investigators.⁹

FDA can also ban individuals from participating in federal healthcare programs. In addition to the Department of Justice, the Office of the Inspector General (OIG) at the Department of Health and Human Services (DHHS) has also announced that they will pursue executives as individuals, under a strict liability provision of the law.¹⁰ In 2007, Purdue’s Michael Friedman, Chief Operating Officer and then Chief Executive Officer, Dr. Paul Goldenheim, Chief Scientific Officer, and Howard Udell, General Counsel, were sentenced to probation and collectively paid \$34 million in fines (in addition to the company’s \$600 million fine).

In January 2009, the [DHHS OIG reaffirmed the exclusion](#) of the three former executives from all federal healthcare programs for 15 years. And in November 2010, Marc Hermelin, chairman of the board of KV Pharmaceuticals, was banned by the DHS OIG from participating in federal healthcare programs. Mr. Hermelin is the first pharmaceutical executive who has not been convicted of a crime to be so banned. His exclusion had potential repercussions for the company, as well, since federal healthcare officials have stated that the government will not conduct business with companies that employ such banned individuals.

Accurate, compliant reports

Clearly, we have entered a new era of accountability and transparency. The publication of spend data in 2013 under the Sunshine Act will only increase public and governmental scrutiny. In light of the furor created by the ProPublica disclosure, Massachusetts data, and revitalized and energetic government investigation, life sciences companies are re-evaluating their technical and information requirements. In-house compliance professionals are rapidly garnering an education in areas that had once been the sole purview of commercial and marketing employees.

With this education, comes the realization that an Aggregate Spend solution, designed to meet the reporting requirements of the various state disclosure and the Sunshine Act reports, has applications and considerations beyond merely getting the report out. It requires a careful consideration of the data that drives the reports, including accurate “compliance-grade” data.

Again, we can look to another article spawned by Dollars for Docs to see why such accurate and compliant data is essential. A [Minneapolis Star-Tribune story](#) compared data reported to Minnesota with that collected from the Dollars for Docs database. The reporters found numerous discrepancies:

- A Minnesota pain specialist was reported to have received \$364,828 in 2009 from four companies through the Minnesota database. The Minnesota report stated that he had received \$67,353 from Eli Lilly in 2009, but Lilly’s website indicated that he had received \$74,050 for the same period.
- Pfizer reported to Minnesota that it had paid a physician \$1,770 for all of 2009, but the Pfizer website reported \$43,827 to the same physician in the second half of 2009.
- Wyeth inadvertently attributed a large payment to an individual doctor that should have been attributed to the doctor’s employer as a clinical research payment.

Some, but not all, of these discrepancies may be attributed to different or conflicting reporting requirements. But three of the companies stated that they had not been aware of the discrepancies until contacted by ProPublica, and each submitted a revised report to Minnesota.

⁹ The Plaintiff’s Bar, shopping for its bigger boat, has picked up on this, as well. See “[GlaxoSmithKline Lawyer Lauren Stevens Charged With Federal Crimes: Miami, Can We Blindly Trust the Drugs We Take?](#)” (visited November 20, 2010)

¹⁰ 21 U.S.C. § 301 et seq.



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To be “compliance-grade,” the Recipient Master must be capable of flexible functionality in three key areas:

1. Finding and cleansing erroneous Recipient records without losing associated data. Consider:
 - A master file that has two or more IDs for a single Recipient. This “false negative” can result in over-reporting spend against the Recipient, causing variance issues, potential fines governed by state and federal limitations, as well as the over-inflation of the Recipient’s 1099 report to the IRS.
 - Two or more Recipients have the same ID. This “false positive” may result in fines against the Reporting Company for exceeding incorrectly aggregated spend limits for an individual Recipient.
2. Validating manual entries made by employees so that titles, specialties, addresses, and other contact touchpoints are accurate. Since we know from the ProPublica and Massachusetts publicity that healthcare professional spend will be carefully scrutinized, Reporting Companies must take particular care to ensure that manually entered and potentially unmatched Recipient records are identified and validated, and correctly included in the state and federal Aggregate Spend reports.
3. Flexibly expanding with enriched data as new Recipients and their affiliations with healthcare facilities (for example, hospitals) are associated with spend activities.

Compliance-Grade Data

One of the challenges that Reporting Companies face in implementing an Aggregate Spend solution is inadequate customer master databases. Most companies today maintain dozens of internal and external systems to facilitate and track expenditures. Because these disparate systems frequently do not contain a common identifier for the recipients of the spend, there might be a number of variations for the same recipient within the company; for example, Dr. Jane Roberts; J. Roberts, MD; Dr. Roberts; and so on. This same doctor may also have multiple addresses associated with her name across systems, and she may practice in multiple states. How, then, do you accurately track spend related only to Dr. Jane Roberts, and not Dr. Roberts’ daughter, Dr. Janice Roberts? Each system should be on the same page with a clean Recipient Master that provides detailed and accurate customer data across *all* systems.

A compliance-grade Recipient Master powering a Reporting Company’s Aggregate Spend solution should provide a

complete and accurate view of current spend, enabling the resolution of compliance and operational gaps before they become a drain on internal resources, or worse.

When evaluating a Recipient Master, keep in mind that some reporting and policies require not only data related to healthcare professionals, but healthcare organizations as well. Compliance-grade data should also allow you to account for affiliations and non-healthcare providers who receive spend, such as Reportable Recipient employees. Carefully tracking affiliations may also remove the risk of misreporting spend, such as the mis-attributed clinical trial payment to the Minnesota doctor.

Your Recipient Master data vendor should describe how their solution will ensure that the data will be cleansed, validated, matched, and properly assigned to each spend amount by category in accordance with current and future state and federal laws, as well as your organization’s internal policy.

Aggregate Spend and Compliance Monitoring

ProPublica’s “Dollars For Docs” series provides further justification for making sure that your data is compliance grade. Of special concern is the public misperception that life sciences companies hire healthcare professionals to educate on behalf of the company without regard for the healthcare professional’s qualifications. Some of the transgressions cited by ProPublica run the gamut from accusations of professional misconduct, to disciplinary actions by state boards, to criminal convictions.

Reporting Companies can take steps now to review their current healthcare professional consultants, and then take further steps to continuously monitor that status through policies and procedures for reviewing consultants who are hired in the future.

A compliance-grade Recipient Master provides compliance professionals with the essential tools for determining whether further insight into a Reportable Recipient may be justified. To enable such a review,

Specific considerations when looking for compliance-grade Recipient data interaction with an Aggregate Spend solution include:

- **What processes and assets are used to secure compliance-grade data to enable accurate reporting?**
- **Are multiple sources of data used, scrubbed, and reconciled before the Recipient data is used for reporting? What are the sources and why are they dependable?**
- **Is *ad hoc* spend tracking enabled by the Recipient Master? Are user alerts active or passive?**
- **Confirm that the selected reporting system can support the data feeds and the reporting requirements. For example, Microsoft has confirmed that SharePoint-based systems are not appropriate for complex solutions.**
- **If a commercial Recipient Master is part of a bundled Aggregate Spend solution, what is the product's roadmap over the next three years? This is especially important as regulations develop to govern the application of the new federal law.**

the compliance-grade Recipient Master must be fully enriched with:

- All known licenses and addresses across state boundaries;
- All known industry identifiers, such as DEA, ME, and NPI numbers;
- State-based special identifiers, such as the Massachusetts identification numbers.

For the Reporting Company's speakers and Key Opinion Leaders, such data should be supplemented with a review of state and federal government sanctions and warning letters, past and on-going civil and criminal actions, FCPA conflict checks, and a verification of claimed journal article authorship. The Recipient Master that includes such sanction information, as well as Medicare and Medicaid inclusion/exclusion flags, are truly compliance grade, and can be used not only for Aggregate Spend reporting applications, but also for more efficient and effective targeting and detailing strategies and tactics.

Summary

Reporting Companies are now entering an entirely new compliance landscape. The implementation of an Aggregate Spend solution covers a number of disciplines with which the compliance professional has not heretofore addressed. The new vocabulary alone can be daunting: SQL databases, ETL, Data Mart, SaaS, Cloud, ERP, T&E, CRM, Recipient Masters, and so on. As one industry veteran put it, implementing Sarbanes-Oxley was a cakewalk compared to Aggregate Spend.

Your data provider—current or prospective—should be prepared to not only educate you in this area, but also explain how your job can be made easier by applying compliance standards and practices to the data that goes into, and formalizes, your Aggregate Spend reports.

We hope that this White Paper series is useful in your continuing Aggregate Spend education. We welcome your comments and requests for further information.



Conveniently, much of the data required under the Sunshine Act (and the various states) for spend recipients is also required for other state and federal regulatory compliance. As a result, Recipient Master data that is also used by providers, pharmacies, and payers is often rigorously updated.

Smaller companies should be aware that commercially available Recipient data products may be scalable to the company's actual customer uses and data requirements. This allows smaller companies to enjoy the benefits of the complete and effective compliance program normally available only to larger companies.