

rates of drugs and devices, and manufacturer transfers of value to physicians—are distinct from each other, they have the potential to be paired together. It is not hard to imagine a prosecutor connecting the dots between a physician who is utilizing a device at a higher than normal rate, and that physician receiving a large quantity of meals, consulting fees, or gifts. In fact, reporters have already compiled an interactive tool that identifies doctors who have prescribed \$500,000 or more of a drug and have also received money from a drugmaker.¹⁸ While there are certainly legitimate reasons for why a physician would rank highly in both categories, the government has already come to a powerful conclusion.

Indeed, prosecutors at a number of conferences this year have indicated that these new data streams allow the government to track outliers in prescribing behavior. The U.S. attorney panel at the 2015 Compliance Congress for Medical Device and Diagnostics, for instance, indicated that the DOJ's ability to find a “needle in the haystack” is much better than now than in the past. Using the data allows them to track situations where doctors are implanting medical devices of a certain type where the area's demographics do not appear to support that level of use.

One question device manufacturers had is whether the government would trace a doctor's abnormal device utilization behavior back to, for example, a stent manufacturer. Would DOJ hold the medical device manufacturer liable for having so many more sales to that doctor than to other doctors? The panel stated that more than likely the government would be going after the doctor in that situation, but only up to a certain point. Prosecutors' chief concern is unnecessary invasive medical procedures—these both defraud the government, but more importantly put patients at risk. These cases are prosecutors' “bread and butter,” noted the panel. “If we find examples where we can show that people are going under the knife for reasons that are not medically justified, we are going to track that back as far as we can.”

Furthermore, prosecutors expect that companies already have processes in place to monitor their customers who purchase and/or utilize devices—both from a business perspective and a risk-management perspective. As a result, the government may soon expect that manufacturers monitor payment trends

not only for compliance with the Sunshine Act, but also for other healthcare compliance reasons to identify potential risks or signs of improper business practices.

The Importance of the Front End of Transparency

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There is a concept in the world of innovation research that distinguishes the front end vs. the back end. This model is very useful because it helps separate the phases of innovation into two large blocks of activity that are quite distinctive in terms of needs, priorities, processes and even mindsets. The “front end” is comprised of the research, discovery, ideation and design processes that make it all possible; whereas the “back end” is all about execution, i.e. the various strategies and activities that take a product or service from idea to market. In biopharma, specifically, the front end includes the all-foundational basic research, product development and clinical research, whereas the back end includes manufacturing, marketing, selling, support services, and more.

A similar model can be described about “transparency.” A great deal of effort and investment has been spent in the last few years—not only in the US but globally—to quickly build capabilities to collect and report physician transfer-of-value data required for public disclosures or for reporting to various authorities.¹⁹ Most of these efforts have been towards the end of the timeline, or the “back end.” This is understandable given the urgency of reporting and the complexity of legacy and source systems and databases.

Now that some of this year's urgency is behind us and we are learning more about where the gaps are, however, we can and should spend more time thinking about “the front end of transparency,” i.e.

¹⁸ “Drugmakers funnel payments to high-prescribing doctors,” *Modern Healthcare* (May 23, 2015) available at <http://www.modernhealthcare.com/article/20150523/MAGAZINE/305239987/drugmakers-funnel-payments-to-high-prescribing-doctors>

¹⁹ Companies operating internationally, for example, must consider the U.S. Physician Payments Sunshine Act (Section 6002 of the Affordable Care Act), the EFPIA Disclosure Code, as well as transparency laws in France and Australia, among others.

The Back End of Transparency



the more important foundational elements to the whole enterprise.

The Back End is where data integration (collection and validation) and reporting take place. Transactions are pulled from a variety of source systems, data is matched against unique HCP and HCO identifiers, and the data is cleaned, validated and tested.

Once there is a high level of confidence that the reports can be certified, they are then submitted to the proper authorities. Following disclosure, there is a phase of dispute resolution that enables recipients, i.e. HCPs and HCOs, to review the disclosed data or request corrections that are warranted. This process offers physicians, for example, the chance to inspect their associated payments or transfers of value before the data is disclosed on a public website.

During analysis and reporting work, companies often discover missing data, outliers, exceptions, or spending patterns that are inconsistent with management expectations. Unfortunately, the Back End is ‘after the fact’ and, except for cleaning and correcting, there is very little that can be done about interactions and transactions that happened months earlier.

This problem is large enough with companies’ own legacy systems and processes, but gets more complicated with data that is collected and submitted by third parties. This data is usually not validated at the point of data entry, and is characteristic for being incorrect or having missing components.

Locating data integrity problems only at the Back End has consequences:

- Data stewardship and cleansing can be difficult, costly and time-consuming. Companies have spent thousands of hours and tens of thousands of dollars addressing this in the Back End.
- Even with all this effort and expense, some of the gaps are uncorrectable and end up being reported, creating legal, perceptual and/or customer-relationship risks.
- Often the time available in the Back End—end-of-timeline, by definition—is so short that even more errors and omissions can be introduced.

The gaps most frequently seen at this stage, and too late to correct, include:

- Inconsistent use of robust fair market value (FMV) rate methodologies
- Inconsistent use of key opinion leader (KOL) scoring methodologies, which enable consistent payment structures
- Missing contracts
- Incomplete/ Inaccurate data entry
- Poor Master Data Management – complicating recipient identification and attribution efforts
- Lack of attention to aggregate spend caps; for example, company meal limits, or state gift bans (i.e. Massachusetts)
- No or deficient background checks
- No consent on file or a change in consent, in countries where HCPs must consent to reporting
- Internal/organizational issues, such as who is responsible and accountable for what in the end-to-end process

The Front End of Transparency



Virtually all of the gaps identified in the Back End and listed above can be prevented or resolved by paying adequate attention to the Front End. These are the upstream policies, processes and events that, if not handled properly, can have significant downstream consequences.

In the past few years, the Back End has been dealing with data obtained from upstream legacy policies, systems and processes that were designed and implemented before many of the today's transparency requirements came to be. In some cases, some of these have been adjusted and patched to accommodate these earlier systems; however, these quick fixes are likely not sustainable in the long run as business becomes more and more complex

There are many areas that can and should be addressed in the Front End. And this should take place right now, early in the spend year, when activities are happening but well before there is a need to collect the data. Here are three core ones:

Policies and SOPs:

Most companies have done a good job in ensuring policies and standard operating procedures (SOPs) are aligned with regulatory requirements. The problem arises when those policies are difficult to locate or understand; or where there are training gaps or the policies are not enforced. There is nothing worse than having a good policy that the organization doesn't understand or simply does not follow.

Tips:

- Review relevant policies and SOPs to ensure they are accurate, complete and clear.
- Ensure all relevant employees are trained on the policies, and re-trained periodically. Also, ensure

proper communication and training as policies are changed and new ones are added.

- Ensure relevant employees have quick tips, summaries or cheat-sheets to simplify their application.
- Don't forget to review and train all third parties and agencies who may spend on behalf of the company or organize activities and events where the standards are relevant.
- Consider certifying third parties to this effect, i.e. do they have the proper SOPs and processes to enable clean and complete data end-to-end?
- Ensure all systems and processes dependent on these policies are up to date and robust, including: FMV calculators, contracting systems, master databases, KOL stratification processes, financial support systems (grants, contributions) etc.
- Do what it takes to ensure enforcement, including the establishment of periodic monitoring and sub-certification.

Decisions to Fund Activities:

Simply having policies, SOPs, systems and training is not sufficient. Errors and omissions can be introduced while making funding decisions. Because these decisions are often entered manually, without the benefit of automated checks, they are highly susceptible to errors.

Tips:

- Though often appropriate, minimize making exceptions to policies. If these happen too frequently, there is a likely problem with the policies, the SOPs or with the systems and tools available.

- Take advantage of front-end validation and error-detection processes built into funding request systems. Their power lies not only in their ability to streamline application and record-keeping processes, but also in their front-end validation logic.
- Ensure clarity in the nature of the engagement or funding request. Ensure the funded activity is what it's purported to be. Don't process if not clear.
- Review decision-making rules, including exception approvals and escalation
- Ensure there is a clear documentation process for decisions and exceptions
- Make sure that contracts are clear, complete and transparent.
- Check for Year-to-Date, historical and aggregate spend for a particular recipient before the next funding decision is made, preferably on a global basis.
- Automate workflows wherever possible. This adds not only efficiency, but also quality to decisions and transactions.
- Enable third-parties to have the means to validate data entry at the source.
- Ensure systems and tools can detect data exceptions and omissions—and correct them right away; waiting for reporting season will compound any issues.
- Implement systems and tools that automate the data collection process and do appropriate cross-checking to ensure the final data is clean when processed and stored.
- Hold all employees and third parties to high standards when it comes to the accurate, complete and timely collection and entry of activity and spend information. Persistent gaps should be subject to re-training and even performance or disciplinary management.

One area I have not addressed here and which will be the subject of a future article is the business benefit of transparency management. Clear policies, systems and reports can be hugely beneficial to the business as it is continually challenged to make the best investment decisions. Maintaining detailed data about requests or costs of funded activities can help management make decisions about the business activities themselves. For example, having a full understanding of the costs of Speaker Programs, or the volume and types of grant requests, or the utilization of KOLs, and so on, can be informative on an ongoing basis. When companies rely on Back End reporting, they not only impact the accuracy of their reports, but they also miss out on the real-time business advantages a robust Front End system can bring.

The field of 'transparency reporting' is relatively new in the industry. Roles and departments have been built very recently and have gone through only a couple of cycles of reporting. In this nascent stage, it may be difficult to take a step back from the intensity and urgency of collecting, validating and reporting in order to scan the whole end-to-end process and address the Front End. However, doing so is critical if this activity will be sustained on a long-term basis.

Funding Activities:

Even after decisions to do an activity or to fund a request such as a grant or an independent study have been made, problems can be introduced, problems that will come back to haunt a year later during reporting season. Data completeness and accuracy are paramount here.

Tips:

- Check for duplication.
- Ensure spend is attributed to the correct HCP and HCO—it is critical to do so at this early stage to avoid unmatched records and disputes after public disclosures.