Use a World Class FFMP to Avoid CIAs

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Introduction

These days, blogs and news sites are awash with articles about the long list of settlements between the Office of Inspector General (OIG) and the pharma industry—with companies being penalized for conducting fraudulent drug marketing and pricing schemes. OIG settlements involve large financial penalties at a time when drug patents are expiring and R&D expenses are high.

In almost every case, the OIG has settled with pharma following promotion of off-label usage of prescribed indications or, to a lesser extent, violation of anti-kickback rules in paying Health Care Providers (HCPs). Among the most prominent examples:

- Abbott for the unlawful promotion of the prescription drug Depakote (May 7, 2012)
- Allergan for the unlawful promotion of its biological product, Botox® (December 14, 2012)
- BMS for giving kickbacks to physicians and HCPs (September 26, 2007)

In light of all the OIG buzz, should you be worried about what a settlement could mean to your company? The answer is yes and no. Part of any settlement with the OIG is the pharma company's board members agreeing to adhere to a five-year Corporate Integrity Agreement (CIA). With that in mind, the more specific question becomes: Has there been an *increase* in OIG settlements over the past five years? The answer is no. In fact, the number of CIAs per year has ranged from three to seven, and it's been up and down every other year (see Table 1).

Year	# of CIAs
2007	5
2008	3
2009	7
2010	6
2011	3
2012	7

Table 1. Corporate Integrity Agreements (CIAs) by year.

What has changed, however, is the value of the settlements (see Table 2).

Year	Total Dollar Amount Per Year
2007	$841
2008	$526
2009	$5,236
2010	$1,111
2011	$1,009
2012	$6,558

Table 2. Settlement amounts (in millions) by year.

Further, the last couple of years have brought the largest settlements, with many hitting at least $500 million if not more than $1 billion dollars. Many of the largest settlements have occurred just in the last year. Of particular note is GlaxoSmithKline's $3 billion settlement. Joining GSK are Abbott ($1.5 billion),

Amgen ($762 million), Allergan ($600 million), and AstraZeneca ($520 million), among others. In other words, settlements are no longer $50 million nuisances. Rather, they are massive financial hits that can constrain a company for years to come.

When a healthcare entity is affected by an OIG settlement, it's critical that it complies with its CIA—and builds a strong foundation for following the rules over the long term.

Understanding CIAs

Each CIA is tailored to address the specific facts of a case, often including draft references to a pre-existing compliance program. For any healthcare entity, these agreements require a substantial effort to ensure that the organization is operating in accordance with federal healthcare program rules and regulations and the parameters established by the CIA. Breach of the agreement may result in a variety of sanctions—including exclusion of the healthcare entity.

The imposition of a CIA generally creates significant risk and compliance overhead, which in turns drives long-term costs for pharma companies. Although a CIA generally lasts for five years, it also includes specific compliance stipulations that must be enacted within specified timeframes (often as short as 90 days). A CIA also frequently mandates specific claims review criteria and reporting of the findings, as well as establishment of processes for managing and communicating "Reportable Events" that might be criminal or fraudulent in nature.

In almost every case, a CIA also requires developing and implementing a "Field Force Monitoring Program," or FFMP, that will proactively monitor compliance trends for what the government considers "acceptable procedures" for field sales conduct (see Table 3).

Promotional	Non-Promotional
Sales Call Planning	Research Monitoring
Call Note Review	Research Payment Review
Field Ride Along	Consultant Payment Review
Physician Verbatims	Publication Monitoring
Speaker Program Monitoring	Advisory Board Monitoring
Incentive Compensation Review	Needs Assessment Process Development

Table 3. Many CIAs require companies to monitor these aspects of field operations.

Additionally, companies must promise to build a "call to action" plan for remediating non-compliant activities. Before acting, companies must take several steps to determine the appropriate action to address. The first step is to categorize the monitoring observations by type (for example, "isolated" o or "first offense"). Second, companies must determine the type of control gap that has led to the observation (such as policies, procedures, or ineffective training). Finally, companies must determine how they will respond (for instance, re-training and/or disciplinary action).

Given the importance of remaining compliant with the CIA, the FFMP is important in showing that the pharma company intends to keep its agreement to be compliant. Yet, when building a program, do all pharma companies *really* know what a state-of-the-art FFMP should look like?

Understanding FFMPs

An FFMP is a formalized process designed and implemented to directly and indirectly observe the appropriateness of field sales representatives' interactions with HCPs and healthcare institutions (HCIs). The goal: to detect and correct any potential off-label promotional activities or other improper conduct and to confirm the compliance controls in place are effective.

Ultimately, the FFMP is an opportunity to stay informed on the company's activities—enabling it to readily implement corrective action plans aimed at remediating any problematic compliance issues that could cause negative and costly investigation outcomes. Indeed, an FFMP is often characterized as a proactive approach with near-time analysis of data to identify signals in activities that may be non-compliant. This is very different from auditing, which is typically characterized as a retrospective analysis limited by frequency and specification.

An FFMP is essentially "Big Brother" for a company—watching over how business is being done and identifying who isn't following the rules. This is why FFMP is part of a CIA: to ensure that off-label prescriptions, kickbacks, and other compliance problems don't happen again. But moving from a reactive approach (in which the company responds after a problem happens) to a proactive approach (in which the company detects and prevents issues before they occur) is not easy. In meeting a CIA agreement, healthcare entities often struggle in developing a program. In many cases, they just don't know if what they are setting up will prove to be an effective FFMP.

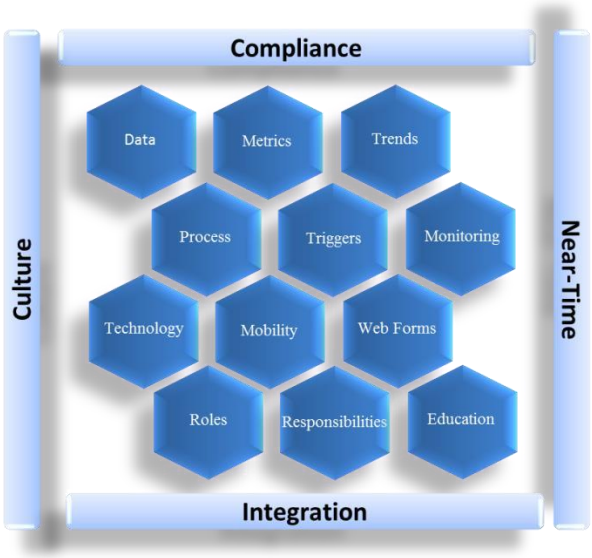

Figure 1. The building blocks of an effective FFMP

In reality, any effective FFMP must have many facets (see Figure 1). A company simply cannot observe every interaction and activity; instead, it must respond to signals or outliers of non-compliant behavior. Doing so requires a lot of information from many sources, such as field sales, compliance, legal, marketing, and financial data. Companies need to develop triggers and trends as tools for measuring and flagging potential problems. Identifying which data is important, tracking it back to the source, and then developing a system to pull it all together and produce evidence are central elements of any effective FFMP.

Other key building blocks of an effective FFMP include:

- Monitoring field interactions with HCPs at conferences/congresses, including events that may take place in close proximity to these events, such as dinners or Advisory Boards
- Reviewing training metrics to determine field representatives' understanding of compliance requirements
- Reviewing sales training materials to ensure proper instruction is provided
- Monitoring field interactions with HCPs and patients at consumer events
- Reviewing sampling practices
- Reviewing requests for off-label information

In recent years, near-time tools have advanced significantly, along with use of mobile solutions in the field. When monitoring activities for sales events are completed, a trigger should be defined that stipulates to field and compliance personnel that they must complete necessary post-activity forms within a certain number of hours. Combining calendars and forms with processes and data analytics provides the neartime component required for an effective FFMP.

Sustainable Monitoring Architecture for an FFMP

As part of an FFMP, a healthcare entity must also develop a sustainable monitoring architecture for its FFMP. It can use its business technology infrastructure to create a scalable, future-state architecture for ongoing promotional monitoring. An effective long-term solution:

- Integrates data directly from the source, eliminating duplicate creation/storage and manual loading processes
- Consolidates data and information into a central organizational repository for better data aggregation and enhanced analysis
- Creates the foundational framework for the enterprise that can be leveraged by other monitoring functions
- Provides robust reporting and analytical tools to create more insightful standard reports and dashboards showing informative trends and patterns of activity over time

Companies need to act on available opportunities for ensuring that everyone is following the rules. Opportunities include:

- Effectively leveraging technologies and data sources using mobile technology
- Integrating regular collaboration and transparency in communications with Compliance, Legal, and Business Colleagues through collaborative tools, such as SharePoint
- Developing organizational standards and processes

Companies are well advised to do the right thing for their organizations and for the patients who are depending on the science to keep them well. The bottom line: Your company needs to implement or improve its FFMP—not tomorrow but today.

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