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FCPA Compliance in the Healthcare Industry

by Christopher A. Iacono

As the healthcare industry grows globally, so does the exposure that hospitals, pharmaceutical companies, and medical device companies face under the Foreign Corrupt Practices Act (FCPA). In just the past two years, companies in the healthcare industry have reached eight-figure settlements with the government to resolve enforcement actions brought under the FCPA, which prohibits payments or offers to pay anything of value to a foreign official in order to retain business. These settlements include:

In 2012

- Smith & Nephew ($22 million)
- Biomet ($22.8 million)
- Orthofix International ($7.4 million)
- Pfizer ($45 million)
- Eli Lily & Company ($29 million)

In 2013

- Stryker Corporation ($13.2 million)

The FCPA enforcement actions against the healthcare industry over the last couple of years demonstrate the challenges global healthcare companies face and highlight the importance of an effective compliance program.

In the 2012 resource guide to the United States Foreign Corrupt Practices Act, the Department of Justice and Securities and Exchange Commission emphasized that FCPA compliance programs should be designed to fit the specific needs and challenges of a particular company. Specifically, the resource guide stated:

> Individual companies may have different compliance needs depending on their size and particular risks associated with their business, among these factors. When it comes to compliance, there is no one-size-fits-all program.
>
> One-fits-all compliance programs are ill-conceived and ineffective because resources are spread inevitably too thin, with too much focus on low-risk markets and transactions to the detriment of high-risk areas.[1]

While companies cannot take a cookie cutter approach to compliance, there are certain hallmarks that make a compliance program most effective. These include:

1. commitment from senior management and clearly articulated policies against corruption;
2. code of conduct and compliance policy and procedures;
3. oversight, autonomy and resources;
4. risk assessment;
5. training and continuing advice;
6. incentives and disciplinary measures;
7. third-party due diligence and payments;
8. confidential reporting and internal investigation;
9. continuous improvement, periodic testing and review; and
10. for mergers and acquisitions, pre-acquisition due diligence and post-acquisition integration.[2]

While each of these is important to ensuring an effective compliance program, there are three areas that can present significant FCPA exposure that are often overlooked by healthcare companies. These are: 1) investigation protocol; 2) pre-acquisition due diligence for mergers and acquisitions; and 3) due diligence of third parties.

Investigation Protocol

Healthcare companies frequently overlook the importance of establishing an investigation protocol for when potential violations occur. Healthcare companies often will have strong policies in place to attempt to prevent violations but do not have adequate (or any) investigation protocols for when a potential violation has occurred. The company should have in place a protocol for receiving, reviewing and investigating alleged misconduct. Additionally, the company should estab-

lish a process for internal reporting of potential misconduct. An employee of the organization should never be left guessing about how to report a suspected FCPA violation.

The company should establish a team within the organization to take the lead in the investigation of the alleged FCPA violation. The team should typically consist of lawyers, internal auditors and other personnel who could assist in the investigation. In certain instances, however, the company may want to consider retaining outside counsel for the investigation. This may depend upon the following: who in the company is allegedly involved; the type of alleged misconduct; the size and scope of the alleged misconduct; and the need for an independent viewpoint. For example, if a high-ranking executive within the organization is alleged to have orchestrated a complex bribery scheme involving foreign officials of several countries, the company may want to consider retaining outside counsel. If, on other hand, the allegations involved one rogue sales representative, the matter probably can be handled internally.

Regardless of whether the investigation will be conducted within the organization or externally, the organization should ensure that a document hold and preservation policy is put in place immediately upon learning of a potential FCPA violation. This is usually accomplished by issuing a company-wide document preservation memorandum. The memorandum should clearly define the parameters of the document hold and also should state that the company is investigating alleged FCPA violations and that the company takes the allegation very seriously.

When an organization decides to discipline employees for committing violations as a result of an investigation, it should make sure the discipline is proportionate to the seriousness of the violation. In determining the appropriate discipline the company should consider whether the employee has committed prior violations, whether the employee had prior training on the issue, and whether the employee cooperated with the investigation.

One of the most difficult decisions a healthcare organization faces once it uncovers an FCPA violation is whether the organization should voluntarily disclose the violation to the government. Self-disclosure can potentially have certain benefits. For example, the company may be better situated to convince the government to formally decline the prosecution or agree to a non-prosecution agreement. Disclosure also increases the likelihood that the government may forgo requiring an external monitor and allow for self-monitoring and reporting requirements.

The most obvious risk of voluntary disclosure is that the company is disclosing violations the government may never have uncovered otherwise. Additionally, it is unclear whether voluntary disclosure results in any more benefit than if the government learned of the violations on its own. Ultimately, each company must consider its own facts and circumstances when determining whether voluntary disclosure is appropriate, including the individuals involved, the amounts involved and whether there were any prior enforcement actions against the company.

Pre-Acquisition Due Diligence

When a healthcare organization is looking to merge with or acquire a target entity, pre-acquisition FCPA due diligence is critical. Waiting until after the transaction is complete to evaluate the target's potential FCPA risk and compliance program could be costly. Prior to completing the transaction, the company should, at a minimum, consider the following: visiting the sites of the target's operations; interviewing employees; reviewing all of the target's policies and procedures; and investigating the backgrounds of all high-ranking personnel of the target and any subsidiaries.

When conducting due diligence, the company should be aware of certain activities and/or arrangements, which should raise red flags, including:

- a failure to execute contracts describing the services to be rendered prior to performance,
- a high volume of cash transactions,
- unusually high commissions or the identification of multiple gifts to a single individual,
- payments outside the country where the goods or services are rendered or payments to third parties,
- the use of a third party, where no prior relationship exists,
- identification of frequently used one-time vendor arrangements, and
- the use of fraudulent invoices

After the transaction is completed, the acquiring company should work quickly to integrate their compliance program with the targets. A major part of the integration is making sure all employees are properly trained and provided with a copy of the code of conduct policy. Depending on the size of the organization, this can be a long process. Accordingly, the company should attempt to complete this process as soon as possible.

Due Diligence of Third Parties

The organization should devote time to developing a comprehensive understanding of its global third-party business relationships. These business relationships could expose the organization to potential FCPA violations if representatives of third parties come into contact with foreign officials. Therefore, the company must be proactive in evaluating the third party's compliance program and the potential risk that may

result from the third-party business relationship. The evaluation should be ongoing, and not just completed at the beginning of the relationship. Like any effective compliance program, an FCPA program must constantly be evaluated to ensure it is taking into account all of the company's specific risks and is operating as effectively as possible. This is true with third parties as well.

Healthcare organizations should demand their third-party vendors make FCPA compliance a priority. Where exposures exist, healthcare companies should require their third-party vendors engage in best practices regarding FCPA compliance, and that they establish a compliance program that is at least equivalent to theirs. Healthcare companies should consider including as part of the relationship the ability to monitor and periodically audit the third parties for FCPA compliance.

Additionally, healthcare organizations should seek third-party business relationships with companies where the top-level management is committed to preventing bribery of or by persons in the organization. Third-party management should promote a culture in which bribery is never acceptable.

An organization should expect that the third-party vendor has their own code of conduct policy with a clear message that bribery is not acceptable conduct for members of the organization. Also, it should provide its employees with a clear direction on how to report potential inappropriate conduct within the organization.

The third party should have a chief compliance officer (CCO). The CCO should have the trust and support of senior management, as well as have a visible presence at the company. Third-party management should provide the CCO and the entire compliance team with all of the necessary resources and training.

Conclusion

The resource guide emphasizes that the adequacy of a company's compliance program can be a factor for the government when deciding whether or not to pursue an enforcement action. It can also factor into how an enforcement action is resolved.[3] Therefore, it is critical that a healthcare company with a global presence consistently review and evaluate its FCPA compliance program. This constant critical analysis of processes and procedures will help ensure that its FCPA compliance program is specifically tailored to effectively deal with the risks the company faces globally. ⚖

Endnotes

1. United States Department of Justice and United States Security and Exchange Commission, A Resource Guide to the United States Foreign Corrupt Practices Act (2012) at 56, 58.
2. *See Id.*
3. *See* United States Sentencing Guideline Manual § 8B2.1 (2013).

Christopher A. Iacono *is a senior associate at the law firm of Pietragallo Gordon Alfano Bosick & Raspanti, LLP. He focuses his practice on the areas of government enforcement, compliance, white-collar litigation and healthcare litigation.*