

A New Trend In Health Care Fraud Settlements

Law360, New York (March 05, 2013, 12:38 PM ET) -- In recent years, pharmaceutical and medical device companies have paid ever larger fines to federal and state governments to settle claims of health care fraud. In connection with these settlements, companies have entered into corporate integrity agreements (CIAs) with the Office of the Inspector General of the U.S. Department of Health and Human Services, which are designed to ensure that controls are in place to prevent and detect conduct similar to the allegations that gave rise to the settlements.

In 2012, these record-breaking settlements and expansive CIAs continued to grow. In some cases, new CIAs built on old ones, which were created for a past offense or by a subsidiary acquired before the company's settlement. However, a new trend has emerged in recent health care settlements, signaling the government's view that CIAs are no longer sufficient tools to police errant conduct. For the first time, companies have been placed on probation, under the supervision of federal courts and the U.S. Department of Justice itself, as part of health care fraud settlements.

While the terms of probation in these cases have been very similar, if not identical, to the conditions imposed under CIAs, these corporate sentences demonstrate the insistence of the DOJ, and in one instance a federal court, on enhanced post-settlement supervision of companies. They also bring a new player into the post-settlement phase of these cases, the United States Probation Office. However, the role probation officers are to play in these cases sometimes remains unclear. In contrast, outside of the health care setting, other corporate plea agreements have more clearly assigned to both the DOJ and Probation a supervisory role. For example, the recent BP PLC settlement signed in connection with the 2010 Gulf oil spill defines the authority of the DOJ and Probation to oversee the post-plea supervision of the company.

A Little History

The federal sentencing guidelines for sentencing corporations provide that a court shall order a term of probation "if such sentence is necessary to ensure that changes are made within the organization to reduce the likelihood of future criminal conduct." Commentary promulgated by the United States Sentencing Commission does not provide much more guidance: "[P]robation is an appropriate sentence for an organizational defendant when needed ... to ensure that steps will be taken within the organization to reduce the likelihood of future criminal conduct."

Historically, in corporate health care fraud cases the DOJ has recognized that CIAs are sufficient to deter future criminal conduct. In plea agreements with companies, the DOJ specifically has agreed not to recommend a term of probation on this basis. For example, in June 2011, UCB Inc. pleaded guilty to a misdemeanor violation of the Food, Drug and Cosmetic Act (FDCA) and agreed to pay approximately \$34 million to resolve criminal and civil liability related to its alleged off-label marketing of the drug Keppra for use in treating migraines.

The U.S. Food and Drug Administration had approved the drug only for the treatment of seizures. As part of this settlement, UCB also agreed to enter into a five-year CIA. In light of this CIA, the government agreed not to seek a term of probation. As the government explained in its sentencing memorandum, because of the “comprehensive and prophylactic terms” of the five-year CIA, “[OIG] is best positioned to monitor the conduct of UCB effectively and ... a term of probation is therefore not necessary.” As a result, the District Court for the District of Columbia did not impose a term of probation.

New Uses of Probation

Just one year after the UCB settlement, Abbott Laboratories pleaded guilty to a misdemeanor violation of the FDCA and agreed to pay \$1.5 billion to resolve its criminal and civil liability arising from off-label promotion of the drug Depakote. Like UCB, Abbott executed a five-year CIA. However, as a provision of its negotiated plea agreement, Abbott also was placed on court-supervised probation for five years, the terms of which included various “compliance measures” similar to those imposed by the CIA. A breach of these obligations would be deemed a violation of the plea agreement.

Under the terms of its probation, Abbott’s CEO must annually certify to Probation that Abbott continues to adhere to the required “compliance measures.” The board of directors, or a committee designated by the board of directors, must also annually certify that Abbott’s compliance program is effective. Abbott must notify Probation of changes to key compliance personnel, including the chief compliance officer, and must provide quarterly reports to Probation regarding potential violations of the FDCA, or “reportable events.”

Notably, the terms of probation provide that Abbott’s commission of a new health care fraud offense will not necessarily constitute a violation of the terms of probation. Probation may consider several factors, including whether Abbott took remedial actions after learning of the offense, before determining that a health care fraud offense constitutes a violation. Probation is not required to, but may, share with the DOJ any information provided by Abbott.

Recently, a federal court imposed probation despite an agreed-upon recommendation of the parties. In December 2012, Orthofix tendered a guilty plea pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) to settle allegations that an Orthofix subsidiary paid illegal kickbacks to physicians in order to induce use of the company’s products. While the government did not seek a term of probation in light of the CIA executed between Orthofix and OIG, the court rejected the agreed-upon plea and instead imposed a five-year term of probation, incorporating as conditions all of the terms of the CIA, until the CIA expires. Since the parties had not contemplated it, the Orthofix plea agreement and judgment do not address the provision of information to Probation regarding compliance with the CIA.

In at least one instance, the DOJ has imposed post-settlement supervisory terms which the DOJ itself will police. In July 2012, GlaxoSmithKline PLC pleaded guilty to three misdemeanors and agreed to pay \$3 billion to resolve its criminal and civil liability arising from its promotion of certain prescription drugs and certain reporting practices. GSK also executed a five-year CIA with OIG. Because of this CIA, the government did not seek a term of probation in connection with the criminal disposition, nor was probation imposed by the court. However, compliance obligations supervised by the DOJ were set out in an addendum to the plea agreement. A breach of these obligations will not constitute a breach of the plea agreement, but it will carry specific, daily monetary penalties, presumably payable directly to the DOJ.

The BP Case

Under its recent plea agreement, BP is subject to a five-year term of probation and to auditing and monitoring requirements set forth in an accompanying court order, all as a term of probation. Probation has a clear role in overseeing the company's compliance efforts. For example, BP, and any monitors or auditors it retains, must notify Probation of any criminal prosecutions or other potential violations of the law.

Nevertheless, the DOJ will play the primary supervisory role in ensuring compliance with BP's probation terms. The DOJ must approve all monitors retained by BP and their work plans. BP may appeal a monitor's recommendation to the DOJ, not Probation, and it must abide by the DOJ's determination. While there are instances in which Probation is given some discretionary authority (for example, to approve a monitor's request to forego the last follow-up review), as a general matter the order grants most discretionary authority to the DOJ.

The DOJ similarly exercises more discretion with regards to auditing provisions. BP must retain an independent auditor to review and report to both Probation and the DOJ on BP's compliance with the terms of the order. While the order requires the auditor to report findings to Probation, only the DOJ must approve BP's plan to address deficiencies identified by the auditor. Similarly, both the DOJ and Probation must approve of BP's plan to implement measures required by the agreement, but only the DOJ will advise BP as it prepares the plan.

Corporate Probation in Health Care Fraud Settlements: How Will It Work?

For pharmaceutical and medical device companies, failure to comply with the terms of a CIA subjects them to steep monetary penalties and potential exclusion from federal health care programs. However, these companies may be exposed to more significant criminal penalties where the terms of a CIA are imposed as conditions of probation.

If a company violates a condition of its probation, the probation officer may seek to revoke or extend the term of probation in a revocation hearing pursuant to Federal Rule of Criminal Procedure 32.1(a)(2). If the court finds by a preponderance of the evidence that the company has violated a condition of probation, the court may extend the term of probation, impose more restrictive conditions of probation, or revoke the probation and resentence the company.

A company that violates a condition of probation therefore would potentially be subject to the maximum statutory fine that could have been imposed at the original sentencing. Most settlements involve a negotiated fine, often tracking guidelines factors, which is significantly less than the maximum fine that could be calculated under the guidelines. A company that violates a condition of probation could be subject to a significant additional penalty beyond that negotiated in the settlement.

It remains to be seen how the DOJ and OIG will coordinate to resolve issues that arise as companies now under probation implement their CIAs. The OIG has years of experience monitoring CIAs. It is fair to say that the DOJ does not. CIAs usually contain provisions for reporting violations and subsequent remediation of violations. Generally, under CIAs companies must report “reportable events” to OIG within 30 days after making the determination that such a violation exists.

In addition, CIAs generally provide companies with an opportunity to cure violations within a specified period of time, as well as a dispute resolution procedure that includes review by an HHS administrative law judge. The Sentencing Commission has commented, with respect to the imposition of conditions of probation, that “the court should consider the views of any governmental regulatory body that oversees conduct of the organization relating to the instant offense,” which, in health care fraud cases, is OIG. There is no commentary, however, that addresses coordinating with an agency such as OIG once a company is placed on probation.

Thus, when faced with a government demand for probation as part of a health care fraud settlement, company counsel must anticipate a number of issues: What role will the DOJ play in connection with enforcement of probationary terms? To what extent will Probation be involved in monitoring noncompliance with the settlement agreement, including the terms of a CIA? How will Probation and OIG coordinate their oversight? Despite limitations on the terms of probation built into the settlement (such as, in the Abbott case, attempts to anticipate what conduct would constitute a probation violation), how will Probation interpret these terms and use its traditional authority to prosecute probation violations?

These questions and others will be answered only as experience under these new settlements creates useful precedents.

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