Individual liability for health care fraud:
Enforcement agencies raise the stakes
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The legacy of health care fraud enforcement has primarily targeted organizations for criminal, civil and administrative liability for fraudulent and abusive practices. These enforcement efforts continue in all sectors of the health care industry, however, a trend in actions against individuals has surfaced in a number of recent cases. An increasing number of management, operational and even legal personnel of organizations have been held individually accountable in direct enforcement actions or through assumed obligations under Corporate Integrity Agreements (CIA) with the Office of Inspector General of Health and Human Services (OIG-HHS). These developments more than adequately reflect what government officials have been saying for some time about holding individuals responsible and using it as a highly effective method to deter future health care fraud. This article will discuss several recent examples of enforcement actions resulting in individual accountability for health care fraud against Federal health programs.

Individual accountability and recent CIAs
In recent years the government has ratcheted up its efforts to prosecute and prevent health care fraud. As a result, an increased number of health care organizations have entered into CIA’s. A CIA is the alternative to excluding a
health care provider or supplier organization from participating in Federal health programs. In September of 2009 Pfizer, Inc. (Pfizer) entered into a five year CIA with the OIG-HHS concerning off-label promotion of several drugs, including Bextra. However, Pfizer’s CIA contains several requirements not previously seen in other CIA’s. The Pfizer CIA designates the type of authority which the Chief Compliance Officer (CCO) must have and the specific responsibilities to be carried out by the CCO. The CIA requires the CCO to be a member of senior management and report to the Chief Executive Officer of Pfizer and specifically prohibits the CCO from being subordinate to Pfizer’s General Counsel or Chief Financial Officer. Furthermore, the CIA requires that an Audit Committee of the Board of Directors be established to meet quarterly and review the effectiveness of the CIA. Additionally, the CCO is required to be the chairman of the Compliance Committee which must support the CCO in fulfilling duties under the CIA. The CCO must also have authority to report compliance matters directly to the Audit Committee of the Board of Directors at any time deemed appropriate. The CIA also explicitly requires the CCO to enforce practices, policies and procedures to ensure compliance with Federal health programs and Food and Drug Administration requirements and the obligations under the CIA. The CCO is also to monitor daily activities of the organization and to make quarterly reports to the Audit Committee and the Board of Directors of Pfizer.

The terms of the CIA also designate individual business unit managers and certain employees to monitor and oversee the compliance activities under the CIA and to certify compliance. The CIA requires these business unit employees to certify to specific statements that they have (a) reviewed reports from an internal group within Pfizer formed to conduct promotional quality assessments; (b) reviewed summary reports of speaker programs, advisory boards, consultant payments, travel and entertainment expenses and (c) reviewed sales compensation exclusion criteria and (d) corporate compliance group statistics and that they are not aware of any violations of law, regulation or of Pfizer policy or the requirements of the CIA. Furthermore, the CIA requires that if there is an issue identified, any potential violations will be referred to the corporate compliance group or a member of the Pfizer legal division for further review and follow-up.
In April of 2010 AstraZeneca Pharmaceuticals LP and AstraZeneca LP (AstraZeneca) also entered into a five-year CIA with OIG-HHS concerning the illegal marketing of a drug for off-label uses. AstraZeneca’s CIA contains individual accountability provisions not unlike the provisions contained in Pfizer’s CIA from 2009. Section III of AstraZeneca’s CIA delineates which members of AstraZeneca’s management team have accountability and certification responsibilities under the CIA.

The requirements of the AstraZeneca CIA parallel the Pfizer CIA regarding compliance officer authority and responsibilities, establishment of a Compliance Committee for U.S. operations and also detailing specific compliance responsibilities for the Board of Directors. The AstraZeneca CIA also requires certain business unit managers and employees to monitor, oversee and certify compliance with the CIA and overall compliance by the organization. The CIA also obligates members of the Board of Directors to explicitly oversee the organization’s Compliance Program and to resolve and attest to the organization’s compliance effectiveness.

Although the management accountability and certification requirements under the Pfizer and the AstraZeneca CIA’s are not identical, the same underlying theme is present under each agreement: individual responsibility and accountability for passive or active noncompliance within the certifying employee’s area of authority. The message is clear; management and other high ranking employees responsible for compliance can no longer turn their back on noncompliance within an organization. Corporate employees may well have to answer to the government for the noncompliance of their organizations.

**Individual liability for aiding in health care fraud**

In September of 2007 the government charged Christi Sulzbach, a Tenet Hospital System (“Tenet”) Compliance Officer and General Counsel, under the False Claims Act in a case in the Southern District of Florida. The allegations against Sulzbach were related to a CIA she signed on behalf of Tenet Healthcare in 1994 which remained in effect until 1999. The Complaint alleged that Sulzbach made a sworn declaration in a compliance report that was prepared under her direction and authority that Tenet was
in conformity with its CIA when in fact, Sulzbach had personal knowledge this was not the case. Sulzbach allegedly had reviewed several contracts between Tenet and physicians in which physicians’ salaries were based on the number of referrals they garnered for the facility in violation of the Stark Law. Because Sulzbach signed off on the compliance report, and it was her responsibility to oversee compliance, and allegedly acted in dereliction of her duties, the government filed a Complaint against her for causing the submission of false claims. However, the government brought suit against Sulzbach ten years after her purported misdeeds. The Court ultimately found that the government had enough knowledge earlier during its investigation of the matter to trigger the three year post-knowledge statute of limitations period. Thus, the court dismissed all claims against Sulzbach on her summary judgment motion because the government’s complaint against Sulzbach was untimely. Nevertheless, the case underscores the extent to which the Department of Justice will go to hold individuals accountable for health care fraud.

The OIG-HHS is not far behind and in October of 2009 it entered into a settlement agreement with, Michael Baskt, Ph.D for $64,000 to settle suspected violations of the Stark Law and Civil Monetary Penalties Law. Baskt was accused of violating the Federal Stark Law and Civil Monetary Penalties Law in connection with his duties as CEO of Community Memorial Hospital in California. The accusations stemmed from Baskt’s personal involvement with arrangements that constituted kickbacks and resulted in false Medicare claims. Baskt denied all suspected violations in his settlement agreement, but agreed to pay $64 K to resolve the action.

Finally, the OIG-HHS is also aggressively holding physicians accountable for violations of the Stark Law and Anti-Kickback Statute. A recent settlement involving a physician’s relationship with two different medical device companies was premised on the contention that the Consulting Agreements between the physician and the medical device companies violated the Federal Anti-Kickback Statute. The merits of the OIG’s contention are debatable, but the settlement signals the intent to aggressively pursue physician liability, as well as organization liability, for violations of the self-referral and anti-kickback laws.
Conclusion
Although neither Baskt, Sulzbach nor Montijo were ever held civilly or criminally liable, the allegations filed against each of them are important because they reflect the government’s willingness to prosecute individuals who aid in the commission of health care fraud. No longer will those engaging in fraud be shielded from liability by the government’s tendency to focus accountability on health care organizations. As the government continues to step up its efforts to prevent health care fraud, individuals involved in compliance and supervision need to tread carefully. When an individual responsible for compliance signs his or her name on a document or becomes personally involved in illegal transactions, he can face civil and criminal liability whether or not he was actively engaged in fraud.