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The Responsible Corporate Officer Doctrine—The New World of Healthcare Compliance –

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In October 2011, DOJ celebrated the 25th anniversary of Congress' 1986 False Claims Act (FCA) amendments. The FCA amendments ushered in an avalanche of FCA actions and recoveries. In those 25 years, DOJ has recovered more than \$30 billion.

As a result of these settlements, healthcare entities have been radically transformed. As a condition of entering into FCA settlements, the government agrees to waive its ability to exclude healthcare providers from Medicare participation in exchange for companies' entering into detailed corporate integrity agreements (CIAs). As a result of these CIAs and related regulatory pronouncements, most companies in the healthcare industry—hospitals, long term care facilities, research-based pharmaceutical and biotechnology companies, clinical laboratories, and even physician practices—have comprehensive compliance programs.

But now, even as the industry has become accustomed to FCA investigations, lawsuits, and compliance programs, the government has brandished a new weapon to enforce fraud and abuse laws. Specifically, recently federal officials have expressed their intent to revive the responsible corporate officer doctrine, which provides that corporate officers may be held criminally liable for certain offenses relating to public health and welfare, even if the individual officers and managers neither knew of nor participated in the unlawful activity. Additionally, the OIG has announced a

new focus on excluding owners, officers, or managers from participation in federal healthcare programs if they should have known of a sanctioned company's misconduct. The OIG announced that the presumption in favor of exclusion may be overcome based on the circumstances underlying the misconduct and the individual's actions in response to the entity's misconduct.

Recently, a notable illustration of this power occurred when the OIG announced the program exclusion of a pharmaceutical company's substantial owner and officer. The exclusion was based upon the guilty plea to criminal charges by the company's wholly owned subsidiary, which paid restitution of approximately \$2.3 million and a \$23.4 million criminal fine. Notably as a condition of the agreement, the government compelled the officer to withdraw from the company management and divest his ownership interest in the company.

The combination of the responsible corporate officer doctrine and the FCA provides the government with a powerful one-two punch. The FCA's whistleblower, or *qui tam*, provisions provide an insider with a strong incentive to report suspected fraud and the responsible corporate officer doctrine will require executives—for fear of losing their livelihood by exclusion—to ensure, at the risk of overreaction, that prompt remedial action is undertaken because the OIG may seek the manager's exclusion if the manager did not appear sufficiently vigilant.

Some, no doubt, will argue that the invocation of the corporate officer doctrine is exactly what is needed to police rampant healthcare fraud and will point to the government's substantial FCA recoveries as proof that the industry is rife with fraud. Others will contend that the government's massive recoveries typically reflect not the strength of the government's case but the leverage it possesses based upon its ability to exclude companies from participation in Medicare. They will point out that, in fact, the vast majority of whistleblower actions are meritless because historically, since the 1986 FCA amendments, DOJ has refused to participate in approximately 75% of all *qui tam* actions.

But no matter what position one may adopt, the fact that is beyond cavil is that healthcare executives will be placed in a seemingly impossible bind. They must balance furnishing streamlined, efficient, high quality healthcare and implementing vast regulatory mandates while receiving shrinking healthcare payments. And, at the same time, so as not to risk exclusion from Medicare for failing to identify perceived misconduct and promptly reporting it to the government under the responsible corporate officer doctrine, they will feel compelled to overcompensate by creating and operating resource-intensive compliance programs that will divert dollars from the provision of patient care.

How healthcare executives manage and navigate these contradictory mandates of providing quality care with shrinking reimbursement and reducing costs, while building expansive compliance infrastructures to protect their livelihood and avoid personal liability, will be one of the major issues to watch in 2012.