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**WHITE COLLAR CRIME
HEALTH CARE FRAUD**

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**Federal Law Preempts Florida
Anti-Kickback Statute**

ROBERT PENEZIC AND EDGAR BUENO

A Florida court of appeals for the first time ruled that the Federal Anti-Kickback Statute preempted the state's Medicaid Anti-Kickback Statute because the state statute did not include an exception for payments made within a bona fide employer-employee relationship. The Florida court also ruled that the Federal Statute's mens rea requirement required the government to prove that a defendant acted with knowledge that his conduct was unlawful. This Florida appellate court ruling is significant not only for the application of the supremacy clause and preemption of state law by Federal law, but also because of its interpretation of the employer-employee exception under Federal law. Furthermore, the ruling reaffirms the more restrictive mens rea requirement adopted by the Ninth Circuit in the case of *Hanlester v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), requiring that the government must prove that a defendant intended to engage in the conduct and knew that the

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**Relationships with Health Care
Professionals and The Pharma Code**

GABRIEL L. IMPERATO

The numerous enforcement actions against pharmaceutical manufacturers in recent years has called into question the legality of previously common payment arrangements with health care professionals who prescribe drugs or order goods and services under Federal health care programs. These enforcement actions have had wide ranging ramifications in the pharmaceutical industry, but also have direct application to the relationships between health care professionals and other health care industry players. This includes medical device manufacturers, hospitals, home health agencies, nursing homes, and any other

providers or suppliers which rely on physician direction for the ordering of goods and services. Those health care organizations who fail to promote compliant practices and relationships with health care professionals will be running a significant risk of liability resulting from criminal and/or civil enforcement actions under the Anti-Kickback Statute, the Stark Law, and the False Claims Act (FCA).

The flagship case against the pharmaceutical industry, which highlighted its payment and referral relationships with prescribing physicians, was the TAP Pharmaceutical

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PHARMA CODE *continued from cover*

case (TAP). This case not only focused on the misconduct of pharmaceutical manufacturers, but also the willingness of physicians to receive remuneration in return for prescribing a specific drug (Lupron) manufactured by TAP, which is a prostate cancer drug administered to patients under the supervision of physicians. It was a reimbursable prescription drug under the Medicare program, with payment at 80 percent of the urologists' actual charge for the drug or the average wholesale price (AWP) reported by the pharmaceutical company. The government alleged in the TAP case that the pharmaceutical manufacturer reported an AWP which was significantly higher than the average sales price which it offered to its physicians and other customers for Lupron. The government further alleged that the pharmaceutical manufacturer marketed the spread between the discounted price actually paid by physicians and the significantly higher Medicare reimbursement based on the manufacturer's AWP as an inducement to physicians to order Lupron for their patients. The case also involved allegations that free samples of Lupron were offered to physicians at no cost, which the physicians also billed directly to the Medicare program for profitable reimbursement.

This opportunity to bill the Medicare program at an amount greater than the price paid by the physicians and the ability of the physicians to retain the difference was alleged to be an item of value in return for ordering the specific drug, Lupron (as opposed to any of its competitor drug products, such as Zolodex). The government alleged that this opportunity to generate and receive this revenue based on the "spread" was a violation of the Federal Anti-Kickback

Statute (the Statute).

The TAP case also identified other practices and payment relationships with health care professionals which allegedly violated the Statute, such as the offering of free consulting services to physicians and physician practices, and money disguised as "educational grants," which were, in fact, intended to be used for any purpose by prescribing physicians. There was also an allegation in the TAP case that a physician for a university medical plan was offered an "educational grant" to reverse a decision made on behalf of the health plan to only use the less expensive prostate drug of a competitor (Zolodex), instead of Lupron.

The TAP enforcement action was followed by numerous settlements with pharmaceutical manufacturers resulting from whistleblower cases which were moved forward by the Federal government in parallel criminal and civil enforcement actions. Those cases included the Astra Zeneca settlement for \$63.9 million in criminal restitution and \$355 million in civil damages and penalties (involving price spread, free drug samples, and educational grant inducements to ordering physicians); the Bayer AG settlement in the amount of \$6 million in criminal restitution and \$257 million in civil damages and penalties (failure to list drug with the Food and Drug Administration (FDA) for private labeling commonly referred to as "lick-and-stick"); and the Glaxo SmithKline settlement for civil payments in the amount of \$87.6 million (misreporting of best price and underpayment of Medicaid rebates and off label use not approved by the FDA).

These criminal and civil settlements against pharmaceutical manufacturers have spawned additional whistleblower cases and also additional enforcement

actions involving relationships with health care professionals in other sectors of the health care industry, including hospital and physician relations, medical device manufacturers, clinical laboratories, and home health agencies. The pending whistleblower case of *U.S. et al v. Medco, et al.*, in the Eastern District of Pennsylvania, involves allegations of payments for inducement to pharmacy benefit managers to switch from one drug to another, but also involves numerous allegations relating to the integrity of prescriptions and the quality of care in the mail order pharmaceutical business. The case of *U.S. ex rel. Urbanek and Courtney v. Laboratory Corporation of America*, is also a whistleblower case involving numerous allegations of improper relationships and payments from the clinical laboratory company to ordering physicians. These improper relationships allegedly include the following: (1) providing free gloves, gowns, and other medical supplies; (2) providing free computers, printers, and similar office equipment and supplies; (3) stationing a phlebotomist inside a physician's office; (4) providing "professional courtesy" discounts to doctors and their families; and (5) waiving of network charges to managed care patients referred by physicians.

These cases demonstrate the growing need for compliance in relationships with ordering health care professionals in all sectors of the health care industry. A number of recent judicial decisions have approved the use of the whistleblower provisions under the FCA to bring cases involving improper payment and referral relationships under the Anti-Kickback Statute and the Stark Law. This will only further the opportunities for whistleblowers to raise these

PHARMA CODE *continued from page 3*

issues in state and Federal courts. This type of case is now becoming a fairly well-worn path in the Federal courts, but is also growing in importance in state courts as numerous states, such as Florida, Louisiana, and New Mexico, have invited these types of suits by passing their own state false claims acts modeled after the Federal FCA.

The pharmaceutical industry has attempted to respond to this growing liability by enacting a voluntary code of conduct (the Pharma Code) to govern its relationships with health care professionals. The Pharma Code was disseminated in July 2002 and even received an endorsement from the Office of Inspector General of the United States Department of Health and Human Services (the OIG) in its Program Guidance for the Pharmaceutical Industry. The OIG noted that compliance with the Code was a positive step in ensuring compliance with the Anti-Kickback Statute in relationships with health care professionals, although it was not elevated to a safe harbor status. There is some question as to what effect the voluntary Pharma Code has had regarding relationships with health care professionals, even though it is intended to promote compliant practices. The Pharma Code allows for the following relationships with health care professionals:

- informational presentations to health care professionals made by a representative of a pharmaceutical company which can be accompanied by moderately priced occasional meals in an educationally conducive setting;

- financial support given directly to sponsors of continuing medical education programs or other types of third-party conferences, but not given to the health care professional attending such pro-

grams;

- occasional gifts that primarily benefit patients, as long as they are valued under \$100, such as practice-related gifts (anatomical model) or pens and notepads;

- consulting agreements with bona fide consultants which mirror Federal safe harbor provisions for personal services arrangements and also reasonable compensation and reimbursement for travel, lodging and meals for such bona fide consultants; and

- funding to allow health care professionals in training to attend major educational, scientific, or policy-making meetings with the selection of the health care professional and the conference left to the educational institution.

The types of activities which are specifically not allowed under the Pharma Code include the following:

- anything provided or offered to a health care professional in exchange for prescribing or for a commitment to continue prescribing products;

- entertainment and recreational events, such as golf outings, visits to resorts, etc.;

- any financial remuneration not associated with bona fide services or expenses associated with bona fide services;

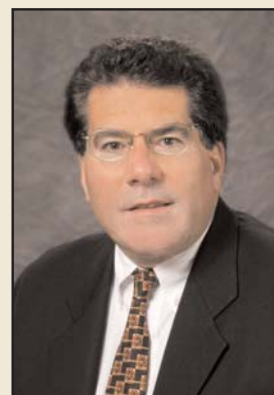
- non-cash items that are not practice-related or that do not benefit patients and that are only intended for personal benefit; and

- no cash equivalents, such as gift certificates, etc.

The legacy of recent enforcement actions and the high risk of whistleblower liability in connection with health care professional relationships clearly poses risks under the Anti-Kickback Statute and the Stark Law. An organization which provides "designated health services" under the Stark Law (i.e., clinical labora-

tory, diagnostic imaging, home health, durable medical equipment) must be even more vigilant because of the strict liability nature of the Stark Law and the narrower exceptions for relationships with referring physicians. An example of how easy it is to be in violation of the Stark Law is reflected in the regulatory exception under the statute for non-cash payments to referral sources, which is limited to items of value no more than \$300 a year. An item of value offered to a health care professional who is in a position to order a plan of home health care for a patient which exceeds \$300 (such as a golf weekend) would violate the Stark Law (a strict liability statute), even though it may not violate the Anti-Kickback Statute. The risks of this liability are significant and growing, and organizations which fail to make a true effort at identifying these risks and forging compliant practices in their organizations may find themselves in the same place as the pharmaceutical manufacturers.

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Criminal Indictment For Inadequacy of Care at Nursing Homes

GABRIEL L. IMPERATO AND ANDREW COTZIN

A criminal indictment was recently filed in the Eastern District of Louisiana, alleging criminal violations of the mail fraud, health care fraud, pension fund fraud, money laundering and asset forfeiture statutes involving the inadequacy of care at several Louisiana nursing homes. This is believed to be the first criminal indictment based on a theory of inadequacy of the quality of care in nursing homes in the United States. The Federal government has initiated several notable civil actions based on theories of inadequacy of the quality of care under the United States False Claims Act, which have resulted in well-publicized settlements. However, this case attempts to break new ground as a basis for criminal culpability for failure to provide required care under the Medicare and Medicaid statutes.

The indictment names an individual nursing home owner and his development company and alleges that by signing cost reports, the individual represented that he was familiar with the applicable laws and regulations regarding the provision of health care services at nursing homes and that all services



identified in the cost reports were provided in compliance with such laws and regulations. The indictment goes on to state that the applicable laws and regulations required that nursing homes: (1) enhance the residents' quality of life and assist them in attaining and maintaining the highest practicable physical, mental and psycho-social wellbeing in accordance with a written plan of care; (2) maintain a sufficient number of qualified nursing personnel to meet the nursing needs of all residents on a 24-hour basis; (3) adhere to all state and Federal health and safety standards; (4) ensure that residents receive all appropriate and necessary services, including, but not limited to, medical treatment, pharmacy services, dietary services, specialized rehabilitative services; and routine dental services; and (5) provide residents with a comfortable and clean environment and protect them from accident, injury and infection and maintain a nursing home care program ensuring that all equipment necessary for medical care remain functional and that supplies are on hand for the proper care and treatment of the

nursing home residents.

The indictment goes on to allege that the scheme to defraud was perpetrated on the Medicare and Medicaid programs by material representations about the level of care provided to the nursing home residents, identifying the following misrepresentations:

- (1) falsely representing that care, services and proper environment were provided to residents;
- (2) failing to provide residents with care, services, and an environment in accordance with all applicable laws and regulations;
- (3) falsely representing on annual cost reports that all identified care and services were provided in accordance with all applicable laws and regulations as set forth in the nursing homes' previously executed provider agreements;
- (4) falsely representing that certain liabilities listed on cost reports had been liquidated within one year;
- (5) falsely representing that home office expenses incurred in support of



CRIMINAL *continued from page 4*

the nursing homes on the cost reports were bona fide; and

(6) concealing the fact that funds paid to the nursing homes by Medicare or Medicaid were diverted to the individual defendant's development company, rather than used to provide residents with the required care or services and proper environment and to pay essential vendors who provided services to nursing home residents.

The indictment specifically alleges the failure to provide the following:

- (1) adequate staffing;
- (2) specialized rehabilitative services, medically related social services; adequate funding for the residents' activities, and routine dental services;
- (3) adequate supplies, including soap, gauzes, bandages, wound-care gloves, and disinfectants;
- (4) a proper and adequate environment, including sufficient working air-conditioners;
- (5) requisite pharmaceutical services;
- (6) a sufficient supply of acceptable linens and sheets;
- (7) a sufficient supply of towels and gowns;
- (8) a preventative maintenance program for critical equipment such as

washing machines, ice machines, freezers, hot water heaters, and air-conditioners;

(9) maintenance of equipment which was integral to the providing of care, such as whirlpools, baths, and lifting equipment for residents who required assistance;

(10) dietary services, including adequate cooking equipment and dining areas;

(11) transportation for residents to medical and dental appointments; and

(12) an environment that enhanced the quality of life of the residents.

The indictment also alleges that the defendants materially misrepresented the provision of the level of care in both the cost reports and the provider agreements with the Medicare and Medicaid programs and made these representations knowing that the defendant was improperly diverting funds from the nursing homes to himself and to his development company, including the following examples:

- (1) the use of the home office corporate American Express card for personal expenses and those of the development company;
- (2) obtaining a degree from Harvard University;
- (3) payment of all mortgage payments, bills and expenses of the defendant's 150 acre estate, which included a refurbished home and two full-time groundskeepers'
- (4) payment of approximately \$300,000 in annual revenue to the individual defendant which was used to pay mortgage payments, bills and expenses on home-stead property;
- (5) payment of all expenses related to the defendant's development projects; and

(6) payment of as much as \$6.6 million for related companies and concealing from Medicare and Medicaid the fact that vendors had not been paid with money received as reimbursement from Medicare and Medicaid.

**THIS CRIMINAL INDICTMENT IS
CLEARLY BREAKING NEW GROUND
AND IS AN AMBITIOUS ATTEMPT TO
ESTABLISH CRIMINAL CULPABILITY
BY FEDERAL GOVERNMENT
ENFORCEMENT AUTHORITIES.**

This criminal indictment is clearly breaking new ground and is an ambitious attempt to establish criminal culpability by Federal government enforcement author-

ities. The basis for liability in those civil cases previously brought under the United States False Claims Act for inadequacy of care in nursing homes depended on establishing that the nursing home services were so worthless as to amount to no services at all. The establishment of criminal culpability in this case may depend on also establishing that the services were worthless. However, culpability in this case additionally will depend on the extent to which the operation of the nursing homes and the diversion of funds were, in fact, as alleged and the alleged fraud on vendors and other creditors can be proven. It will also remain to be seen if these facts are established, whether it will support the level of intent required for criminal conviction under the relevant Federal statutes. **BC**

The principal members of the Firm's White Collar and Health Law Practice Groups include: Gabriel L. Imperato, Chairman, White Collar Group; Andrew Cotzen, Lester J. Perling, Anne Novick Branan, Robert Penexic and Edgar Bueno (Fort Lauderdale); Douglas Mannheimer, Donna Holsbouser-Stinson, Jay Adams and Dave Thomas (Tallahassee); Edward Hopkins (West Palm Beach); and Mike Segal, Chairman, Health Law Group and Robyn Carney (Miami).

It is critical that those in the health care field understand the opportunities and limitations of the new Stark II Phase 2 Final Rule. Broad and Cassel's health care attorneys are available to address your organization and explain how the new rule affects your members. To schedule a speaker, contact **Edward Hopkins** at ehopkins@broadandcassel.com, **Gabriel Imperato** at gimperato@broadandcassel.com, **Lester Perling** at lperling@broadandcassel.com, or **Mike Segal** at msegal@broadandcassel.com.

ANTI-KICKBACK *continued from cover*

conduct was unlawful in order to prove a violation of the Federal Statute.

The case involved a nine-count information against a defendant who was paying drivers who were alleged to be “employed by or associated with” three corporate entities. These corporations were engaged in the business of providing dental services to children and paid drivers a per-head fee or commission for the “solicitation and transportation” of Medicaid-eligible children to dental facilities for treatment. The State of Florida argued in its appeal that the recruiting or solicitation of patients by these Medicaid dental providers through its paid employees who were paid a per-head payment for each child a driver could find and bring to the dental clinic was unlawful under both the Federal and state law and amounted to kickbacks for patient referrals. The trial court in the case had decided that the state’s attempt to prosecute the wages paid by the defendant to certain of its employees for purposes of soliciting and transporting Medicaid-eligible patients to the dental facilities was preempted by both an express provision of the Federal Act as well as a parallel administrative “safe harbor” provision under the Federal Act.

The Florida Court of Appeals noted that the trial court applied an implied conflict preemption analysis and found that the Florida Anti-Kickback Statute was unconstitutional. The appellate court additionally found that the trial court found that the mens rea requirement under the Florida Statute was preempted by Federal law and was also unconstitutional.

The Florida Court of Appeals noted in its ruling that implied conflict preemption occurs when (1) compliance with both Federal and state regulations is a physical impossibility or (2) a state law is an obstacle to the execution and accomplishment of the objectives and purposes of a Congressional enactment. The Court of

Appeals reviewed the Federal Anti-Kickback Statute and noted that the prohibition against remuneration in return for referrals did not apply to any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment and the provision of covered items or services.

The Court of Appeals went on to note that the Florida Statute appeared to track the language of the Federal Statute by prohibiting the knowing solicitation, offer, payment, or receipt of any remuneration in return for the referral of patient, in whole or in part, paid for under Medicaid. The Court of Appeals went on to say that upon closer examination, there were two significant differences between the Federal Statute and the Florida Statute. First, the court noted that the Federal Statute contained several so-called “safe harbor” provisions that exclude certain types of payments from being considered “illegal remuneration” under the statute. Specifically, the court said that the statute protects employer employee payments for the provision of covered items or services from criminal prosecution. The Court of Appeals also noted that Federal Medicaid statutes affirmatively require participating states to provide transportation to those eligible for dental services. Accordingly, the Court of Appeals concluded that the Florida Anti-Kickback Statute, which did not contain any “safe harbor” provisions, criminalizes an activity that is protected under the Federal Anti-Kickback Statute and stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Furthermore, the court noted that the Federal Anti-Kickback Statute contains a “knowing and willful” mens rea requirement. In its decision, it stated that under Federal law, in order to establish a “willful” violation of the statute, the government must prove that the defendant acted with knowledge that his conduct was unlawful. The Court of Appeals said that the Florida Anti-Kickback Statute, in con-

trast, only requires that the defendant act “knowingly,” which is defined under Florida law as actions “done by a person who is aware or should be aware of the nature of his or her conduct and that his or her conduct is substantially certain to cause the intended result.” The Court of Appeals concluded that the Florida definition of “knowingly” would include “mere negligence,” thereby criminalizing activity that the Federal statute intended to protect. The Court of Appeals stated that the legislative history of the Federal Anti-Kickback Statute included the phrase “knowingly and willfully” to describe the types of conduct prohibited under the anti-kickback laws and intended to shield from prosecution only those whose conduct “while improper, was inadvertent.”

This ruling by the Florida Court of Appeals is also significant because it follows the Ninth Circuit decision in *Hanlester v. Shalala*, which held that in order to violate the Federal Anti Kickback Statute, one must intend to engage in the conduct and also know that the conduct is unlawful. This decision is not in accord with those cases in other circuits which have examined the mens rea requirement, under the Federal Anti-Kickback Statute, but is in accord with Eleventh Circuit law, which requires that conduct be knowing and that the parties know that the conduct is, at least, improper.

The decision in *Hanlester v. Shalala* is often criticized by government enforcement authorities as “bad law,” yet its interpretation of the intent standard required under the Federal Anti-Kickback Statute apparently continues to survive judicial scrutiny. The decision of the Florida Court of Appeals is expected to be appealed to the Florida Supreme Court, where it could attract the interest of not only various friends of the court supporting the defendant-appellee, but also those in support of the government’s interpretation of the Florida law. **BC**

Corporate Liability and Compliance In the Health Care Industry

GABRIEL L. IMPERATO AND EDWARD HOPKINS

The advent of corporate liability disasters such as Enron, Arthur Andersen and most recently Health South, precipitated the passage of the Sarbanes-Oxley Act of 2002 to restore investor confidence in corporate America. The Sarbanes-Oxley Act is directed specifically at public companies and seeks to improve the accuracy and reliability of corporate financial disclosures made by these organizations. The Sarbanes-Oxley Act also mandates that public companies disclose the existence, or lack thereof, of certain corporate measures, ensuring the independence of audit committees and attempts to mandate the way public companies are governed. The standards reflected in the Sarbanes-Oxley Act are grounded in principles of independence, minimizing conflicts of interest, and encouragement of credible reporting of financial information and promoting sound governance of these public companies.

The goals and objectives of promoting independence and minimizing conflicts of interest in corporate governance and decision-making are minimally essential if the objective is better corporate accountability, responsibility and behavior. The foundation of corporate and/or individual fraud starts with decisions that are compromised by underlying conflicts of interest and a resulting lack of truly independent decision-making which fail to fully take into account the best interests of the organization.

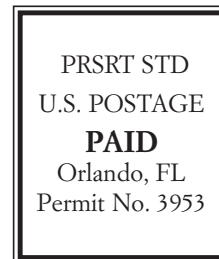
The message by the Federal government through passage of the Sarbanes-Oxley Act and the themes of independent decision-making and minimizing conflicts of interests are not new to the health care industry. The government has dedicated substantial resources in the past decade to investigating and prosecuting health care fraud, since at least the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Providers and suppliers of health care goods and services have

been, and will continue to be, subject to administrative, civil and/or criminal sanctions for a range of misconduct, including improper billing, receiving improper payment for referrals, participating in schemes to defraud the government, and failing to provide services with a level of quality that meets professionally recognized standards of care. The legacy of enforcement of the health care fraud and abuse laws has been to encourage, and even mandate, the themes of independent decision making and minimizing conflicts of interest and best practices for governance of health care organizations. Those enforcement actions which have set the Federal and state government's agenda over the past decade have raised the stakes for not only public companies in the health care industry, but for private and not-for-profit organizations. The growth of the compliance profession in the health care industry is a reflection of the effectiveness of increased enforcement of the health care fraud and abuse laws and the industry's reaction to responding and managing this liability. The themes generated by this experience in the health care arena have been a precursor to the evolution and application of the same themes through the passage of the Sarbanes-Oxley Act.

The truth is that the stakes had been raised in the health care industry prior to the passage of the Sarbanes-Oxley Act to such an extent that it virtually demanded that compliance in the health care industry adhere to the standards which were only later reflected in the Sarbanes-Oxley Act. A recent conviction of a not-for-profit community hospital for criminal fraudulent activity was the first of its kind involving corporate responsibility for hospital conduct, including the actions of its administrators and medical staff. This was not a public company or even a large private company, but a small not-for-profit community hospital, which was held criminally responsible and

accountable (along with its individual administrators and physicians) for the health care fraud activity of its employees and agents. This type of enforcement action is not novel in the health care industry and, in fact, investigation, prosecution and conviction of corporate health care providers for crimes, whether they be hospitals or other health care facilities and/or profit or not-for-profit entities, is consistent with the Department of Justice's announced intentions in 2003 to hold business organizations subject to criminal charges.

There are other developments in the health care industry and across the private and not-for-profit sector which clearly reflect that the standards contained in the Sarbanes-Oxley Act have been, and will continue to be, imposed on health care organizations of all types and varieties. For instance, the Internal Revenue Service ("IRS"), which regulates tax-exempt organizations, is authorized to impose personal excise taxes upon "interested" individuals who receive an excess benefit from an exempt organization. There are also corresponding IRS sanctions and penalties for the tax-exempt organization. There are also two bills pending in Congress which would require CEOs of tax exempt entities to explicitly certify the accuracy of the organization's tax returns. Furthermore, states Attorney General are vested with authority to oversee and preserve charitable donations made to exempt organizations and have been paying closer attention to the independence of various exempt organizations governing bodies and audit committees, their process of decision-making and the reliability of their respective financial statements. Additionally, the Office of Inspector General of the United States Department of Health and Human Services recently acknowledged the expansion of health care regulatory



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enforcement and has sought to heighten the scrutiny of corporate directors in fulfilling their oversight responsibilities by publishing a resource guide for health care board of directors, whether they are profit or not-for-profit organizations. Finally, the New York Attorney General has already proposed legislative standards similar to the Sarbanes-Oxley Act, which if passed, will apply to not-for-profit organizations in the State of New York. The fact of the matter is that the Sarbanes-Oxley standards and the collapse of organizations like Enron and Arthur Andersen and the recent Health South scandal will almost assuredly mean that public company standards will be applied to all sizeable institutional health care organizations.

The complexities associated with compliance in the health care industry will also mean that a director's fiduciary duty of oversight and care will require that individuals with a variety of experience

(i.e., regulatory, financial, clerical) participate on the board of directors of health care organizations. It will also mean that sophisticated health care organizations maintain a code of conduct as part of their corporate compliance program and furthermore will require that such programs be effective in detecting and preventing activities that can give rise to liability for the organization. It is clear that health care organizations should continue to take steps to implement internal controls to prevent and detect non-compliant activity and promote positive business practices, which will minimize "enterprise" liability. An effective process for ensuring independence of decision-making and dealing with conflicts of interest should be developed and maintained in every organization. Finally, a system for preserving the independence and integrity of the audit function and the reporting of financial information should be also established and monitored.

The directors of health care organizations have unique challenges associated

with doing business in the health care industry that may be unfamiliar to those who spend their time in other industrial or service sectors. A provider and supplier of health care goods and services is subject to a complex statutory and regulatory scheme governing the coverage and reimbursement for medical services. The rules which govern the industry are specific, and some of them can make actions illegal that in other industries may not apparently violate the law. The sentinel effect of the Sarbanes-Oxley Act and the legacy and continuing enforcement of the health care fraud and abuse laws have strongly established the need for all health care organizations to be vigilant and comprehensive in their compliance efforts and operations. If a continuing effort to detect and prevent activities giving rise to liability is not sustained by an organization, then both public, non-public, and not-for-profit health care organizations may become the next corporate disasters publicized in the media. **BC**